



Inspiring Generations of Play

1200 G Street NW • Suite 200 • Washington, DC 20005
t. 202.459.0354 • e. info@toyassociation.org

January 2, 2024

European Commission
EU-TBT Enquiry Point
DG for Internal Market, Industry, Entrepreneurship and SMEs
Avenue d'Auderghem 45
1000 Bruxelles
Belgique

VIA U.S. TBT enquiry point

RE: Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC

Dear Sir/Madam:

These comments are provided on behalf of The Toy Association, and our 800+ members, in response to the European Commission's notification (G/TBT/N/EU/1017) to the World Trade Organization on October 4, 2023. We appreciate the opportunity to comment and thank the European Commission ("Commission") for inviting input via the WTO TBT network, consistent with EU's obligations under the WTO *Agreement on Technical Barriers to Trade*.

Toys are sold globally with generally the same specifications, facilitated by an increasingly aligned set of international standards and norms to address the safety of the products, reduce risks to consumers, and reduce the impact on the environment. Safety is a paramount concern for the U.S. toy industry, as evidenced by the fact that the industry and The Toy Association have been global leaders in toy safety for decades. The Toy Association continues to work with medical experts, governments, consumers, and industry to provide technical input to ensure that the ISO 8124, EN71, ASTM F963, IEC 62115, and other international and domestic standards/regulations keep pace with innovation and potential emerging issues and are aligned as closely as possible, taking into consideration legal mandates.

The Toy Association welcomes the Commission's proposal to update its Toy Safety Directive to the Toy Safety Regulation. We consider this to be a real opportunity to identify new and effective approaches to strengthen toy safety, especially when it comes to counterfeit toys being sold online. At the same time, there are several provisions within the EU proposal that require further consideration and clarification. Without further amendment, some of the provisions will undermine the Commission's working objective to enhance toy safety, and in some cases could present a potential barrier to trade and thus be inconsistent with WTO TBT principles.

We have provided detailed comments and recommendations on the Commission's proposal within the **Appendix** to this letter. Please also note that our recommendations closely align with the comments provided by Toy Industries of Europe (TIE). Although the Appendix affirms much of our position, there are a few significant issues that we want to emphasize in support of the Commission's working efforts and in the hope that additional consideration will be granted to help improve the proposed new Toy Safety Regulation, most notably:

1. We recommend expanding the proposed market surveillance and enforcement provisions to address the increasing challenges from the selling of counterfeit and non-compliant toy products through online marketplaces, which compromise toy safety. The Digital Product Passport (DPP) will trigger additional administrative burdens on responsible companies who already work to provide safety products, but it will fail in mitigating the source of non-compliant products widely being sold through online marketplaces.
2. We recommend adjusting some of the proposed testing controls by considering leading science and current best practices for risk mitigation. There are several proposed provisions in the Toy Safety Regulations that are not based on science or do not offer any additional benefit in pursuit of enhancing toy safety.
3. We recommend adjusting the proposed implementation timeline and incorporate a “grandfathering” provision of safe products already being sold at retail after the new Toy Safety Regulation takes effect. Based on the scope of new provisions, the Commission’s deadlines for implementation are unrealistic and manufacturers will simply be unable to comply. The disruption to the supply of safe and otherwise compliant products will present a dangerous opportunity for suppliers of counterfeit and non-compliant products to meet consumers’ demand in the marketplace.

1) Enhancing Product Surveillance & Enforcement – Observations on the Digital Product Passport:

With the expansion of e-commerce channels, there has been a steady increase in the quantity of infringing and unregulated products offered online. Infringing goods include counterfeit products, trademark infringing products, unlicensed merchandise, and knock-off products. They can be found in all corners of the internet, including popular online marketplaces. This growing phenomenon negatively impacts consumers, legitimate companies, and the economy across all product categories. For consumers, the proliferation of infringing and unregulated toys raises significant hazards to health and safety. For the toy industry, it also directly harms toy companies’ ability to compete effectively in the marketplace, affecting core assets, company reputation, and financial health. We welcome the Commission’s expressed desire to work to help curb this serious issue that is compromising the integrity of Europe’s sound and strict toy safety measures, but more needs to be done. The Toy Association and its members believe there are numerous potential solutions to combat this issue.

Although the Commission’s proposal for a digital product passport (DPP) has merit, we fear the initiative will not achieve the desired result. The DPP may be perceived as a mechanism to ease procedures for market surveillance authorities in the EU; however, in application, we do not believe it will facilitate greater toy safety for the EU market. If a toy can be faked, so too will the DPP. The number of unsafe toys sold in the EU through online marketplaces that originate from outside the EU remains high. Our industry believes this problem can only be tackled through strong prevention along with corrective measures.

While the ease of selling through online marketplaces benefits legitimate companies of all sizes, it also permits unscrupulous and illegitimate sellers to flourish. The challenge is not only detrimental to consumer safety, but it also distorts competition and will inevitably contribute to even higher consumer prices for legal and safe products. The DPP along with several other new requirements in the Commission’s proposal will inherently trigger increased compliance costs, in turn increasing the sale price of toys being sold in the EU. For some consumers, this will push them to seek out cheaper alternatives, often through online marketplaces, which are most often non-compliant counterfeits. We strongly recommend the Commission take advantage of

this effort to update its requirements for toys and develop targeted controls to help curb this growing issue. The Commission should also consider incorporating a new liability structure that would handle the challenge connected to online sellers from third-party countries who continue to sell toys through online marketplaces and similar platforms. Further, we recommend the Commission consider incorporating provisions that would require online marketplaces to proactively screen sellers and the products sold.

Online marketplaces also largely lack proactive monitoring of the goods offered by the sellers on their sites. In some instances, the online marketplace is a venue to connect the seller and buyer, with the products never passing through the hand of the online marketplace. In other instances, the online marketplace will receive the sellers' goods to be held in the marketplace's warehouse and once ordered, the marketplace will ship the product to the purchaser from the marketplace's warehouse. Neither situation entails proactive monitoring by the marketplace as to whether the product is legitimate, whether it infringes intellectual property, or whether it meets regulations such as consumer product safety regulations. Instead, the marketplaces treat themselves as a "pass-through" for the products.

2) Avoiding Unnecessary Administration and Compliance – Observations on the Chemical Amendments:

We support added safety measures that are geared to protect children from any exposure of harmful chemicals. The use of safe and approved chemical substances in the manufacturing of toys is strictly regulated in Europe and by other leading international regulators. In addition, well-established production controls ensure harmful substances do not enter the manufacturing process. Consumer safety is a paramount goal for the toy industry, and we are proud of our decades of work with governments and product safety experts around the world to ensure toys remain as safe as possible for children.

As an industry that creates fun and entertaining products for children, toy companies are held to a higher standard of care. In turn, our member companies work year-round to ensure that toy safety standards are diligently applied. If a toy fails to meet these strict standards, it cannot be in the stream of commerce. Our members also recognize the importance of continually monitoring current standards and enhancing toy safety when risks emerge; this approach applies to any substance used in the manufacturing of our products. Toy manufacturers use only substances and materials that have been subject to science-and-risk-based assessments and are approved for sale in Europe.

We have detailed several concerns on the proposed measures targeting chemical safety within the Appendix of this letter. We urge the Commission to consider the science by which it is basing its proposal and to ensure it is benchmarking leading best practices on toy safety. A few notable points we would like to underline:

- We are concerned with the way the Commission is proposing to apply the specific chemical substances limits under the current Toy Safety Directive now to all toys for all ages. The existing limits already consider a science-based approach to assessing risk, incorporating exposure pathways and developmental factors relevant to children. The proposed changes to the approach present a significant concern since the existing restrictions are based on the consideration of children under three years who regularly mouth items as a means of exploring their environment, calculating exposure thresholds based on the very small body weights of children in this age group. Simply transposing these requirements onto all children under the age of 14 years ignores the reality that older children do not mouth toys and have significantly larger body masses. It is common practice amongst other leading regulators to set different levels for the two categories of

children. We strongly recommend that the Commission reconsider its proposal and apply a more scientific approach to developing this requirement.

- The generic bans for harmful substances should consider the form under which a substance is classified. For example, if only the powder-form of a certain substance is harmful, it is not reasonable to ban uses of such materials where the substance is not present in that form (e.g., embedded into a plastic material). Otherwise, the toy industry and ECHA will be wasting resources on scientific opinions to demonstrate the safety of materials where the substance is not present in the form that has been classified as harmful. It will also trigger an unnecessary waste of resources by market surveillance authorities to enforce these bans without providing any added safety benefit to the consumers in the EU.
- We are also concerned that the Commission appears to be blurring environmental policy controls within its proposed regulatory controls for toys. There are a few proposed provisions that go beyond the regulatory intent of the Commission's proposal to enhance toy safety. We understand the extension of the ban of CMRs to also cover endocrine disruptors (EDs), despite a lack of evidence of TSD-compliant toys that pose a risk. Furthermore, the text does not differentiate between those EDs that are harmful to health and those that are harmful to the environment. Those where the concern is environmental should not be banned through toy safety legislation. If there is an environmental concern, this should be addressed through horizontal legislation instead of being limited to a certain product category.

3) Orderly and Timely Implementation – Observations on Dates of Enforcement:

The deadlines in the proposal do not accurately represent the timelines needed to implement the proposed changes and manufacturers will simply be unable to comply. Updating the EN71 series of standards to address the changes required through the Toy Safety Regulation will not be able to be revised and published within the 30-month timeline even without considering the time needed for those standards to come into force after they are published. The scale of effort anticipated to comply with the DPP and adjust the administrative mechanisms to affirm compliance with the new regulations will take an extensive amount of time and effort. A more detailed account of our corresponding concerns that impact timing for compliance is included in the Appendix to our letter. Having considered the related challenges that are anticipated, we respectfully ask for a transition period of at least 54 months for the date of enforcement of the new Toy Regulations once it has been finalized.

Further, we strongly recommend the Commission incorporate a 'grandfather clause' to allow the continued sale of products that comply under the prior TSD that will already be on the market prior to the new regulations taking effect. The proposed 12-month cut-off date for all toys will have several negative effects, including further disruption of supply chains as well as triggering a needless environmental waste situation by requiring the removal and destruction of all the safe toys already in the marketplace. The cost implications for toy manufacturers and retailers will be significant. We respectfully request the Commission to remove the 12-month maximum sell-through period so that the safe, compliant toys already in the marketplace can continue to be sold.

Again, we thank the Commission for the opportunity to comment on its proposal and we look forward to contributing further in support of the Commission's working efforts. Should you have any questions regarding these comments, please do not hesitate to contact me or my colleague Joan Lawrence. I can be reached at jhuxley@toyassociation.org, and Ms. Lawrence can be reached at jlawrence@toyassociation.org.

Sincerely,



Jos Huxley
Senior Vice President, Technical Affairs

Enclosure - APPENDIX: Detailed Observations on the Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC

About The Toy Association and the toy industry:

The Toy Association is the North American based trade association; our membership includes more than 800+ businesses – from inventors and designers of toys to toy manufacturers and importers, retailers, and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US\$90 billion annually, and our members account for more than half this amount.

Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard, and it serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children.

The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

APPENDIX: Detailed Observations on the Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC

- 1) **Scope:** Proposed Article 2 gives the Commission the empowerment to adopt implementing acts determining whether specific products or categories of products can or cannot be considered toys within the meaning of the Regulation. If this provision is maintained in the final text, we believe it should be specified that relevant stakeholders ought to be consulted.
- 2) **Online Marketplaces:** There is no level-playing field between reputable economic operators and sellers of dangerous toys on online marketplaces. We believe the proposed Regulation has missed an opportunity to adequately tackle the constant stream of unsafe toys reaching children through online platforms. If this is not adequately addressed, the revision of the Directive will lead to less toy safety. In response we recommend other relevant EU legislative provisions be leveraged and incorporated into the regulations as it relates to this ongoing concern of noncompliant/counterfeit toy products. In particular:
 - a) In the event where it is found that no economic operator as required by Article 4(1) of Regulation (EU) No 2019/1020 (Market Surveillance Regulation) is present in the Union.
 - b) Where an online marketplace fails to comply with any of the requirements of Article 30 on the traceability of traders by providers of online platforms allowing consumers to conclude distance contracts with traders in Regulation (EU) 2022/2065 (Digital Services Act), and where, as a result, the trader is or becomes untraceable.
 - c) Clarify how online marketplaces should apply Article 31 of the Digital Services Act (Compliance by design for providers of online platforms allowing consumers to conclude distance contracts with traders) for toys regarding compliance with the Toy Safety Regulation.
- 3) **Psychological and Mental Health:** We believe the reference to “*psychological and mental health, well-being and cognitive development of children of children*” should be removed from Article 5 and Recital 14. We understand that the text has not been subject to an impact assessment, nor to a subsidiarity check. Also, whereas Recital 14 refers to digital technologies, this is absent from Article 5. This issue has not been subject to an impact assessment. Given the absence of a clear definition of what constitutes “*psychological and mental health, well-being and cognitive development*” in the context of toy safety, the current wording causes vast legal uncertainty. Any definition would be highly subjective and based on cultural and personal values, and there are no agreed criteria to determine this. The proposed text thus gives toy manufacturers no legal certainty that their toys comply with the Toy Safety Regulation and assumes that 27 Member States will all make the same assessment whereas this type of assessment is extremely subjective and may very well differ between different market surveillance authorities and individuals within one Member State.
- 4) **Noise requirements:** Annex II, part I, point 10 would mean all types of (unintended) sound should be tested and restricted. This would include sounds that are non-intended and not reproduceable (for example: marbles on a track, bouncing of a ball, bursting of a balloon). The current Directive refers to ‘toys which are designed to emit a sound’. In very exceptional cases where the sound from toys is unintended and still poses a risk, the general safety requirement can be and has been applied. The consequences of widening this provision to all sounds have not been subjected to an impact assessment and are thus not sufficiently understood. We recommend that Annex II, part I, point 10 refers to ‘toys which are designed to emit a sound’.
- 5) **Digital Product Passport (DPP):** Many of the details on the product passport have not been assessed in terms of administrative practicality and it remains unclear for manufacturers how they must apply the new rules and if they will have sufficient time to do so. The choice to implement the product passport in the toy safety rules, which are part of the New Legislative Framework (NLF) legislation without updating the NLF at the same time leads to several duplications and complications that could be addressed. We have several concerns with the DPP and have included recommendations, as follows:

- a) **CE marking:**
- In the Commission’s proposal, CE marking remains mandatory on/with the product.
 - The product passport has a similar objective to CE marking. By creating the product passport, the manufacturer declares that the toy compliant with the requirements of the Regulation and that the manufacturer takes full responsibility thereof. The product passport will also be directly accessible for market surveillance authorities.
 - The CE marking should also be included in the product passport. This means an unnecessary duplication and is in contrast with the ‘one in, one out’ approach. Also given the limited space available on products and the packaging, it should be allowed to include the CE-marking in the Product Passport only. We also recommend that – at least before a fundamental review of the NLF takes place – including the CE marking only in the product passport is voluntary, not mandatory.
- b) **Provision of Declaration of Conformity (DoC) for other EU legislation.** Toys are often subject to several pieces of EU legislation (for example, the Electromagnetic Compatibility Directive (EMCD) 2014/30/EU, the Radio Equipment Directive (RED) 2014/53/EU and the Restriction of Hazardous Substances (RoHS- Directive 2011/65/EU). Under the NLF, manufacturers use a single DoC for several pieces of legislation. Since the Toy Safety Regulation is now proposing a product passport instead, toy manufacturers in many cases will need to attest compliance in two different ways. This is unnecessarily complex and will be particularly burdensome on toy companies. In line with the spirit of the NLF and the ‘one in, one out approach’, we recommend that the proposed Toy Safety Regulation be clarified that by fulfilling the requirements for a product passport, the manufacturer is also deemed to be in compliance with these other legislative provisions.
- c) **Addresses:** EU legislation now requires several addresses and contact points to be provided, at different locations. We believe this could be simplified through the product passport:
- The electronic address is now also required to be present on the product. For small companies this will mean a large operation to change all injection molds ahead of the new legislation entering into force. This is not reflected in the impact assessment, and we recommend further consideration be applied to this issue. In many cases, it may be more appropriate to require the electronic address to be present in the product passports. We recommend that Article 7(6) be amended to give manufacturers the option to either provide the postal or the electronic address on the toy.
 - Annex VI, Part I, point b could be amended to require that both addresses be included in the product passport.
- d) **Affixing Data:** The rules for affixing the data carrier are a crucial element for toy companies. For many toys, it will not be feasible to attach a QR code in a legible way to the toy directly. For example, toys might be too small, the material might not allow it, or a toy might exist as sets with many different elements. Also, with numerous labelling requirements such as addresses, warnings and CE marking, available space on toys and packaging is limited. It will be crucial that greater flexibility is incorporated into the proposal to accommodate the reality by which toys are manufactured. Considering these concerns, the proposal contains several points of ambiguity that do not consider the sizing challenges of toys, for instance:
- Clause 42 states that the data carrier should be affixed to the toy, its packaging, or the accompanying documentation.
 - Article 7 (2.b) mentions that the data carrier should be affixed to the toy or to a label attached to the toy in accordance with Article 17(5)
 - Article 9 (2.d) states an obligation to ensure that the toy bears a data carrier in accordance with Article 17(5)
 - Article 10(2.b) refers to the requirement that the toy bears a data carrier in accordance with Article 17(5) (*nb.* point b of Article 10(2) appears to be redundant as this is already covered by point c of Article 10(3))
 - Article 17 (5) stipulates that 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.

- e) None of the above-listed provisions reference situations where the size or nature of the toy does not allow the data carrier to be affixed to the toy or a label attached to the toy. It also does not address the cases of toys sold in counter displays where it is not technically possible to affix the data carrier to each individual toy. We recommend that this issue be addressed and accommodated for in recital 42 and Article 17. Articles 7, 9 and 10 should simply refer to Article 17.
- f) Further, the rules on affixing the data carrier should be aligned with other European Union legislation requiring a product passport. Otherwise, manufacturers could be obliged to affix several data carriers. It should therefore be clarified that for toys, the rules on affixing the data carrier per the Toy Safety Regulation prevail.
- g) **Separate access for market surveillance and customs authorities:** As understood, the DPP has been proposed in support of market surveillance and customs controls. However, not all information should be publicly accessible. It is imperative for toy manufacturers to protect confidential information, such as that provided ahead of a product launch. We recommend that further consideration be applied to this fact and amendments be made.
- h) **Timing:** Toy manufacturers will struggle to meet the proposed timeline to implement the DPP, even if all our recommendations are incorporated into the policy.
 - It remains unclear when the Commission will have adopted the implementing acts determining the specific and technical requirements related to the product passport for toys and the product passport registry referred to in Article 19. It is therefore important that either a strict timeline is set for adoption of such acts, or that the deadline for manufacturers to comply with the product passport requirements is dependent on the date of publication in the Official Journal of relevant implementing acts.
 - Some of the components of the DPP appear to be required to be in place *before the product is produced* (e.g., requiring the link or QR code to be generated and maintained prior to the manufacturing or production begins in order for that information not be present on the product itself or the printed packaging/instructions). Since it is not unusual for products in development to be dropped and/or changed prior to the actual point of introduction in the marketplace, this will incur significant logistical and administrative costs relating to products that never make it into the EU marketplace as well as the products that are actually present.
- i) **Ambiguity:** Some parts of the DPP proposal also remain unclear, including those related to customs control:
 - Clause 49 states that, reference to a product passport [...] should be made available to the customs authorities by the economic operator. However, Article 20 states that declarants should include the unique product identifier in the customs declaration. The unique product identifier will be publicly available through the product passport and will be easily accessible to anyone, including counterfeiters. By having this information publicly available, counterfeiters will be able to abuse the system by using an identifier of a reputable company. We strongly recommend this provision be amended.
 - Clause 49 states that customs authorities should carry out an automatic verification of the product passport, while Clause 42 indicated that customs authorities should have immediate access to the information on the toy through the data carrier. It is not clarified how customs authorities have access to the data carrier. Article 20 does not refer to a verification of the product passport itself, nor does it mention that a data carrier should be included in the customs declaration.
 - It remains unclear how reference codes, product identifiers and operator identifiers are created.
 - Article 20 (8) states that “*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.*” However, commodity codes are not aligned with the scope of the Toy Safety Regulation. There will be many toys that fall under other commodity codes, whereas some non-toys will fall under the listed commodity codes. It is not clear to us how that will be dealt with in practice by customs authorities, for instance:

- Does that mean that a wide range of toys will not be subject to checks for a product passport?
 - Does that mean that it will not be possible anymore to import non-toys falling under customs codes listed in Annex VI?
 - We would support the proposal approach to apply for the product passport per ‘toy model’. However, for several cases, such as for large series of toys (dolls, cars, surprise bags, etc.), a level of aggregation could be applied. For greater ease of implementation, we recommend that the definition of a toy model (Article 3 (13, point d)) is amended to include ‘assortment number’.
- 6) **Warnings:** Warnings are important, but are only effective if they are relevant, accurate, understandable and if the information is clearly displayed. It is important to keep in mind that any excess information on the product packaging will be counterproductive to conveying the importance of safety messaging. Further, increasing the labeling obligation will necessitate a need to increase the packaging size of some toy products. This would increase transit costs as well as introducing unnecessary impacts to the waste/recycling stream. In turn, we recommend:
- a) Regarding Article 6(1), we believe it should be clarified that user limitations regarding the minimum or maximum age are not always relevant and therefore should only be included when appropriate to the safe use and enjoyment of the product.
 - b) Article 6(2) lists the categories of toys listed in Annex III. However, Annex III can be amended through a delegated act, whereas Article 6 cannot. This will lead to discrepancies and possibly conflicts once Annex II is amended. We recommend that Article 6(2) does not list all categories of toys but refers directly to Annex II.
 - c) Article 6(3) requires all warnings to be visible before purchase. This is very problematic in our view. The Toy Safety Directive referred to ‘warnings which determine the decision to purchase the toy’. We believe this concept should be re-introduced. Otherwise, a plethora of warnings (such as not to use a trampoline while eating, how to change a battery....) need to be added on pack in numerous translations. This will increase packaging waste and distract us from warnings that need to be seen before purchase, such as for risk from small parts.
 - d) In Annex III, point 2, regarding the pictogram for toys which might be dangerous for children under 36 months, it could be clarified that the pictogram size should be at least 10mm in red circle, white background and black words and face. This would be in line with the relevant EN 71 standard.
 - e) In Annex III, point 7: The warning for aquatic toys has changed. We recommend using the gender-neutral warning text included in the Toy Safety Directive. That warning is clear, and it would avoid companies having to incur unnecessary costs for changing their warnings.
 - f) Annex III, point 9: For toys included in or are co-mingled with food, it should be clarified that the warning should be affixed to the food-packaging, rather than the toy as the warning should be visible before consuming the food.
 - g) Annex III, point 11: Warning for fragrances in olfactory board games, cosmetic kits and gustative games. We believe the warning should be required for fragrances referred to in entries 1 to 71 in the table in Part B, point 1, of the Appendix to Annex II.
 - h) Languages: The different translations should be assessed carefully. There are at the moment discrepancies between different language requirements. For example, numerous language versions wrongly translate Annex III, point 10.
- 7) **Common specifications:** The Toy Safety Regulation introduces the power for the European Commission to adopt common specifications (Article 14). We recommend alignment with the recently adopted Machinery Regulation to ensure consistency between different EU laws introducing common specifications.
- 8) **Market surveillance/procedures for toys presenting a risk - Article 41:** When decisions on corrective actions are taken by a market surveillance authority at a national level, this sometimes happens without involvement of the manufacturer or importer or other responsible person in the EU. For instance, when the authority consults only with the retailer, the responsible economic operator concerned is not given the

opportunity to comment or sufficiently cooperate before the toy is notified to the Safety Gate (the EU rapid alert system for dangerous non-food products). As a result, recall procedures will be delayed and the operator is denied the possibility to provide clarifications early in the process. We therefore recommend that a clarification is added to Article 41 that the market surveillance authority shall, without delay, inform the relevant economic operator pursuant to Article 4(1) of Regulation (EU) 2019/1020 who is responsible for the tasks set out in Article 4(3) of that Regulation, of the reasons why the toy presents a risk to the health and safety of persons, and shall provide an appropriate time limit to that economic operator for comments.

- 9) **Chemicals:** The proposal significantly complicates the sale of compliant toys on the market, especially for SMEs. We are also very concerned that many of the new requirements serve no safety purpose. We do not believe these provisions have been adequately considered nor has a proper impact assessment been completed. Were these provisions to be implemented as drafted, they will severely compromise the availability of safe toys already being provided on the EU market, yet not make such toys any safer, specifically because of the challenges to demonstrate compliance with the new requirements. On top of that, the impact assessment specifies that there will not be new resources to support any increase in market surveillance. This means that there will be an even bigger advantage for rogue traders while companies who want to comply will be unable to provide safe and certified products. On primary concerns are as follows:
- a) **Analysis of alternatives:** Article 46 (7) requires that ECHA concludes that there are no suitable alternative substances or mixtures available, before a derogation can be granted for use (presence) of a substance banned under Annex II, part III, point 4. Safe use always needs to be assured to obtain a derogation. A further analysis of alternatives is not strictly required for safety reasons. Therefore, an obligation to demonstrate that there are no suitable alternatives should only be required for the most hazardous substances (category 1 substances for human health). ECHA and industry (including SMEs) would need to dedicate significant resources and expertise to request a derogation and this amendment ensures that these resources are focused on the most hazardous substances. This is consistent with the revised Carcinogens and Mutagens and Reprotoxic Substances at Work Directive (89/391/EEC) that requires category 1 CMR substances to be considered as mandatory candidates for substitution whilst category 2 substances are not. Similarly, under the REACH regulation, category 1 CMR substances may be listed on Annex XIV (the Authorization list) for mandatory substitution, whilst category 2 substances may not. Moving away from this approach risks that safe uses will be banned, potentially leading to regrettable substitution. It also introduces large uncertainties for SMEs, which should not be underestimated.
 - b) **The classified form:** The proposed generic bans for harmful substances disregard the form under which a substance is classified (Annex II, part III, point 4). We believe only the classified form should be addressed in toy safety legislation. For example, if only the powder-form of a certain substance is harmful (indicating inhalation concerns, for example), there is no need to ban materials where the substance is not present in that form (e.g. embedded into a plastic material). Otherwise, manufacturers will be wasting resources to demonstrate compliance with a ban that has no safety purpose. This will also waste resources for market surveillance authorities that have to enforce these bans and better spend their resources on real safety issues. The toy industry and ECHA will be wasting resources on scientific opinions to demonstrate the safety of materials where the substance is not present in the form classified as harmful.
 - c) **Endocrine disruptors:** In principle, the toy industry supports the ban of endocrine disruptors for human health (provided the legislation is adapted to ensure manufacturers can demonstrate compliance and market surveillance authorities can adequately enforce the bans). However, we believe it is important to stress that children are currently not at risk because of exposure to endocrine disruptors from toys that are compliant with the current toy safety rules. The 'significant health benefits' attributed to the proposed full ban by the impact assessment can therefore not be expected to materialize. Worse, if the new rules are difficult to apply by reputable manufacturers and difficult to enforce, we can expect rogue traders to benefit. Significant health benefits can only be expected if new provisions against the sale of unsafe toys on online marketplaces are added, market surveillance is improved, and it becomes easier to place safe toys on the market – not more difficult. Unfortunately, this is largely missing from the proposal. Annex II, part 3, point

- 4b, refers to the category ‘endocrine disruption’. However, this category is not included in the CLP Regulation. It should refer to ‘endocrine disruption for human health’. Environmental concerns should be addressed through other legislation, ideally horizontal, for better impact and to ensure reputable toy manufacturers are not put at a disadvantage vis a vis other sectors and rogue traders.
- d) **Specific target organ toxicity:** Annex II, Part III, point 4c provides a full ban on chemicals classified for specific target organ toxicity category 1, either in single exposure or in repeated exposure: Classifications for specific target organ toxicity are usually associated with a specific route of exposure (e.g. inhalation, ingestion). If this route of exposure can be ruled out for the toy in question, there is no scientific justification for a full ban of the substance.
- e) **Respiratory sensitization:** Annex II, Part III point 4d provides for a full ban of substances classified as respiratory sensitization category 1. However, there is no scientific justification for banning respiratory sensitization category 1 when these substances do not present an inhalation exposure as there is no safety risk involved.
- f) **Trace-levels:** We believe it is crucial that the allowance for derogation from full bans for unintended trace levels is maintained (Annex II, Part III, point 5). Without this provision, it will be virtually impossible to place safe and compliant toys on the market.
- g) **Coherence with other EU legislation/REACH:** We believe there should be more coherence with chemicals legislation applicable to toys. Not only do toys need to comply with restrictions for chemical substances under both pieces of legislation, suppliers of the toy industry also need to consider REACH for other sectors they cater to. The toy sector is only a very small customer for our suppliers. We therefore recommend that:
- Annex II, Part III point 7a is extended to substances that are restricted in toys in Annex XVII of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), under the conditions specified therein. Otherwise, the substances will be subject at the same time to a REACH restriction and to the full ban and applicable derogations under the Toy Safety Regulation.
 - It should be clarified in Article 46 that, for the purposes of paragraphs 6 and 7 of that Article, the most appropriate legislation is used. The Toy Safety Regulation should specifically include restrictions if a risk is toy specific. In case the risk is not toy-specific, but related to any consumer product a child comes into contact with, restrictions through REACH Annex XVII should be prioritized as that is more protective for children and will ensure a level playing field for industry.
 - The Formaldehyde emission limit in wood toy material (Annex II, Appendix, Part A, point 3) is now covered by a REACH annex XVII restriction, entry 77. To avoid duplication, inconsistencies in wording, scope, and test methods this restriction should be removed from the Toy Safety Regulation
 - The restriction for Aniline in textile and leather toys should be deleted (Annex II, Appendix, Part A, point 3). The reason is that this restriction is extending the current REACH annex XVII restriction on azo dyes (entry 43) to aniline for toys only, whilst entry 43 does not restrict aniline in textile and leather consumer products. It is inconsistent that textiles and leather toy materials, such as children disguise costumes are subjected to an aniline restriction whereas normal children's clothing are not. If aniline is indeed a concern for consumer safety, then a revision of the current REACH Annex XVII restriction would be the appropriate route.
- h) **Derogation based on the CLP threshold:** To make the large increase of full bans workable we strongly suggest re-introduction of the derogation based on the CLP thresholds which is included in the current Toy Safety Directive. Otherwise, industry, and especially SMEs, will be forced to substantially increase their testing costs. Based on the proposal, they are expected to have knowledge of the content of their materials way beyond what is required for any other sector. There are currently no commercially available methods to test all CMRs, EDs, RSs and STOT substances. Were it to be implemented as proposed, companies simply could not realistically apply these provisions to demonstrate compliance. Further, the provisions would be unenforceable as officials would also be unable to assess for compliance. The European

Commission has provided no evidence in the impact assessment on the evaluation of the TSD that there is an actual problem with compliant toys. Moreover, the possibility to set limit values for chemicals in all toys will make it possible to deal with any actual cases where the CLP threshold is not protective enough when they arise. Reintroduction of this derogation will make it workable to introduce the full bans under point Annex II, Part III point 4. This will limit the need for companies, especially SMEs, to perform many expensive tests without added safety benefit. Stricter limit values can be set in the Appendix to Annex II or REACH if appropriate.

- i) **Inaccessible materials:** Bans for inaccessible substances and mixtures in toys are unnecessary. If there is no exposure, there is no risk. If introduced for environmental purposes, this should be done across different sectors. The inaccessibility derogation from the TSD is now limited only to electric and electronic components and batteries. This implies for instance that a mechanical bell inside a rattle – which is not accessible – will also need to comply with the same substance restrictions as other accessible parts. The same interpretation could be applied to an internal screw in a child's swing or trampoline, or a non-electrical musical feature in a soft-filled toy etc. This type of approach is not based on scientific evidence. No exposure equals no risk when components are not accessible. We therefore recommend that the derogation for inaccessible electronics (Annex III, part II, point 7c), is extended to all inaccessible materials.
- j) **N-nitrosamines and N-nitrosatable substances.** We believe the proposed restriction of N-nitrosamines and N-nitrosatable substances should be corrected (Annex II - Appendix -Part A, point 2). We strongly recommend including the correct limit values as stipulated in standard EN 71-12, which appears to have been the intention and basis of the impact assessment.
- k) **Extension of limit values for toys for children under 3-years-old to all ages:** We welcome the possibility to set limit values for all toys. However, we would suggest a different approach. Two separate tables with restrictions: one for toys intended for children below 3 years of age or toys intended to be placed in the mouth – and a separate table for other toys. In some cases, these 16 limit values would be identical, but not in all cases. Mouthing behavior is prevalent until the age of 18 months and the limits set in Appendix C of the Toy Safety Directive are based on this fact as well as the body weight of a baby. We recommend that the Commission assess the correct limit values for toys for older children and introduce them through comitology procedures. Also, the migration limits for phenol and formaldehyde in polymeric materials are only relevant due to mouthing behavior of babies and should therefore not be applied to toys for children above 36 months of age. These limits should therefore not be applied to all toys.
- l) **Fragrance allergens:** We recommend several changes to the obligations on fragrance allergens. The lists of fragrances restricted and to be labelled need to be reviewed for alignment with the legislation related to cosmetics. Also:
 - A correction is needed on the tailor-made requirements for certain experimental toy sets as identified in the evaluation of the Toy Safety Directive (Annex II - Appendix - Part B, point 2). The proposed text refers only to 10 fragrances that shall be allowed in olfactory board games, cosmetic kits, and gustative games. However, the list of fragrances has been extended to include 71 fragrances. As identified in the evaluation of the Toy Safety Directive, this could not be amended under the current Directive, but it should be reflected in the new Regulation. The same change should be reflected in Annex III, point 11 (warnings).
 - Alignment of all the names and CAS-numbers with the Cosmetics Products Regulation is needed. Most of the fragrances listed in Annex II, Appendix, Part B, point 1, have a different name under the Cosmetic Product Regulation than under the Toy Safety Regulation. This is problematic for toys that are subject to both pieces of legislation. We recommend that the Toy Safety Regulation is aligned with the Cosmetic Products Regulation.
 - 'Lilial' is included in the list of 'substances subject to specific labelling requirements' (Appendix II, Annex, Part B, point 1, entry 7). However, Lilial is banned in cosmetic products. We believe its use should also be restricted in toys and should be included in Annex II, Appendix, Part 1, point 4 (although the substance name 2-(4-tert-butylbenzyl) propionaldehyde should be used).

- m) **Provision of information on substances of concern:** We believe the requirement to provide a list of substances of concern in the product passport (Annex VI, Part I, point k) should be removed. The requirement:
- Is not enforceable for market surveillance authorities.
 - Is highly misleading for consumers. Exposure is not considered a risk, and non-reputable manufacturers will not list substances that are dangerous.
 - It would penalize reputable manufacturers - especially SMEs.
 - Depending on the exact definition of 'substances of concern', it will lead to a high amount of unnecessary testing to assess whether certain substances are present.
 - It goes beyond the subject matter of the proposed Regulation.
 - The proposed requirement has not been subject to an adequate impact assessment.
 - It is an unnecessary addition to existing reporting requirements, such as for substances of very high concerns, through the existing SCIP database.

- 10) **Transition period:** The proposed transition period is too short to ensure toys can comply with the new rules on time. We therefore recommend a transition period of at least 54 months. This is based on the following rationale. While the development of a new toy typically takes up to 24 months, manufacturers need clarification on the applicable rules and standards to meet before they can start that process. For chemicals, the proposed transition period is too short to ensure necessary derogations based on Article 46(6) are in place in advance for manufacturers to apply them. As an example: the EU Scientific Committee started investigating industry requests for derogations for the use of titanium dioxide and metallic cobalt in October 2020 and there is still no final adoption of the derogation. Such derogation request under the new Regulation requires several steps:
- a) Industry needs to investigate and develop a dossier for a derogation request based on the final text of the Toy Safety Regulation.
 - b) Industry should have the possibility to submit such derogation request to ECHA. ECHA therefore needs to have in place the relevant format and tools to submit such a request. ECHA should also have in place the procedures to assess such a request.
 - c) ECHA has to investigate a derogation request, which can take up to 18 months.
 - d) The European Commission should draft a derogation based on ECHA's final opinion. Based on recent experience (Metallic Cobalt: SCHEER opinion adopted December 2022, derogation not yet finalized) this can take-up significant time.
 - e) The derogation also needs to be included in the legislation before it can be applied.

Given the very ambitious transition period, we believe that it should be specified that ECHA should have the format and tools to submit requests for assessment for the purposes of Article 46(6) (Article 48(2)) and they are made available very shortly after entry into force of the Toy Safety Regulation. The EU toy safety standards that provide presumption of conformity with the toy safety legislation will need to be amended. The Commission will need to mandate CEN/CENELEC to start working on the standards. Just writing out one standardization request and having it approved and published can take a year at best, but it typically takes much longer. The subsequent discussions and approval of a standard typically takes around 36 months to 48 months (as shown in the current standardization request M/589). If the changes to the standards are minimal, this can be done in 12 to 18 months.

However, if for example acoustic requirements need to be developed for new categories of toys, this will take much longer. It is also not yet clear whether all delegated acts for the introduction of the product passport (under the Eco-design for Sustainable products Regulation and under the Toy Safety Regulation) will be in place in time to enable manufacturers to apply the product passport.

Further, the proposed inclusion of a cut-off date after which safe toys previously placed on the market are no longer allowed to be made available on the market (Article 54(1) is unprecedented and has not been subject to an impact assessment. There are several downstream issues that will have a very negative impact on our sector, while at the same time will not provide any additional safety benefit to consumers. For example:

- Retailers will not order new toys before the deadline. This will lead to empty shelves and could render manufacturers and retailers (especially SMEs) bankrupt.
- Millions of safe toys that are still on the shelves or warehouses when the 12 months end will have to be destroyed.
- Consumers will be nudged to unsafe alternatives, for example through online platforms.

11) Further Clarifications on Proposal Required:

- a) **Essential safety requirements:** Article 3 (20) and Recital 40 refer to ‘*essential requirements*’. We believe this should read ‘*essential safety requirements*’.
- b) **Functional toys:** To ensure equal interpretation throughout the EU, we recommend adding clarifications to Article 3(29) of what a ‘functional toy’ is. This can be based on existing Guidance to the Toy Safety Directive. For example, by specifying that the same or similar level of risk is involved and providing some examples of functional toys.
- c) **Instructions for use:** Article 7(7) & Article 10(2.a) uses the term ‘*instructions*’, whereas Article 6(3), Article 6(4) & Article 9(2.b) use the clearer and more specific term ‘*instructions for use*’. We recommend ‘*instructions for use*’ is used throughout the Regulation to avoid confusion and foster common understanding by authorities and economic operators.
- d) **Communication channel:** For consumers to file complaints concerning the safety of toys and to inform the manufacturers of any accident or safety issue:
 - Article 7 (11) requires that manufacturers set up such a communication channel. However, this is contradicted by Article 9(9) which allows importers to establish such a channel in case the manufacturer has not done so.
 - Further it is also not clear in which cases compliance should be verified by the manufacturer and when by the importer.
- e) **Informing consumers of safety concerns with a toy:** Article 9(2) and Article 10(2) require importers and distributors to inform consumers in instances when a toy has not been placed on the market yet. As in those cases, there is no consumer to inform, we presume this requirement should be covered by Article 9(6) and Article 10(4) instead.
- f) **Processing and storing data in line with the General Data Protection Regulation (GDPR):** For several provisions, we question if they are in line with GDPR. For clarity and consistency in legislation, it could be improved by specifying that processing and storing of data should be done in accordance with the GDPR. This concerns Article 7(13), Article 9(11), and Article 18(6).
- g) **CE marking:** In case CE marking will still be mandatory, we strongly recommend that Article 16 (3) is amended. The proposed text states that 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. There is, however, no reason to ever require CE marking to be placed next to warnings. This would be unnecessarily complex. We recommend to either use the wording of the Toy Safety Directive (‘*may*’ instead of ‘*shall*’) or to delete the paragraph entirely as it has no added value.
- h) **Language requirements can function as a barrier to trade, especially for SMEs:** We would welcome solutions to tackle this. For example, where standardized information is requested for market surveillance authorities – such as in the product passport - these authorities should have automatic translation tools at their disposal.
- i) **Harmonized standards published with a restriction:** In Article 22(3, point c) it should be clarified that where a harmonized standards has been published with a restriction, it may not be used to demonstrate compliance only in cases that restriction is relevant to the toy in question. Otherwise, harmonized standards published with a restriction can never be used to demonstrate compliance.
- j) **Notified Bodies:** In the requirements related to Notified Bodies, in particular Article 28(10), we recommend that it is clarified to state that proprietary rights and trade secrets shall also be protected (next to intellectual property rights). This would be in line with other recently updated harmonized EU legislation, i.e. the Machinery Regulation.
- k) **Confidential Business Information:** Regarding exchange of confidential information with regulatory authorities of third countries (Article 51), we recommend that it is specified that Member States and the Commission may exchange such information in case they have

concluded bilateral or multilateral confidentiality arrangements, when those agreements and arrangements ensure that any exchange of information is in accordance with applicable European Union law. This recommendation is in line with the recently adopted Machinery Regulation.

- l) **Electrical properties:** We believe the proposed wording for Annex II, part IV, point 1, will have unintended consequences that have not been assessed. The proposed text now also relates to harmless electrostatic discharge. We believe it should be clarified that the current combination generated does not lead to any risk for health and safety, for example from a harmful electric shock.
- m) **Technical documentation for internal production control:** We believe it should be specified in Annex IV - Part I - Module A, point 2, that the elements set out in Annex V should only be included when relevant. Two of these refer to EU-type examination procedures, which are not required under internal production control.