



Council of the
European Union

Brussels, 28 July 2023
(OR. en)

12234/23

**Interinstitutional File:
2023/0290(COD)**

**MI 669
ENT 172
CONSUM 295
SAN 475
IA 199
COMPET 800
CHIMIE 77
ENV 898
CODEC 1457**

COVER NOTE

| | |
|------------------|--|
| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| date of receipt: | 28 July 2023 |
| To: | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union |
| No. Cion doc.: | COM(2023) 462 final |
| Subject: | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the safety of toys and repealing Directive 2009/48/EC |

Delegations will find attached document COM(2023) 462 final.

Encl.: COM(2023) 462 final



Brussels, 28.7.2023
COM(2023) 462 final

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)

{SEC(2023) 297 final} - {SWD(2023) 268 final} - {SWD(2023) 269 final} -
{SWD(2023) 270 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Toys are regulated by Directive 2009/48/EC on the safety of toys (the Toy Safety Directive or the Directive)¹. This Directive lays down the safety requirements that toys must meet in order to be placed on the EU market, whether they are manufactured in the EU or in non-EU countries. At the same time, the Directive aims at ensuring the free movement of toys within the internal market.

The Commission evaluation of the Directive² (the Evaluation) identified a number of deficiencies that have emerged during the practical application of the Directive since it was adopted in 2009. In particular, the Evaluation identified certain shortcomings in ensuring a high level of protection of children from possible risks in toys, in particular from risks posed by harmful chemicals. The Evaluation also concluded that the enforcement of the Directive lacked effectiveness, in particular in the context of online sales, and there remain many unsafe toys on the Union market.

The chemicals strategy for sustainability³ (CSS) called for extending the so-called generic approach towards harmful chemicals (based on generic preventive bans) to ensure that consumers, vulnerable groups and the natural environment are more consistently protected. In particular, the CSS called for strengthening the Directive with regard to protection from the risks posed by the most harmful chemicals and with regard to possible combination effects of chemicals. The Directive already contains a general prohibition on substances in toys that are carcinogenic, mutagenic or toxic for reproduction (CMRs). However, it does not refer to other substances of particular concern, such as endocrine disruptors or substances affecting the immune, nervous or respiratory systems.

On 16 February 2022 the European Parliament adopted almost unanimously an own initiative report on the implementation of the Directive⁴. In its report, the European Parliament calls on the Commission to revise the Directive to: (i) strengthen the protection of children against chemical risks; (ii) ensure that risks posed by internet-connected toys are addressed by EU law; and (iii) improve enforcement of the Directive in particular in relation to online sales.

Finally, the Commission Communication of 16 March 2023 on the long-term competitiveness of the EU⁵ outlines how the EU can build on its strengths and go beyond merely bridging the growth and innovation gap. To foster competitiveness, the Commission proposes in this

¹ 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.

² Commission Staff Working Document - Evaluation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, SWD(2020) 288 final

³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, 14 October 2020, COM/2020/667 final

⁴ Report on the implementation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (Toy Safety Directive), 2021/2040(INI)

⁵ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Long-term competitiveness of the EU: looking beyond 2030, 16 March 2023 COM(2023) 168 final.

Communication to work on nine mutually reinforcing drivers of competitiveness, including a functioning internal market and digitalisation through broad-based take-up of digital tools across the economy. This focus on the internal market and digitalisation is taken up in the current proposal.

To deal with the issues highlighted in the Evaluation and developed in the accompanying impact assessment report⁶, and to respond to the Commission's CSS, this proposal expects to tackle the following two problems found in the Directive.

The first problem is that the Directive does not sufficiently protect children from the risks posed by hazardous chemicals in toys. The power given to the Commission to amend the Directive and adapt it to scientific knowledge is too limited. In particular, it is not possible to adapt the Directive in relation to limit values for toys intended for children over 36 months.

In addition, there are many toys on the EU market which do not comply with the Directive. Unsafe toys put children at risk and may lead to accidents that can even be fatal. Not all toys on the market can be subject to checks. This means that the exact share of non-compliant toys in the Union market cannot be quantified with precision. However, there are sufficient separate indicators that confirm that the number of non-compliant toys on the Union market is very high. Whenever market surveillance actions or inspections take place, the percentage of non-compliant and unsafe toys that are found is consistently high.

- **Consistency with existing policy provisions in the policy area**

This proposal is based on Decision No 768/2008/EC⁷ on a common framework for the marketing of products, which ensures consistency with other pieces of EU harmonisation legislation that may apply to other aspects of toys, such as the Radio Equipment Directive (RED)⁸. This proposal is also consistent with Regulation (EU) No 2019/1020 on market surveillance⁹ which sets out the regulatory framework for market surveillance checks and customs controls on toys. In addition this proposal is consistent with priorities and current trends on 'digitalisation by default' including the conclusions on digitalising product information in the evaluation of the new legislative framework¹⁰. By relying on the 'product passport' proposed by the Commission in its proposal for a regulation on ecodesign Requirements for sustainable products ('ESPR')¹¹ consistency of the product passport under both Regulations will be guaranteed and synergies can be achieved once toys are covered by delegated acts under ESPR. The safety of toys will be regulated within the scope of this proposal, while in the medium term sustainability aspects of toys may be covered within the

⁶ SWD(2023) 269 final, Impact assessment on the revision of the Toy Safety Directive.

⁷ 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).

⁸ 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, pp. 62-106, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014L0053-20180911>

⁹ 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 5OJ L 169, 25.6.2019, p. 1).

¹⁰ SWD(2022) 365 final.

¹¹ [Sustainable products initiative \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0142). Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC of 30 March 2022, COM(2022) 142 final.

framework of the ESPR. Moreover, the proposal acknowledges the Commission Recommendation (EU) 2022/2510¹² which establishes the ‘safe and sustainable by design’ framework for chemicals and materials.

- **Consistency with other EU policies**

This initiative is consistent with wider EU policy and regulatory developments, in terms of future and ongoing regulatory actions following the CSS. This proposal relies on existing and future hazard classes to be included under 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 (the CLP Regulation)¹³ and is consistent with the overall objectives of the CSS to strengthen the protection of consumers, and in particular vulnerable groups, from the most harmful chemicals. This proposal is also consistent with and complemented by Regulation (EU) 2023/988¹⁴ of the European Parliament and of the Council on general product safety, which contains in particular provisions on online sales, or on the right to information and remedy, which are applicable to toys.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

This proposal is based on Article 114 of the Treaty on the Functioning of the European Union. This is because its purpose is to harmonise the health and safety requirements for toys in all Member States, and to ensure that there are no obstacles to the free movement of toys between the Member States. This Regulation should replace the current Directive 2009/48/EC which has the former Article 95 of the Treaty establishing the European Community (current Article 114 TFEU) as its legal basis.

- **Subsidiarity**

This initiative addresses the issues identified in the Evaluation of the Toy Safety Directive. The Evaluation concluded that the Directive is generally relevant, effective, efficient and coherent, and has EU added value, but that there was a need for specific improvements.

The main objectives of this regulation are to ensure the highest level of safety for children, and to enable the free circulation of toys in the EU. A key rationale for a piece of EU-level toy safety legislation is to provide harmonisation across Member States based on Article 114 TFEU. The Toy Safety Directive is a total harmonisation measure for the safety aspects of toys, so Member States are not allowed to introduce additional or different safety requirements for toys.

¹² Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and materials C/2022/8854 (OJ L 325, 20.12.2022, p. 179)

¹³ OJ L 353, 31.12.2008, p. 1. And the Commission Proposal for Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (COM (2022) 748 final).

¹⁴ 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).

Nevertheless, Member States are required to transpose the regular amendments of the Directive, which in the past has led to regulatory amendments applying inconsistently across the EU. The regular adaptations of the Directive have also proven to be resource intense for Member States. A regulatory action at EU level would ensure consistent implementation of any new safety requirements for toys and any subsequent amendment to them, and thus a greater level of safety. It would also provide legal certainty and a level playing field for industry. Furthermore, the introduction of a product passport and the relevant controls at the Union external borders require that the underlying legal instrument be a Regulation.

- **Proportionality**

The approach proposed in this regulation will address all the problems identified in the most effective and efficient manner. This regulation will strengthen the protection of children from the most harmful chemicals when playing with toys by introducing generic bans on the most harmful substances. It will also allow for derogations to those generic bans under limited circumstances where the use of these substances in toys do not pose a risk to children and where there are no alternatives. Introducing generic bans for the most harmful substances as soon as their hazards have been established under the CLP Regulation will guarantee that children are more swiftly protected from the possible risks of these substances when present in toys. In addition, by allowing for derogations to these generic bans under limited circumstances, it will limit the costs for industry from introducing such bans in those cases where the safety of children is not compromised.

The introduction of a product passport that contains compliance information will be effective in reducing the number of non-compliant toys in the Union market, including through online sales. The regulation will ensure that any toy which is presented at customs is released for free circulation and placed on the Union market only if it has a corresponding product passport. This will lead to significant efficiency gains for both market surveillance authorities and customs authorities. This will achieve the objectives in an effective manner without disproportionate costs on industry¹⁵; while the introduction of the product passport will lead to costs for businesses to set up the systems and create the digital passports, it will also lead to savings in producing the necessary documentation digitally rather than on paper and when dealing with inspections from authorities. In addition, it is expected to lead to a significant reduction of non-compliant toys on the Union market, thus benefitting the competitiveness of compliant industry. The product passport will meet the same technical requirements as the product passport proposed under the ESPR in order to: (i) avoid duplications of industry's digitalisation efforts; and (ii) ensure interoperability with product passports created under other EU legislation.

- **Choice of the instrument**

The proposal takes the form of a regulation. The proposed change from a directive to a Regulation takes into account both the Commission's general objective to simplify the regulatory environment and the need to ensure uniform implementation throughout the EU of the proposed legislation.

In addition, the Toy Safety Directive is a total harmonisation directive. In this respect, a regulation would by its legal nature, better ensure that Member States do not impose national technical requirements that go beyond the safety requirements laid down in the current

¹⁵ See the section on the 'one in, one out' below for a full estimate of such costs.

Directive and/or contradict those safety requirements. Furthermore, the introduction of a product passport including compliance information as well as the related customs controls on toys entering the Union market require that the underlying legal instrument be a Regulation.

The change from a directive to a regulation will not lead to specific changes in the regulatory approach. The characteristics of the new legislative framework to which the Directive is already aligned will be fully preserved, in particular the flexibility given to manufacturers: (i) in the choice of the means employed to comply with the essential requirements (harmonised standards or other technical specifications); and (ii) in the choice of the procedure used to demonstrate compliance from among the available conformity-assessment procedures. The existing mechanisms supporting the implementation of the legislation (standardisation processes, expert groups, market surveillance, Member States' administrative cooperation (AdCo), the development of guidance documents, etc.) will not be affected by the nature of the legal instrument and will continue to operate in the same manner under the Regulation as they currently do under the Directive.

Finally, the use of regulations in the area of internal market legislation (in accordance also with the preference expressed by stakeholders) avoids the risk of 'gold plating', in which the requirements in an EU directive are extended when transposed into the national laws of a Member State. It also allows manufacturers to work directly with the regulation text instead of needing to identify and examine 27 national laws transposing the Directive. A Regulation will also lead to savings for the industry and benefit the internal market, as it will enter into force simultaneously across the EU, as will any subsequent amendment to it. On this basis, it is considered that the choice of a regulation is the most appropriate solution for all involved parties as it will allow a more rapid and coherent application of the legislation adopted at EU level and will establish a clearer regulatory environment for economic operators.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The Evaluation of the Directive concluded that the Directive was generally effective in protecting children when playing with toys. However, it also identified a number of deficiencies that have emerged during the practical application of the Directive since its adoption in 2009. In particular, the Evaluation identified two main problems. The first main problem were certain shortcomings in ensuring a high level of protection of children from possible risks in toys, in particular from risks posed by harmful chemicals. The second main problem identified is that the enforcement of the Directive lacks effectiveness, in particular in the context of online sales, and that there remain many unsafe toys on the Union market. The Evaluation also concluded that the legal instrument being a Directive lacked effectiveness, in particular in view of the fact that the repeated amendments of the Directive had to be transposed into national legislation.

The results of the Evaluation have been taken on board in this proposal, which addresses the two main problems identified in it.

- **Stakeholder consultations**

The Commission carried out a number of consultation activities to collect: evidence and views from a broad range of stakeholders on the identified problems with the Toy Safety Directive.

The activities included (i) a twelve-week dedicated public consultation concluded in May 2022; (ii) a stakeholder workshop held on 26 April 2022; (iii) discussions with Member States and other stakeholders in the Expert Group on Toy Safety; and (iv) feedback collected in response to the Commission's inception impact assessment. As part of the impact assessment study, an external contractor also organised interviews with 41 relevant stakeholders, and an online targeted consultation for SMEs ran between 7 April 2022 and 15 May 2022. Consulted stakeholders included EU and national consumer associations; industry associations; economic operators; citizens; and national authorities.

Industry stakeholders supported the idea that new limit values could be added to the toy-safety rules for all toys, but did not support the extension of generic bans to other harmful substances. In particular, industry voiced strong opposition to removing derogations to generic bans. Their main concern was that removing derogations completely would have strong consequences preventing the making available on the market of a significant number of toys (for example electric toys). Industry supported the digitalisation of compliance information in the product passport.

Member States expressed clear support for revising the Toy Safety Directive and strengthening the chemical requirements, both with specific limit values and additional generic prohibitions for certain substances. There was also support for digitalising product information as well as for extending third party conformity assessment, albeit to a lesser extent. Consumers favoured the options with: (i) stricter chemical requirements for products for children; and (ii) more limited derogations, or in some cases no derogations. Consumers also favoured the introduction of a product passport as well as the extension of third-party conformity assessment.

- **Collection and use of expertise**

The Evaluation of the Toy Safety Directive¹⁶ was supported by a study by an external contractor¹⁷.

The impact assessment accompanying this proposal is also supported by a study undertaken by another external contractor¹⁸, which carried out interviews, analysed data from public and targeted consultations and complemented this with desk research.

The Commission has consulted widely and has received input from various sources during the preparation of this proposal. In addition to the studies mentioned above, the Commission has relied on publicly available information and scientific opinions available in the field of chemical substances and input received from relevant stakeholders.

- **Impact assessment**

The Commission carried out an impact assessment on the revision of the Toy Safety Directive. The Regulatory Scrutiny Board issued a positive opinion on the draft impact assessment on 28

¹⁶ Commission Staff Working Document - Evaluation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys SWD(2020) 288 final.

¹⁷ Technopolis, EY, VVA (December 2014) Evaluation of Directive 2009/48/EC on the Safety of Toys - Final Report
<https://ec.europa.eu/docsroom/documents/23843/attachments/1/translations/en/renditions/native>.

¹⁸ VVA with CSES and Asterisk (2022) Impact Assessment study on the revision of the Toy Safety Directive.

October 2022. The opinion of the Board as well as the final impact assessment and its executive summary are published together with this proposal.

Based on the available information, the impact assessment examined and compared three policy options to address each of the two main problems identified. These policy options were in addition to the baseline option of no change, which would still allow for the possibility to introduce specific restrictions on harmful chemicals for toys intended for children under the age of 3.

To strengthen the requirements to protect children from harmful chemicals, there were three options:

- **Policy option 1a** proposes to empower the Commission to add and amend limit values for chemicals in any toy (not only for children under the age of 3), as well as to lower the limit values for nitrosamines and nitrosatable substances.
- **Policy option 1b** includes the same measures as option 1a but also extends the current generic ban on CMRs to other most harmful chemicals in toys (e.g. endocrine disruptors). This means that substances under these most harmful hazard classes would be automatically banned in toys, without having to assess the specific risk they pose for children in toys. This option would still allow for derogations to the generic bans under certain conditions, when the use of the substance in toys is considered to be safe by the relevant scientific committee in the European Chemicals Agency and there are no alternatives.
- **Policy option 1c** is the same as policy option 1b (generic bans for most harmful chemicals) but without derogations being possible to the generic bans.

To reduce the high number of non-compliant and unsafe toys that can still be found on the market, the impact assessment identified three options:

- **Policy option 2a** would extend third-party conformity assessment to (i) toys intended for children under the age of 3; and (ii) toys which are chemical mixtures. These categories of toys were identified as having higher rates of non-compliance or presenting higher risks.
- **Policy option 2b** would require the compliance documentation to accompany the toy digitally, relying on the digital product passport under the ESPR. It would also require this information to be presented at customs. Based on the model already set out in the ESPR, the reference to the product passport containing compliance information should be included in a Commission central registry. The reference of the passport and of its inclusion in the Commission registry would be presented at customs when a toy is placed under the customs procedure of release for free circulation. Through interconnection of the Commission central registry and Customs systems, the reference of the passport in the registry could be automatically checked, and toys which do not have a valid reference to the product passport in the Commission registry would not be released for free circulation.
- **Policy option 2c** would be the combination of policy option 2a and policy option 2b.

The preferred option is **policy option 1b** together with **policy option 2b**. In terms of protection of children from harmful substances, **policy option 1b** will lead to a significant reduction in children's exposure to these harmful substances but limit negative impacts for industry by providing for appropriate derogations to generic bans. It will also ensure that the toy safety rules can continue to adapt to new scientific knowledge. **Policy option 2b** will ensure that toys presented at customs without the declaration of conformity included in the product passport would be automatically prevented from being released for free circulation in the Union market. In addition, there will be significant efficiency gains for market-surveillance authorities when inspecting toys. Accordingly, policy option 2b has the potential to significantly reduce the number of non-compliant toys in the internal market. Other options that included third party conformity assessment were not considered to be as effective or efficient; it was assessed that they would increase costs for compliant manufacturers while not leading to a significant reduction of non-compliant toys.

The combination of options will help to better protect children from harmful chemicals, as well as reducing the number of unsafe toys on the Union market. This combination is also expected to contribute to the United Nations Sustainable Development Goals (SDGs)¹⁹, in particular SDG#3 on good health and well-being. In addition, it will contribute to SDG#9 (industry, innovation and infrastructure); SDG#12 (responsible production and consumption); and SDG#6 (clean water and sanitation).

Regarding **fundamental rights**, none of the policy options is expected to have significant impacts. Policy option 1b should generally have a positive contribution to the overall rights of the child and to the possibility of children to play. Equality, including gender equality, is not significantly impacted by this initiative. While the objectives of the revision of the Directive are focused on strengthening the protection of children health, the preferred option is expected to have a limited positive impact on the environment, given the expected reduction in paper-based documentation. Therefore, the current initiative is consistent with the fulfilment of the climate-neutrality objective as requested by the European Climate Law. The proposal respects **'do not significant harm'** to the environment principle but do not address it specifically. The proposal is consistent with the 'digital by default' principle.

The impact assessment considers that banning the most harmful substances from toys (policy option 1b) would have considerable **health benefits (between EUR 240 million and EUR 1.2 billion per year) in terms of avoided health damage from endocrine disruptors alone**. These benefits would accrue over the life time of a child exposed (or not exposed) to endocrine disruptors now which means that the time span could be over several generations and exceeding standard appraisal periods of 20-30 years. In addition, policy option 2b would lead to significant efficiency gains for market surveillance authorities (the number of inspections could increase from around 25 000 per year by a maximum of between 2 500 and 5 000, assuming that the dedicated budget remains equal and that the efficiency gains are dedicated to more toy inspections). In addition, the **provision of digital information by manufacturers could lead to savings of between EUR 2.62 million and EUR 3.93 million per year**. Policy option 2b would also lead to **savings for industry in dealing with market surveillance inspections** that could range from **EUR 13 million to EUR 20 million per year**.

Both options combined will significantly improve the protection of children when playing with toys, because: (i) the most harmful substances will be better addressed by the toy-safety-rules; and (ii) the number of non-compliant and unsafe toys will be significantly reduced. It will also

¹⁹ <https://www.un.org/sustainabledevelopment/sustainable-development-goals/>

improve the functioning of the internal market and the competitiveness of industry when facing illicit competition.

The impact assessment makes the assumption that the number of substances covered by generic bans under Policy option 1b might increase by about 10-30%. This could affect a significant number of toy models, but derogations will limit the toy models that will need to be subject to product adaptations or which could no longer be made available. A total of 8.4-12.8% of toy models may be impacted under policy option 1b and for which a derogation may not be possible, with 4.6-7.2% subject to product adaptation efforts (including chemical substitution efforts) and 3.8-5.6% which could no longer be made available on the market if no alternatives to the restricted chemicals are found. The estimated impact on 4.6-7.2% of EU toy models could result in total incremental one-off adjustment costs associated with **product redesign and redevelopment of between EUR 23.5 million and EUR 396.66 million**. The costs of requesting derogations could range between EUR 100 000 to EUR 300 000 per year for the overall industry. With more substances being subject to generic bans, as well as limit values added for new substances in toys, new toy models will need to be tested to ensure compliance with such limit values. Due to the need for more complex and sensitive testing, the costs of testing may increase from EUR 2 200 at present to EUR 3 900 per toy model. It is estimated that **yearly testing costs will increase compared to the baseline by between EUR 7.31 million and EUR 11.70 million**. In terms of toy models that could no longer be made available, the actual impacts will depend on the value of the toy models impacted, but based on the EU industry turnover, **this option could affect between EUR 249 million and EUR 367 million worth of products**²⁰. This is not expected to lead to a direct market contraction of that size, given that manufacturers will be provided with an appropriate transition period in which they will be able to assess the viability of existing products and, if needed, shift resources to the production and sale of alternative toy products. Moreover, consumers will in many cases simply purchase an alternative toy product rather than not purchase anything. SMEs are expected to have higher costs per new toy model than larger firms, as they face higher unit costs.

For the introduction of the digital product passport under policy option 2b it is estimated that the cost for EU manufacturers could be around **EUR 18 million in one-off costs and a subsequent EUR 10.5 million per year**. After the systems are set up and most initial data are entered, there are only expected to be additional costs related to updating and maintenance costs.

- **Application of the ‘one in, one out’ approach**

The reinforcement of the chemical requirements for toys included in this proposal is only expected to lead to an increase in the administrative burden if derogations are requested to continue using in toys substances which have been banned. It could be estimated that the cost per derogation request could range between EUR 50,000 and EUR 150,000 per derogation request, and that there would be a maximum of two derogation requests per year (with an **average of EUR 200,000 per year**). Option 2b would entail administrative costs for businesses and benefits. The overall **additional administrative burden of the introduction of the digital product passport** has been estimated, based on current market structure and expected average production per enterprise, at approximately **EUR 18 million one-off and EUR 10.5 million recurrent, per year**.

²⁰ Based on provisional EU industry turnover of EUR 6.56 billion for 2020.

The introduction of the digital product passport is likely to bring some reduction of the administrative burden on authorities and companies. It has the potential to reduce the administrative burden on public authorities, in particular customs, since the product passport would allow for more automatic controls on imported products from third countries and prevent the import of non-compliant toys that would be held on border premises and subject to physical controls. The product passport could lead to **savings for companies from moving to digitalised information of around EUR 2.62 to EUR 3.93 million (EUR 3.275 million on average) per year.**

- **Regulatory fitness and simplification**

The Evaluation assessed the potential for simplification of the Directive and concluded that there was no potential for simplification on the substantial obligations and administrative burden of the Directive. This is because simplification entailing fewer obligations for economic operators would risk reducing protection for children. Similarly, under the Directive there is currently no requirement to go through third-party conformity assessment if there are harmonised standards covering all aspects of toys; this could not be simplified further.

The option to move to digital compliance information will lead to simplification and improved efficiency in the contacts between economic operators and market surveillance authorities. There will be costs in adapting to the digital provision of information, but also cost savings and overall simplification for industry in providing compliance information digitally rather than on paper. In addition, market surveillance authorities will be more efficient and able to conduct more inspections of toys (see the section on the impacts above). This is supported by the outcome of the Evaluation of the new legislative framework that considered that **digitalisation of the declaration of conformity / technical product information / technical file would improve the efficiency of the conformity-assessment procedure**, without hindering market surveillance activities. Stakeholders from all groups in that consultation agreed that digitalisation offers a potential solution to simplify administrative obligation related to product-information requirements and CE marking, which is also applicable to toys.

Finally, one aspect for simplification that was raised very frequently by stakeholders was the need for the warnings required by the Directive to be preceded by the word ‘Warning’ which needed to be translated into all languages required by the Member States in which the toy was going to be made available. Replacing the word ‘Warning’ by a generic pictogram would lead to simplification for the industry without compromising the protection of children. It would also lead to savings to the industry when producing the labels but these savings cannot be quantified with precision.

4. BUDGETARY IMPLICATIONS

This proposal does not have any implications for the EU budget. One of the retained measures will require additional scientific assessments to be performed by the European Chemicals Agency. It is expected that these scientific assessments will require the work of 2 FTEs in ECHA. As announced²¹, the Commission is currently carrying out a review of the European Chemicals Agency, which will include a wider reassessment on the tasks of the European Chemicals Agency. Any potential resource implications of the scientific assessments linked to the regulation will be incorporated in that reassessment.

²¹ See [European Chemicals Agency – proposal for a basic regulation \(europa.eu\)](https://european-chemicals-agency.eu/proposal-for-a-basic-regulation)

5. OTHER ELEMENTS

• Implementation plans and monitoring, evaluation and reporting arrangements

The Commission will evaluate the Regulation five years after its entry into force and every five years thereafter, with a view to assessing its effectiveness, efficiency, relevance, added-value and coherence. The Commission will submit a report on the main findings to the European Parliament and to the Council. In an effort to rationalise the reporting obligations, Member States will no longer be obliged to submit reports on the application of the regulation every 5 years.

• Detailed explanation of the specific provisions of the proposal

Chapter I

Scope and definitions

The scope of the proposed regulation remains the same; the definition of ‘toy’ is not changed from Directive 2009/48/EC.

The general definitions of Decision 768/2008/EC have been kept. However, additional definitions in relation to the introduction of the product passport have been added.

Exclusions

The products that are not covered by the proposed regulation have been set out in Annex I, which is now a single list. The products exempted from the scope of the proposed regulation remain the same as in the current Directive, with the exception of slings and catapults, which are no longer excluded from the scope of the Regulation. Article 2 empowers the Commission to determine via implementing acts whether a specific product or category of products should be considered as a toy or not.

Requirements for toys

Articles 5 and 6 contain the obligation: (i) for toys to conform with the general and particular safety requirements; and (ii) to affix specific warnings when these are necessary for the safe use of the toys. While the categories of particular safety requirements in Annex II remain the same as for Directive 2009/48/EC, the general safety requirement goes beyond protecting the physical health and safety of users, to include the psychological well-being and cognitive development of children.

Particular safety requirements for toys

The main categories of essential requirements for toys are set out in Annex II and they concern: (i) physical and mechanical properties; (ii) flammability; (iii) chemical properties; (iv) electrical properties; (v) hygiene; and (vi) radioactivity. The chemical properties are amended and simplified. The generic restrictions of particularly harmful substances now include: (i) substances which are carcinogenic, mutagenic or toxic for reproduction; (ii) endocrine disruptors, (iii) respiratory sensitisers and (iv) substances toxic to a specific organ. The possibilities for a derogation to this ban have been limited, and an assessment is now required by the relevant scientific committees in the European Chemicals Agency (ECHA) to conclude on: (i) the safety of certain substances; (ii) the lack of alternatives to the presence of these

substances. In addition, derogations will only be possible if these substances are not prohibited for use in consumer articles under Regulation (EC) No 1907/2006. Businesses will be able to ask ECHA to examine possible derogations. ECHA is expected to develop guidance for businesses, and especially SMEs, to help them with: (i) the practical aspects of these requests; and (ii) the application of the chemical requirements for toys more generally. Based on the ECHA's opinion on a derogation request for a specific substance, the Commission will insert permitted uses in the proposed regulation, as these derogations will be of general application. A single appendix contains all the specific restrictions for chemicals in toys, which the Commission is empowered to amend.

Obligations of economic operators

The proposal incorporates obligations for manufacturers, importers and distributors aligned with Decision 768/2008/EC, as is already the case in the current Directive. This clarifies the respective obligations, which are proportionate to the economic operators' role. The manufacturer is required to create a product passport for the toy including the relevant compliance information which will replace the EU declaration of conformity. The designation of the authorised representative as the economic operator responsible for the tasks set out in Article 4 of Regulation 2019/1020 is also specifically provided for.

Presumption of conformity of toys

The presumption of conformity of toys when manufacturers apply the relevant harmonised standards or parts thereof published in the Official Journal of the European Union remains. However, in order to ensure the presumption of conformity when there are no relevant harmonised standards the Commission will be empowered to adopt common specifications. This will be a fall-back option to be used only when the standardisation bodies are not able to provide standards or provide standards that do not respond to the Commission standardisation request and the essential requirements of Annex II.

Product passport

The EU declaration of conformity is replaced by the obligation to have a product passport available for toys to declare compliance with the requirements of this proposed regulation. The product passport will be connected through a data carrier to a unique product identifier, and meet the same technical requirements for a product passport contained in the ESPR. The reference of the product passport must be included in a Commission central registry that will be set up under the ESPR, and this information needs to be indicated at customs when toys coming from outside the EU are placed under the customs procedure of release for free circulation.

Conformity assessment

The proposal keeps the manufacturer internal control option when the manufacturer applies the relevant harmonised standards or common specifications. Third-party certification by a notified body will continue to be necessary where harmonised standards or common specifications: (i) do not exist; (ii) are not followed; or (iii) do not cover all the risks of the toy. The proposal includes the corresponding modules in line with the Decision 768/2008/EC. The proposal specifies that, as part of the safety assessment, the manufacturer needs to consider the possible risks of the combined or cumulative presence of chemicals in the toy.

Notified bodies

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and for the confidence of all interested parties in the new approach. Therefore, in line with Decision 768/2008/EC, the proposal maintains the requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State. This proposal specifies that notified bodies must: (i) have the competence to verify the tasks subcontracted; and (ii) be able to oversee the work carried out by subcontractors.

Union market surveillance and union safeguard procedure

The proposal keeps the provisions based on Decision 768/2008/EC in respect of the safeguard-clause procedure. In addition, a specific provision based on Decision 768/2008/EC gives specific grounds for acting against toys that comply with the essential requirements but pose a risk to children. The provisions also give the Commission the power to adopt measures against specific toys under very specific circumstances.

Implementing acts

The proposal empowers the Commission to adopt, where appropriate, implementing acts to ensure the uniform application of this Regulation. In particular, implementing powers should be conferred on the Commission to establish the detailed technical requirements for the product passport. Exceptionally, the Commission should also be granted implementing powers to take measures in respect of compliant toys which are found to pose a risk to health and safety of persons. Those implementing acts will be adopted in accordance with the provisions on implementing acts laid down in Regulation (EU) No 182/2011.

The Commission should be granted implementing powers to establish whether a national measure in respect of a toy presenting a risk to health and safety of persons is justified and on requesting a Member State to take measures against a notified body which is found to be no longer competent to carry out the conformity assessment tasks under this Regulation. Given their special and technical nature, those implementing acts will not be adopted in accordance with the provisions on implementing acts set out in Regulation (EU) No 182/2011.

Delegated acts

The proposal empowers the Commission to adopt delegated acts in order to adapt: (i) the provisions on warnings in Annex III to adapt these provisions to technical and scientific progress; and (ii) provisions to permit specific substances and mixtures indicating their permitted use in toys and new limit values for specific substances in toys. In relation to the product passport, the proposal empowers the Commission to amend the specific information that should be included in the passport, as well as the information to be included in the Commission registry. The Commission should also be empowered to determine the additional information stored in the registry to be controlled by customs authorities, as well as amend Annex VII to this Regulation containing a list of commodity codes, as set out in Annex I to Regulation (EEC) No 2658/87, and product descriptions of toys and update such Annex.

Evaluation and review

The Commission shall evaluate the Regulation five years after its entry into force and every five years thereafter, with a view to assess effectiveness, efficiency, coherence, relevance and

EU added value. The Commission shall submit a report on the main findings to the European Parliament and to the Council.

Final provisions

The proposed regulation will become applicable 30 months after its entry into force, on the one hand, to allow the Commission to prepare the implementation of the product passport's technical requirements and, on the other hand, to allow manufacturers, notified bodies and Member States time to adapt to the new requirements. However, the provisions on notified bodies, and on the Commission implementing and delegated powers need to be applied shortly after the entry into force of this Regulation. Transitional provisions are laid down for both products manufactured and the certificates issued by notified bodies under Directive 2009/48/EC so as to allow stocks to be absorbed and ensure a smooth transition to the new requirements. Directive 2009/48/EC will be repealed and replaced by the proposed regulation.

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)

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 Committee²²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Directive 2009/48/EC of the European Parliament and of the Council²³ was adopted to ensure a high level of safety of toys and their free movement on the internal market.
- (2) Children are a particularly vulnerable group. It is essential to ensure a high level of safety of children when playing with toys. Children should be adequately protected from possible risks stemming from toys, in particular from the chemical substances that toys may contain. At the same time, compliant toys should be able to move freely across the internal market without additional requirements.
- (3) The Commission evaluation of Directive 2009/48/EC concluded that the 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 the 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.

²² OJ C , , p. .

²³ 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).

- (4) The Chemicals Strategy for Sustainability²⁴ 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 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.
- (6) Toys are also subject to Regulation (EU) 2023/988 on general product safety²⁵, 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 distance and online sales, 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 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 Council²⁶ 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 Council²⁷ 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 be drafted, to the extent possible, in accordance with those common principles and reference provisions.
- (9) This Regulation should lay down essential requirements for toys to ensure a high level of protection of health and safety of children when playing with toys as well as the free movement of toys in the Union. This Regulation should be applied taking due account of the precautionary principle.

²⁴ COM(2020) 667 final

²⁵ OJ L 11, 15.1.2002, p. 4.

²⁶ 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).

²⁷ 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).

- (10) To facilitate the application of this Regulation by manufacturers and national authorities, 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 may 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 toys which are new to the Union market when placed on the market, i.e. either new toys made by a manufacturer established in the Union or toys, whether new or second hand, imported from a third country. The safety of other second hand products falls within the scope of Regulation (EU) 2023/988 of the European Parliament and of the Council²⁸.
- (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 Council²⁹.
- (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.
- (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

²⁸ 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).

²⁹ 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).

accordance with Directive 2014/53/EU of the European Parliament and of the Council³⁰. 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]³¹. Therefore, particular safety requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys should not be set out. However, protecting the health of children should not merely ensure the absence of disease or infirmity and relying on digital technologies may pose risks to children which go beyond their physical health. To ensure that children are protected from any risk coming from the use of digital technologies in toys, the general safety requirement should ensure the psychological and mental health, as well as the well-being and cognitive development, of children.

- (15) Toys should comply with physical and mechanical requirements that prevent children from getting physically injured when playing with toys and should not pose a risk of choking or suffocation to children. In order to protect children from the risk of impaired hearing, maximum values should be set out for both impulse noise and continuous noise emitted by toys. Toys or their parts and their packaging which can be reasonably expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use are subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council³². In addition, it is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys in food, since the association of a toy and food could cause a risk of choking which is distinct from the risks presented by the toy alone and which is, therefore, not covered by any specific measure at Union level. Toys should also ensure sufficient protection as regards flammability or electric properties, in particular to prevent burns or electric shocks. Moreover, toys should meet certain hygiene standards to avoid microbiological risks or other risks of infection or contamination.
- (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

³⁰ 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).

³¹ 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.

³² 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).

of consumers, and other persons, that legal framework should be supplemented by generic prohibitions in toys covering certain hazardous chemicals, as classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council³³. Those generic prohibitions should apply to CMR substances, endocrine disruptors, respiratory sensitisers and substances targeting a specific organ, as soon as those substances are classified as hazardous under Regulation (EC) No 1272/2008³⁴. In order to ensure toy safety, prohibited substances should be acceptable at trace levels but only if their presence at such levels is technologically unavoidable with good manufacturing practices and if the toy is safe.

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

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

³⁴ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

³⁵ 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.

include batteries should be designed in such a way that the batteries are difficult for children to access.

- (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.
- (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.
- (23) To ensure adequate protection from specific chemical substances in case of new scientific knowledge, the Commission should be empowered to adopt delegated acts establishing specific limit values for any chemical substance used in toys. If justified in cases of toys involving a higher degree of exposure, those delegated acts should set out specific limit values for toys intended for use by children under 36 months and in other toys intended to be put in the mouth, taking into account the requirements set out in Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food or articles from which risks may arise due to oral contact through their use as a food contact material. Fragrances in toys entail special risks for human health. Therefore, specific rules should be set out for the use of fragrances in toys and for the labelling of fragrances. The Commission should be empowered to adopt delegated acts to amend those rules to allow for adaptations to technical and scientific progress.
- (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.
- (25) To prevent misuse of warnings to circumvent the applicable safety requirements, the warnings provided for certain categories of toy should not be allowed if they conflict with the intended use of the toy. To ensure that supervisors are aware of any risks associated with the toy, it is necessary to ensure that the warnings are legible and visible.
- (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 jeopardise the safety and health of children under normal and reasonably foreseeable conditions of use, and that they make available on the market only toys which comply with the relevant Union legislation.
- (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.
- (37) Economic operators that either place a toy on the market under their own name or trademark or modify a toy in such a way that compliance with applicable requirements of this Regulation may be affected, should be considered to be manufacturers and should assume the obligations of manufacturers.
- (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.
- (39) In order to facilitate the assessment of conformity with the requirements of this Regulation it is necessary to provide for a presumption of conformity for toys which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council³⁶ 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 requirements of this Regulation, provided that in doing so it duly respects the standardisation organisations' role and functions, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with the essential requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards.
- (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.

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

- (42) Manufacturers should create a product passport to provide information on the compliance of toys with this Regulation and with any other Union legislation applicable to toys. The product passport should replace the EU declaration of conformity under Directive 2009/48/EC and include the elements necessary to assess the conformity of the toy with the applicable requirements and harmonised standards or other specifications. In order to facilitate checks on toys by market surveillance authorities and to allow the actors in the supply chain and consumers to access information on the toy, the information on the product passport should be provided digitally and in a directly accessible manner, through a data carrier affixed to the toy, its packaging or the accompanying documentation. Market surveillance authorities, customs authorities, economic operators and consumers should have immediate access to the information on the toy through the data carrier.
- (43) To avoid duplication of investment into digitalisation by all actors involved, including manufacturers, market surveillance authorities and customs authorities, when other Union legislation requires a product passport for toys, a single product passport should be available containing the information required under this Regulation and the other Union legislation. In addition, the product passport should be fully interoperable with any product passport required under other Union legislation.
- (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 Council³⁷ also lays down requirements and technical specifications for a product passport, the establishment of a Commission central registry where passport information is stored and the interconnection of that registry with the customs IT systems. That Regulation may include toys within its scope in the medium term, thus requiring that a product passport is available for toys. Therefore, it should be possible in the future to include more precise information in the product passport, in particular information related to environmental sustainability, such as the environmental footprint of a product, information useful for recycling purposes, the recycled content of a certain material, information about the supply chain, and other similar information. The product passport for toys created under this Regulation should therefore comply with the same requirements and technical elements as those set out in Regulation (EU) .../... [P.O. insert serial number for the Regulation on ecodesign requirements for sustainable products], including the technical, semantic and organisational aspects of end-to-end communication and data exchange.
- (45) As the product passport is to replace the EU declaration of conformity, it is crucial to make clear that by creating the product passport for a toy and by affixing the CE marking, the manufacturer declares that the toy is in compliance with the requirements of this Regulation and that the manufacturer takes full responsibility thereof.
- (46) Where other information than the elements required for the product passport is provided digitally, it is necessary to clarify that the different types of information need to be provided separately and clearly distinguished from each other but through a single data carrier. This will facilitate the work of market surveillance authorities but also provide

³⁷ 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.

clarity to consumers regarding the different types of information that are available to them in a digital format.

- (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 Council³⁸, 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 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.
- (49) When toys coming from third countries are placed under the customs procedure of release for free circulation, the reference to a product passport for those toys should be made available to the customs authorities by the economic operator. The reference to the product passport should correspond to a unique product identifier that is stored in the product passport registry established under Article 12 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for Sustainable Products] (the 'registry'). Customs authorities should carry out an automatic verification of the product passport presented for that toy, so as to ensure that only toys with a valid reference to a unique product identifier as included in the registry are released for free circulation. To carry out that automatic verification, the interconnection between the registry and the customs IT systems as provided for in [Article 13 of Regulation (EU) .../... on ecodesign requirements for sustainable products] should be used.
- (50) Where other information than the unique product identifier and the unique operator identifier is stored in the registry, the Commission should be empowered to adopt delegated acts allowing customs authorities to verify the consistency between that additional information and the information made available by the economic operator to customs, in order to ensure the compliance of toys placed under the customs procedure of release for free circulation with this Regulation.
- (51) The information included in the product passport allows customs authorities to enrich and facilitate risk management and enables more targeted controls at the Union's external borders. Therefore, customs authorities should have the possibility to retrieve and use the information included in the product passport and the registry for carrying out their tasks in accordance with Union legislation, including for risk management in accordance with Regulation (EU) No 952/2013.
- (52) It is appropriate to provide for the publication of a notice in the *Official Journal of the European Union* indicating the date when the interconnection between the registry and

³⁸ 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).

the EU Customs Single Window Certificates Exchange System referred to in Article 13 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for Sustainable Products] becomes operational in order to facilitate public access to that information.

- (53) The automatic verification by customs of the reference to the product passport for toys entering the Union market should not replace or modify the responsibilities of the market surveillance authorities but only complement the overall framework for controls on products entering the Union market. Regulation (EU) 2019/1020 should continue to apply to toys so as to ensure that market surveillance authorities carry out checks of the information contained in products passports, checks on toys within the market in accordance with that Regulation and, in case of suspension of release for free circulation by the authorities designated for controls at the Union's external borders, determine the compliance and risks of toys pursuant to Chapter VII of Regulation (EU) 2019/1020.
- (54) Children are daily exposed to a wide range of different chemicals originating from various sources. Significant progress has been made to close some knowledge gaps on the impact of the combination effect of those chemicals. However, the safety of chemicals is usually assessed through the evaluation of single substances and in some cases of mixtures intentionally added for particular uses. In order to provide the highest protection for children, the most harmful substances should be generally banned in toys to ensure that there is no exposure to them in toys. The specific limit values for chemicals in toys should account for combined exposure from different sources to the same chemical substance. In addition, manufacturers should be required to carry out an analysis of the various hazards that the toy may present and an assessment of the potential exposure to such hazards and, as part of the assessment of chemical hazards, to consider known cumulative or synergistic effects of the 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.
- (56) To ensure that toys comply with the essential 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, it 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 legislation. 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 State 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.
- (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. The Commission should, by means of implementing acts, determine whether a national measure in respect of compliant toys which a Member State finds to pose a risk to the health and safety of children or other persons is justified.
- (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 amending this Regulation with regard to the information that is to be included in the

product passport and the information that is to be included in the product passport registry.

- (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 supplementing this Regulation by determining the additional information stored in the registry to be controlled by customs authorities, and 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 Council³⁹.
- (71) When adopting delegated acts under this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁴⁰. 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 establish the detailed technical requirements for the product passport for toys, and to determine whether a specific product or group of products is to be considered a toy for the purposes of this Regulation. In exceptional cases where it is necessary in order to address new emerging risks that are not appropriately addressed by the particular safety requirements, the Commission should be empowered to adopt implementing acts setting out specific measures against toys or categories of toys made available on the market which present a risk for children. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁴¹.
- (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. In addition, the period during which toys already placed on the market in compliance with that Directive may continue to be made available on the market after this Regulation becomes applicable should be limited.
- (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

³⁹ 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.

⁴⁰ OJ L 123, 12.5.2016, p. 1.

⁴¹ 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).

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, 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, or by children of any other specific age group below 14 years, where a parent or supervisor can reasonably assume, by virtue of the functions, dimensions and characteristics of that product, that it is intended for use in play by children of the relevant age group.

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

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

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;
- (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 2, 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) ‘online marketplace’ means 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 legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies;
- (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;
- (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,
 - (d) they are defined by a type number or other element allowing them to be identified as a group;
- (14) ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device;
- (15) ‘unique product identifier’ means unique string of characters for the identification of toys that also enables a web link to the product passport;

- (16) ‘unique operator identifier’ means a unique string of characters for the identification of actors involved in the value chain of toys;
- (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;
- (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 Council⁴²;
- (20) ‘conformity assessment’ means the process demonstrating whether the essential 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;
- (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,

⁴² 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).

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

Article 4

Free movement

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

Product 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, including the psychological and mental health, well-being and cognitive development of children, 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 a general warning specifying appropriate user limitations. The user limitations shall include at least the minimum or maximum age of the user and, where appropriate, the required abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.
2. The following categories of toys shall bear warnings in accordance with the rules for each category set out in Annex III:
 - (a) toys not intended for use by children under 36 months;
 - (b) activity toys;
 - (c) functional toys;
 - (d) chemical toys;
 - (e) skater, roller skates, inline skates, skateboards, scooters and toy bicycles;
 - (f) aquatic toys;
 - (g) toys in food;
 - (h) imitations of protective masks and helmets;
 - (i) toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps;
 - (j) packaging for fragrances in olfactory board games, cosmetic kits and gustative games.

Toys shall not bear one or more of the warnings set out in Annex III where such warnings conflict with the intended 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. Small toys which are sold without packaging shall have appropriate warnings affixed to them.

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

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

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

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 product passport for the toy in accordance with Article 17;
 - (b) affix the data carrier to the toy or to a label attached to the toy, 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 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 keep the technical documentation and the product passport for a period of 10 years after the toy covered by that documentation and 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 manufacturers, with regard to the risks presented by a toy, consider it necessary for the protection of health and safety of consumers, manufacturers shall, carry out sample testing of marketed toys.

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 possible, on its packaging or in a document accompanying the toy. Manufacturers shall indicate a single point at which they can be contacted.
7. Manufacturers shall ensure that the toy is accompanied by instructions 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.
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.

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 26 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 online marketplaces, in the supply chain concerned, are kept informed in a timely manner of any non-conformity that the manufacturers have identified.
 11. Manufacturers shall make publicly available a telephone number, an electronic address, a dedicated section of their website or another communication channel, allowing consumers or other end-users to file complaints concerning the safety of toys and to inform the manufacturers of any accident or safety issue they have experienced with such toys. 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 product passport is available, in accordance with Article 17(2), for a period of 10 years after the toy covered by those documents has been placed on the market;
 - (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;
 - (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.
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.

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 of use and safety information in accordance with in Article 7(7) in a language or languages which can be easily understood by consumers or other end-users, as determined by the Member State concerned;
- (c) the manufacturer has created a product passport for the toy in accordance with Article 7(2);
- (d) the toy bears a data carrier in accordance with Article 17(5);
- (e) the relevant information in the product passport has been included in the product passport registry in accordance with Article 19(1);
- (f) the toy bears the CE marking 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 the essential safety requirements, they shall not place the toy on the market until it has been brought into conformity.

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

- (a) the manufacturer;
- (b) the market surveillance authorities, via the Safety Business Gateway referred to in Article 26 of Regulation (EU) 2023/988 ;
- (c) consumers or other end-users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, or both.

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 possible, on its packaging or in a document accompanying the toy.
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 importers, with regard to the risks presented by a toy, consider it necessary for the protection of health and safety of consumers or other end-users, they shall 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 the relevant Union harmonisation legislation, they shall immediately take the corrective measures necessary to bring that toy into conformity, withdraw it or recall it, as appropriate.

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

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.
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 a communication channel as referred to in Article 7(11) publicly available to consumers or other end-users, allowing them to present complaints concerning the safety of toys and provide information on any accident or safety issue they have experienced with the toy. If a communication channel is not available, importers shall provide for such a channel, taking into account accessibility needs for persons with disabilities.
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, 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.

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 and safety information in a language or languages which can be easily understood by consumers or other end-users as determined by the Member State in which the toy is to be made available on the market;
- (b) the toy bears a data carrier 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 the essential safety requirements, they shall not make 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 immediately provide information thereof to:

- (a) the manufacturer or the importer;
- (b) the market surveillance authorities through the Safety Business Gateway referred to in Article 26 of Regulation (EU) 2023/988;
- (c) consumers or other end-users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, or both.

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 taken.

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.

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 11

Cases in which obligations of manufacturers apply to importers and distributors

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

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 III

CONFORMITY OF TOYS

Article 13

Presumption of conformity

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. The Commission may, by means of implementing acts, establish common specifications for the essential safety requirements 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 or the standard does not satisfy the requirements it aims to cover;
 - (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 either of the following conditions is fulfilled:
 - (1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed;
 - (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) have not been adopted within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.

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

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

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 to the toy, to a label attached to the toy or to the packaging of the toy.

By way of derogation from the first subparagraph, in the case of small toys and toys consisting of small parts, the CE marking may be affixed to a leaflet accompanying the toy.

By way of derogation from the first subparagraph, in the case of toys sold in counter displays where it is not technically possible to affix the CE marking to each individual toy, the CE marking may be affixed to the counter display on the condition that the counter display was originally used as packaging for the toy.

Where the CE marking affixed to the toy 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 shall, 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 **PRODUCT PASSPORT**

Article 17

Product passport

1. Before placing a toy on the market, manufacturers shall create a product passport for that toy. The product passport shall meet the requirements laid down in this Article and Article 18.
2. The 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 information set out in Part I of Annex VI;
 - (d) be 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;

- (g) be available for a period of 10 years after the toy is placed on the market, also in cases of insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created the product passport;
 - (h) be accessible through a data carrier;
 - (i) fulfil the specific and technical requirements laid down pursuant to paragraph 10.
3. In addition to the information referred to in paragraph 2, the product passport may contain the information set out in Part II of Annex VI.
 4. By creating the product passport, the manufacturer shall assume responsibility for the compliance of the toy with this Regulation.
 5. The data carrier shall be physically present on the toy or on a label attached to the toy, in accordance with the implementing act adopted in accordance with paragraph 10. In the case of small toys and toys consisting of small parts, the data carrier may alternatively be affixed to its packaging. It shall be clearly visible to the consumer before any purchase and to market surveillance authorities, including in cases where the toy is made available through distance sales.
 6. Where other Union legislation 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 legislation.
 7. Where other Union legislation applying to toys requires a product passport, a single product passport shall be created for toys containing the information required under this Regulation as well as any other information required for the product passport by that other Union legislation.
 8. By way of derogation from paragraph 2, point (c), where information requirements relating to substances of concern in toys are established in a delegated act adopted in accordance with Article 4 of Regulation .../... [OP please insert: the Ecodesign for Sustainable Products Regulation], the information referred to in Part I, point (k), of Annex VI to this Regulation is no longer required.
 9. Economic operators may, in addition to the information 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 legislation.
 10. The Commission shall adopt implementing acts determining the specific and technical requirements related to the product passport for toys. Those requirements shall cover in particular the following:
 - (a) the types of data carrier 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 may introduce or update the information in the product passport, including where needed the creation of a new passport, including manufacturers, notified bodies, competent national authorities, and the Commission, or any organisation acting on their behalf, and the types of information they may introduce or update.

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

Article 18

Technical design and operation of the product passport

1. The product passport shall be fully interoperable with product passports required by other Union legislation in relation to the technical, semantic and organisational aspects of end-to-end communication and data exchange.
2. All information included in the product passport shall be based on open standards developed with an interoperable format and shall be machine readable, structured and searchable.
3. Consumers or other end-users, economic operators and other relevant actors shall have access to the product passport free of charge.
4. The data included in the product passport shall be stored by the economic operator responsible for its creation or by operators authorised to act on their behalf.
5. Where the data included in the product passport is stored or otherwise processed by an operator authorised to act on behalf of the economic operators placing the toy on the market, that other operator shall not be allowed to sell, re-use or process such data, in whole or in part, beyond what is necessary for the provision of the relevant storing or processing services.
6. Economic operators may not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the information on the product passport online.

Article 19

Product passport registry

1. Before placing a toy on the market, economic operators shall upload, in the registry established under Article 12(1) of Regulation (EU) .../... [PO insert serial number for Ecodesign Requirements for Sustainable Products] (the ‘registry’), the unique product identifier and unique operator identifier for that toy.
2. The Commission, market surveillance authorities and customs authorities shall have access to the information stored in the registry referred to in paragraph 1 for carrying out their duties pursuant to this Regulation.

Article 20

Customs controls relating to the product passport

1. Toys entering the Union market shall be subject to verifications and other measures laid down in this Article.
2. Declarants as defined in Article 5, point (15), of Regulation (EU) No 952/2013 shall include the unique product identifier in the customs declaration for release for free circulation of any toy.
3. Customs authorities shall verify whether the unique product identifier indicated by the declarant in accordance with paragraph 2 of this Article corresponds to a unique product identifier included in the registry in accordance with Article 19(1).
4. In addition to the verification referred to in paragraph 3 of this Article, customs authorities shall verify the consistency of information made available to customs by declarants with other information stored in the registry and listed in the delegated act referred to in Article 46(3).
5. The verifications referred to in paragraphs 3 and 4 of this Article shall take place electronically and automatically using the interconnection between the registry referred to in Article 19(1) and the EU Customs Single Window Certificates Exchange System referred to in [Article 13 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for Sustainable Products]].
6. Paragraphs 3, 4 and 5 of this Article shall apply from the day when the interconnection between the registry and the EU Customs Single Window Certificates Exchange System referred to in [Article 13 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for Sustainable Products]] becomes operational.

The Commission shall publish a notice in the *Official Journal of the European Union* to that effect indicating the date when the interconnection is operational.
7. Customs authorities may retrieve and use the information on toys included in the product passport and in the registry for carrying out their duties pursuant to Union legislation, including for risk management in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.
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.
9. The verifications and measures laid down in this Article shall not affect the application of other Union legal acts governing the release for free circulation of products, including Articles 46, 47 and 134 of Regulation (EU) No 952/2013, and the controls referred to in Chapter VII of Regulation (EU) 2019/1020.

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

CHAPTER VI

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

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.

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.
6. A notifying authority shall have a sufficient number of competent personnel 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.

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

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) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the requirements set out in this Regulation, of the applicable harmonised standards referred to in Article 13 of this Regulation and the common specifications referred to in Article 14 of this Regulation;
 - (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 with regard to all information obtained in carrying out their tasks under Annex IV, except in relation to the competent authorities of the Member State in which its activities are carried out. Intellectual property rights shall be protected.
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.

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.

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.

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 is no longer in compliance, 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 is not in conformity 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.

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.

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.

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.
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 legislation, 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.

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 product passport has not been drawn up in accordance with Article 17;
 - (d) the data carrier through which the 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.
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.

Article 44

National measures concerning toys which are compliant with the particular safety requirements but which present a risk

1. Where, having carried out an evaluation under Article 41(1), a market surveillance authority finds that, although a toy made available on the market is in compliance with the particular safety requirements it poses a risk to the health and safety of persons, it shall require the relevant economic operator to take all appropriate measures, within a reasonable period of time prescribed by the market surveillance authority taking into account the nature of the risk to ensure that the toy, when made available on the market, no longer presents that risk, to withdraw the toy from the market or to recall it.
2. The economic operator shall ensure that corrective action is taken in respect of all the toys concerned that the economic operator has made available on the market throughout the Union.
3. The market surveillance authority of the Member State shall immediately inform the Commission and the other Member States of its findings and any subsequent actions taken by the economic operator. That information shall include all available details, in particular the data necessary for the identification of the toy concerned including the

unique product identifier, the origin and the supply chain of the toy, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. 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 and, where necessary, propose appropriate measures.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

5. The information referred to in paragraph 3 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 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).

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 amend Annex VI as regards the information to be provided in the product passport, in order to adapt it to technical and scientific progress and to the level of digital readiness of market surveillance authorities and of users and their supervisors.
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 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.
3. The Commission is empowered to adopt delegated acts in accordance with Article 47 to supplement this Regulation by determining which of the information stored in the registry is to be controlled by customs authorities, in addition to the information set out in Article 20(3).
 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 in order to permit a certain use in toys of a specific substance or mixture that is prohibited under Part III, point 4, of Annex II, or to limit a certain use that has been permitted.

7. The use in toys of a substance or mixture prohibited under Part III, point 4, of Annex II may only be permitted when all of the following conditions are met:
 - (a) it has been found to be safe by the European Chemicals Agency (ECHA), in particular in view of exposure, including the overall exposure from other sources, and taking particular account of the vulnerability of children;
 - (b) there are no suitable alternative substances or mixtures available, as established by ECHA based on an analysis of alternatives;
 - (c) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.
8. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Parts A and B 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 traces of prohibited substances or mixtures as referred to in Part III, point 4, of Annex II;
 - (b) modifying the conditions or limit values for the presence of substances and mixtures in toys.
9. For the purposes of paragraphs 6 and 7, the Commission shall systematically and regularly evaluate the occurrence of hazardous chemical substances or mixtures in toys. In those evaluations, the Commission shall take into account reports of market surveillance bodies and scientific evidence presented by Member States and stakeholders.

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

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, of Annex II for the purposes of Article 46(6) shall be submitted to ECHA using the format and submission tools referred to in paragraph 3 of this Article.
2. Any person submitting a request for assessment under paragraph 1 may request that certain information is not to be made publicly available. The request for confidentiality shall be accompanied by a justification as to why the disclosure of the information could be harmful to the commercial interests of the person submitting the request for assessment or of any other party concerned.
3. ECHA shall draw up and make publicly available a format and tools for the submission of requests for assessment referred to in paragraph 1 as well as technical and scientific guidance on how to submit such requests.

Article 49

Opinions from ECHA

1. For the purposes of Article 46(6), ECHA shall provide opinions to the Commission on the use in toys of substances or mixtures that are prohibited under Part III, point 4 of Annex II, where a request for an assessment is submitted to it in accordance with Article 48(1). ECHA shall assess in its opinions whether the criteria set out in Article 46(6), second subparagraph, points (a) and (b), are met for a specific use.
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 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 use 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).
6. The Commission shall request an opinion from ECHA on the use in toys of substances or mixtures listed in Part C of the Appendix to Annex II as soon as new scientific information that may affect the permitted use of a specific substance or mixture in toys becomes known to the Commission.
7. For the purposes of Article 46(7), the Commission may request an opinion from ECHA on the safety of a specific substance or mixture in toys, which shall take into consideration the overall exposure to the substance or mixture from other sources and the vulnerability of children.
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.

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.
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 and the Commission shall respect the confidentiality 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.
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 taking into account the opinion of 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.

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.

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 *30 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. Toys placed on the market in conformity with Directive 2009/48/EC before ... [OP please insert the date = the first day of the month following 30 months after the date of entry into force of this Regulation] may continue to be made available on the market until ... [OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].
2. Chapter VII of this Regulation shall apply mutatis mutandis instead of Article 42, 43 and 45 of Directive 2009/48/EC to toys which were placed on the market in conformity with that Directive before ... [PO insert date: the first day of the month following 30 months after the date of entry into force of this Regulation], including toys for which a procedure has already been initiated under Article 42 or 43 of Directive 2009/48/EC before ... [PO insert date: the first day of the month following 30 months after the date of entry into force of this Regulation].
3. EC type-examination certificates issued in accordance with Article 20 of Directive 2009/48/EC shall remain valid until ... [PO insert date: the first day of the month following 42 months after the date of entry into force of this Regulation], unless they expire before that date.

Article 55

Evaluation and review

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

It shall apply from ... [OP please insert the date = the first day of the month following 30 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
The President

For the Council
The President