Council of the European Union

Brussels, 28 July 2023
(OR. en)

12234/23
ADD 3

Interinstitutional File:
2023/0290(COD)

MI 669
ENT 172
CONSOM 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.:	SWD(2023) 269 final
Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT Accompanying the document 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 SWD(2023) 269 final.

Encl.: SWD(2023) 269 final

EUROPEAN
COMMISSION

Brussels, 28.7.2023
SWD(2023) 269 final

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{COM(2023) 462 final} - {SEC(2023) 297 final} - {SWD(2023) 268 final} - {SWD(2023) 270 final}

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Glossary

Term or acronym	Meaning or definition
AI	Artificial Intelligence
AdCo	Administrative Cooperation
CASP	Coordinated Actions on the Safety of Products
CE	European conformity marking
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CLP	Classification, Labelling and Packaging
CLP Regulation	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.
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
CSS	Chemicals Strategy for Sustainability
DoC	Declaration of Conformity
DPP	Digital Product Passport
EC	European Commission
ED	Endocrine Disruptors
EN	European Standard
ESO(s)	European Standardisation Organisation(s)
ESPR	Proposal for an Ecodesign for Sustainable Products Regulation
ETSI	European Telecommunications Standards Institute

EU	European Union
GPSD	General Product Safety Directive
IA	Impact Assessment
IoT	Internet of Things
IDB	European Injuries Database
MS	Member State(s)
MSA	Market Surveillance Authority(ies)
NB	Notified Body(ies)
OJEU	Official Journal of the EU
PBTs and vPvBs	persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances
PROSAFE	Product Safety Forum of Europe
RAPEX	EU Rapid Exchange System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RED	Radio Equipment Directive
RoHS	Restriction of Hazardous Substances
RPS	Regulatory Procedure with Scrutiny
SCCS	Scientific Committee on Consumer Safety
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SME(s)	Small- and Medium-sized Enterprise(s)
TIE	Toy Industries of Europe
TSD	Toy Safety Directive

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Play is an essential part of growing up: children discover the world and develop their capabilities through play. However, toys have to be safe for children. They are regulated by Directive 2009/48/EC on the safety of toys (the Toy Safety Directive, TSD)[1]. This Directive lays down the safety requirements that toys must meet in order to be placed on the market in the EU, whether they are manufactured in the EU or in third countries. At the same time, the Directive aims at ensuring the free movement of toys within the Single Market.

The Commission Evaluation of the Toy Safety Directive[2] (the Evaluation) identified a number of deficiencies that have emerged during the practical application of the TSD since its adoption 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 a high number of unsafe toys on the Union market[3].

The Chemicals Strategy for Sustainability[4] (the CSS) called for extending the 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 aimed at strengthening the TSD with regard to the protection from the risks of the most harmful chemicals and with regard to possible combination effects of chemicals. Although the Directive already prohibits generally substances that are carcinogenic, mutagenic or toxic for reproduction (CMRs) in toys, it does not refer to other substances of particular concern such as endocrine disruptors, substances affecting the immune, neurological or respiratory systems or substances toxic to a specific organ.

Finally, on 16 February 2022 the European Parliament adopted almost unanimously an own initiative report on the implementation of the Toy Safety Directive[5]. In its report, the European Parliament calls on the Commission to revise the Directive to strengthen the protection of children from chemical risks, ensure that risks posed by connected toys are addressed by EU law and improve enforcement of the Directive in particular in relation to online sales.

Given the objectives of this initiative of better protecting children from harmful chemicals, as well as reducing the number of unsafe toys on the Union market, it is expected to contribute most significantly to the United Nations Sustainable Development Goal (SDG) #3 for 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.

1.1. Regulatory context: the Toy Safety Directive

The TSD is an EU product harmonisation measure which has the twofold objective (1) to maintain a high level of safety for children and protection against possible health threats from toys, while (2) allowing the free movement of toys in the internal market.

[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] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1852-Evaluation-of-the-Toy-Safety-Directive

[3] See annex 8 for an overview of the conclusions of the Evaluation.

[4] https://ec.europa.eu/knowledge4policy/publication/communication-com2020667-chemicals-strategy-sustainability-towards-toxic-free_en

[5] https://www.europarl.europa.eu/doceo/document/A-9-2021-0349_EN.html

The scope of the Toy Safety Directive covers all '***products designed or intended, whether or not exclusively, for use in play by children under 14 years of age***'.[6] The Directive explicitly excludes certain products from its scope[7]. Moreover, Annex I to the TSD enumerates examples of products that are not considered to be toys but could be confused with toys[8]. In this Annex, the Directive excludes from its scope "*electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals…*" and "*interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs*". Therefore, **whilst a physical toy which has play value and incorporates software would be considered a toy within the scope of the Directive (for example, a talking doll or animal), a videogame or other similar software would not**.

The TSD lays down the safety criteria ('**essential safety requirements**') that toys must meet to be marketed in the EU. The essential safety requirements are designed to ensure a high level of safety; they cover identified hazards related to the characteristics of the toy or to its performance.[9] Essential requirements are supported by **harmonised standards**, which set out the technical specifications to comply with the essential requirements and once referenced in the Official Journal of the EU, provide presumption of conformity with the essential requirements they aim to cover.

The essential safety requirements in the Toy Safety Directive cover:

- general risks**:** the health and safety of children, as well as other people such as parents or supervisors;
- particular risks**:** physical and mechanical, flammability, chemical, electrical, hygiene and radioactivity risks. In particular, as regards chemical risks, there is (i) a general prohibition of CMR substances subject to derogations, (ii) specific limit values for specific CMR substances (nitrosamines and nitrosatable substances), as well as for 19 'elements' in different toy materials, (iii) prohibitions of certain allergenic fragrances and labelling requirements for others, and (iv) specific limit values in toys for children under 36 months or to be put in the mouth.

In order to keep pace with latest technical and scientific developments, **the Commission can amend certain parts of the TSD** via the Regulatory Procedure with Scrutiny (RPS).[10] The Commission may adapt Annex I that lists examples of products that are not toys (but may be confused with them), the list of prohibited allergenic fragrances and the list of allergenic fragrances to be labelled in Annex II. It may adapt the limit values for heavy metals and other hazardous metals in Annex II, and the warnings for toys in Annex V. In addition, the Commission may establish maximum limit values for any chemical in toys intended for children under 36 months of age and in all toys intended to be placed in the mouth, and it may also amend those limits (Appendix C to Annex II). **Since its adoption the TSD has thus been amended 17 times[11].** Finally, the Commission may allow the use of chemicals that are carcinogenic, mutagenic or toxic to reproduction (CMRs), albeit only following a strict scientific-technical assessment including an independent Scientific Committee.

[6] Article 2.1 of the Toy Safety Directive.
[7] For example, slings and catapults or playground equipment intended for public use (see article 2.2 of the TSD).
[8] For example, decorative objects for festivities or celebrations, fashion accessories for children, or puzzles with more than 500 pieces.
[9] The 'Blue Guide' on the implementation of EU product rules, p. 32.
https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en
[10] Article 46 of the Toy Safety Directive.
[11] See annex 6 for the list of amendments to the TSD.

The TSD requires that **conformity assessment** is carried out to verify whether a toy complies with the applicable essential requirements. It is to be carried out by the manufacturer or with the intervention of a third party – a 'Notified Body' test laboratory that has been previously designated at EU level for the purposes of such assessments under the TSD. The TSD requires the intervention of a Notified Body only in certain cases, in particular when harmonised standards do not cover all relevant safety requirements or when the toy manufacturer has not applied such harmonised standards[12]. It is the manufacturer, whether established in the EU or outside the EU, who is responsible for the compliance of the toy with the applicable requirements. When a toy is in conformity with the applicable requirements, the manufacturer must affix the CE marking to it.

Market surveillance to ensure compliance with the Toy Safety Directive is currently regulated by Regulation 2019/1020[13]. This Regulation replaced Regulation (EC) No 765/2008[14] and became fully applicable on 16 July 2021. This Regulation requires that in order to place toys on the Union market, there must be an economic operator established in the EU and responsible for a number of tasks set out in that Regulation to facilitate market surveillance.

More details on the current legal provisions of the TSD can be found in Annex 6.

1.2. Link with other initiatives

Revision of the CLP Regulation[15] - Regulation (EC) No 1272/2008 on hazard classification, labelling and packaging of chemicals (the CLP Regulation) is the core piece of Union legislation for the hazard assessment of chemicals (human health, environment and physical hazards). It sets out the hazard classification of chemicals and how to communicate those hazards to consumers and workers. The CLP Regulation follows the United Nations' Globally Harmonized System (GHS) of classification and labelling of chemicals setting up criteria for classification and communication of physicochemical, health, and environmental hazards. The CLP Regulation is currently under revision and the introduction of new hazard classes (such as endocrine disruptors) is considered. Hazard assessment is the starting point for risk-assessment and -management measures, which are in turn provided for in **downstream legislation, such as the Toy Safety Directive**. This means the hazards that chemicals present are established under the CLP Regulation: they may be carcinogenic, lead to skin allergies or to irritation in the eyes for example, in certain of their forms. The decision of how to address those hazardous substances in certain products are taken then in other legislation that apply to the product. For example, the Toy Safety Directive already prohibits the use of substances which are classified under the CLP Regulation as CMRs. Therefore, the future hazard classes to be introduced in the CLP Regulation would be relevant for defining the regulatory consequences in certain products, such as in the context of the current revision of the Toy Safety Directive. The measures proposed under options 1b and 1c in this Impact Assessment are based on banning chemical substances classified under certain hazard classes of the CLP Regulation. To fully implement the generic bans of endocrine disrupting substances in a revision of the Toy Safety Directive (proposed in options 1b and 1c), it is necessary that the CLP Regulation be amended to include the hazard class for endocrine disrupting chemicals. This has been done in the

[12] This procedure is also required when the harmonised standards have been published with a restriction that may change or invalidate certain specification(s) in the standard referenced. The manufacturer may voluntarily have recourse to a Notified Body for the conformity assessment.

[13] 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.

[14] 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

[15] Revision of EU legislation on hazard classification, labelling and packaging of chemicals (europa.eu)

recent Commission Delegated Regulation (EU) 2023/707[16]. Any of the other hazard classes considered for generic bans under options 1b and 1c already exist under the CLP Regulation and therefore do not require any change to this Regulation.

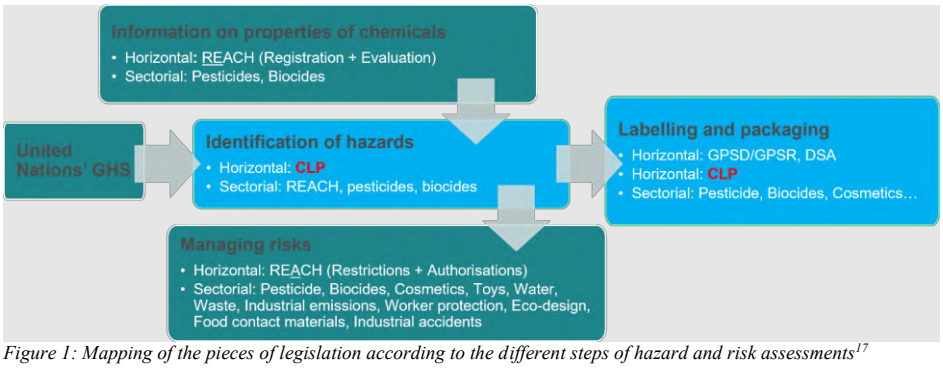

Figure 1: Mapping of the pieces of legislation according to the different steps of hazard and risk assessments[17]

Revision of the REACH Regulation[18] - The REACH Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals, together with the CLP Regulation, are the key Union legislation for the assessment and management of chemicals. In accordance with the CSS, a targeted revision of REACH will explore extending the generic risk approach to restrictions to most harmful chemicals while allowing their use only when essential. In particular, criteria for essential uses will be defined to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. **Toys are within the scope of REACH as consumer articles where REACH addresses environmental or human health concerns**. However, the Toy Safety Directive provides for a more comprehensive and targeted approach to toys as regards aspects relating to human health, in view of the vulnerable population group toys are addressed to.

[16] Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures,
OJ L 93, 31.3.2023

[17] See the Impact Assessment for the Review of the CLP Regulation, SWD(2022) 435 final, part 1.

[18] Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment (europa.eu)

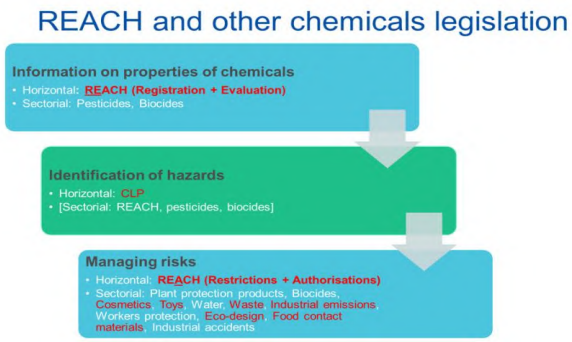

Figure 2: Hazard identification and risk management in EU legislation

The proposed measures under this Impact Assessment do not rely on any changes to be introduced in the REACH Regulation. The REACH revision could introduce generic bans for the most harmful chemicals themselves and for certain uses, in particular in consumer products. This may have an indirect impact on the functioning of the toys industry and the options presented. This is because alternative chemicals will be more likely to be available on the market, including for toy manufacturers, which would limit the negative impacts of options 1b and 1c proposed in the toy industry. However, these changes are not necessary for the revision of the Toy Safety Directive. Thus, the quantitative analysis of impacts of the different policy options in this impact assessment does not factor in the possible effects from the REACH revision.

Digital Services Act (DSA)[19]: The DSA includes a new set of horizontal rules to regulate the responsibility of online intermediaries, including online marketplaces. It will establish new obligations for online intermediaries inter alia in relation with how they handle all types of illegal content hosted on their websites **including unsafe products**. The DSA will reinforce actions to be taken on non-compliant toys sold online, such as mechanisms to counter illegal content online, new rules to trace sellers on online marketplaces and an obligation by online marketplaces to randomly check against existing databases whether products or services on their sites are compliant.

General Product Safety Regulation[20]: The recently adopted Regulation (EU) 2023/933 on General Product Safety replaces the General Product Safety Directive[21]. One of the objectives of the proposal is to offer better protection of consumers when shopping online, including on online marketplaces, and from dangerous products coming from the EU and outside. The General Product Safety Regulation, as the current Directive, will continue to **address only products, risks and aspects which may not be specifically covered by the Toy Safety Directive**. It is expected to include specific provisions on recalls, accident reporting and online marketplaces which would apply to all consumer products, including toys.

Artificial Intelligence (AI) horizontal framework[22]: The new legislative proposal for the AI horizontal framework (AI Act) will lay down harmonised rules for the placing on the market, the

[19] Digital Services Act – deepening the internal market and clarifying responsibilities for digital services (europa.eu)
[20] General Product Safety Directive – review (europa.eu)
[21] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4.
[22] Artificial intelligence – ethical and legal requirements (europa.eu). Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, of 21 April 2021 and available at https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623335154975&uri=CELEX%3A52021PC0206

putting into service and the use of artificial intelligence systems ('AI systems') in the Union. It lays down specific requirements for high-risk AI systems, and it is expected to cover, as high-risk, AI systems intended to be used as safety components of toys covered by the TSD. Therefore, any risks posed specifically by the incorporation of AI in toys would be addressed by that Regulation. Nevertheless, the AI Act refers to the EU product legislation applicable to the product (in this case the Toy Safety Directive) to determine the conformity assessment procedure which needs to be followed, also with regards to the verification of compliance with the essential requirements concerning AI systems that are to be imposed by the AI act.

Delegated acts under the Radio Equipment Directive (RED)[23]**:** the RED establishes the possibility for the Commission to adopt delegated acts in relation to several aspects, including requiring protection of networks, personal data and privacy and protection from fraud for specific categories of radio devices. As all internet-connected wireless devices fall under the RED, the Commission adopted on 29 October 2021 a delegated act under that Directive strengthening the level of cybersecurity, personal data protection and privacy of certain categories of radio equipment. This delegated act applies to radio toys (protection of privacy) and to internet-connected radio toys (protection of networks and from fraud) and will become applicable as of 1 August 2024[24]. It will require that radio toys incorporate safeguards to ensure that the aforementioned assets are protected.

Circular Economy: The **proposal for a Regulation on Ecodesign for Sustainable Products**[25] will set a framework and a process through which the Commission will be empowered to progressively set out sustainability requirements for each product or group of products. Safety concerns will not be a criterion to include products under the ESPR; this inclusion will be based on sustainability concerns. The ESPR will not regulate the safety of products. Toys may be covered in the long-term by one of the delegated acts setting sustainability requirements, however they are not included in the list of high priority sectors identified in the Circular Economy Action Plan (CEAP) adopted by the Commission in March 2020. The ESPR will set out the principle of the Digital Product Passport (DPP) and will develop its technical design and operation. The technical design and operation of the DPP are already being developed, following the general principles of the proposed DPP. The ESPR also foresees that the reference of the DPP is included in a central registry managed by the Commission[26], that this reference is declared at customs, and that this central registry is interconnected with the customs IT environment[27]. This will allow an automatic verification of the existence of the DPP for products presented at customs prior to their release for free circulation. It is expected that the DPP will become the vehicle to provide digital information on products in the future.

[23] 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- 106, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014L0053-20180911

[24] Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that directive, OJ L 7/6 of 12.01.2022.

[25] Sustainable products initiative (europa.eu). 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.

[26] See the proposed article 12.

[27] See the proposed article 13 on customs controls relating to the product passport.

Customs Union Reform[28]: The Commission has recently proposed a revision of the Union Customs Code in order to strengthen the legal framework for customs and address recent challenges such as e-commerce and to protect the single market from non-compliant goods imported from non-EU countries, among others. This initiative is expected to complement the current revision of the TSD by strengthening risk-based controls at the border and improving the supervision of the supply chain. The exact requirements for toys entering the Union market and being released for free circulation need to be set out in the toy safety rules.

1.3. Economic context: The market for toys in the EU

The European toy market size was estimated to be worth around **EUR 20 billion in 2020**[29] **in terms of overall value**, making it the third-biggest global market after North America and Asia. Online sales are increasing and reach over 1 in every 4 toys in some countries[30]. Market research estimates place the size of the global toy industry in the range of **EUR 86-109 billion in sales in 2019**, growing from around EUR 81.7 billion in 2016.[31,32] The European toys manufacturing market achieved turnover of at least EUR 8.3 billion in 2019, increasing from EUR 7 billion in 2016.[33] However, as for much of the global economy, 2020 also saw a downturn in turnover within the EU toys industry, to around EUR 6.6 billion (based on provisional Eurostat SBS data). In 2017, the EU was reportedly the biggest global importer of toys with EUR 7.2 billion worth of toys imported. The value of EU toy imports had grown by an estimated 70% during the preceding decade. Most toys imported to the EU come from Asia, with China the biggest supplier and the ASEAN countries, such as Thailand and Vietnam, increasing the volume of exported toy products.[34]

Almost 50,000 people are working in the EU toy sector. The structure of the EU toy industry is complex and very heterogeneous, ranging from large world-wide operating companies to very small producers of certain specific kinds of toys. The number of enterprises has been progressively increasing from circa 5,332 in 2016, to an estimated 6,313 in 2020. Around 99% of European toy companies are SMEs, employing around two thirds of employees in the sector. Toy production is highly concentrated, with 96.2% of production value generated across ten countries and 88% of turnover concentrated in seven EU Member States[35].

Online sales have grown significantly, accelerated by the global pandemic[36]. Consumers are increasingly buying toys online instead of in brick and mortar stores. For instance, according to a study by a market research firm, all national markets in the EU recorded growth in **online toy sales**

[28] Revision of the Union Customs Code (europa.eu). Proposal for a Council Regulation amending Regulation (EEC) No 2658/87 as regards the introduction of a simplified tariff treatment for the distance sales of goods and Regulation (EC) No 1186/2009 as regards the elimination of the customs duty relief threshold (COM(2023) 259 final

[29] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/

[30] ECSIP Consortium (2013). Study on the competitiveness of the toy industry – Final Report, p. 17. https://ec.europa.eu/DocsRoom/documents/6653/attachments/1/translations/en/renditions/native

[31] Khajeheian, D. (2018). *Market analysis, strategy diagnosis and opportunity recognition in toy industry* [in:] "International Journal of Entrepreneurship and Small Business", 33(2), DOI:10.1504/ijesb.2018.090138, p. 221.

[32] https://www.toyassociation.org/ta/research/data/population/toys/research-and-data/data/global-sales-data.aspx

[33] As described further in Annex 4, the Eurostat Structural Business Statistics (SBS) data for 2016-2020 has a range of data gaps and the data for 2020 is provisional.

[34] Ismail, R., et al. (2020). *Toy Safety in the ASEAN and European Union: A Comparative Approach* [in:] International Journal of Innovation, Creativity and Change, vol. 10/11, online, p. 118-119.

[35] See Annex 4 for the details on the methodology and annex 7 for a more detailed overview of the data sources. Study for the revision of the Toy Safety Directive, 2022, by VVA, CSES and Asterisk, to be published.

[36] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/

in **2020-2021**. At the global level, online sales of toys were estimated to have increased markedly, by an estimated 20%, in 2020-2021.[37] See annex 7 for a more detailed overview of the toys market.

2. PROBLEM DEFINITION

2.1. What are the problems?

In the context of toy safety, two main separate problems can be currently identified. As the Evaluation concluded, the first problem is that the Directive does not ensure adequate protection of children when playing with toys from risks posed by hazardous chemicals: the Directive does not sufficiently address the risks of certain harmful chemicals such as endocrine disruptors (EDs) and CMR substances. The possibilities to amend the TSD in relation to limit values for toys intended for children over 36 months, or for certain problematic substances such as nitrosamines, are limited. In addition, there are a high number of non-compliant and unsafe toys on the Union market, which also put children at risk and create an uneven playing field for compliant companies. See Annex 8 for the main findings of the Evaluation.

2.1.1. Problem 1- Insufficient protection of children from harmful chemicals

The objective of the TSD is to ensure that toys, including the chemicals they contain, do not jeopardise the safety of children. However, as the Evaluation concluded, the protection from most harmful chemicals in toys in the current Directive is not complete. Almost 60% of respondents (116 out of 196) to the public consultation believed that the TSD should set stricter requirements for chemicals: however, 47% representatives of business associations and companies (strongly) disagreed (42 out of 89), while all the environmental and consumer organisations agree to some degree with the statement (57 out of 61 - over 90%). Similarly, 90 % of public authorities (28 out of 31) agreed or strongly agreed. Concerning other risks from toys (for example, preventing suffocation of small children by requiring that toys for younger children do not contain small parts), the Evaluation concluded that the protection in the TSD is adequate and no evidence has appeared since its publication which would affect that conclusion[38].

Chemicals with hazardous properties can cause harm to human health and the environment. Chemical substances may be classified under the hazard classes of the CLP Regulation on the basis of the hazardous properties they present to human health, the environment or their physical hazards. The classification under the CLP Regulation informs on the hazardous properties of a chemical substance, but does not provide for the management of the risk. Other legislation, such as the TSD, is to define whether and how the risks posed by certain chemical substances must be addressed in specific products. While not all hazardous chemicals raise the same concerns, certain chemicals are particularly harmful as they can cause cancers, affect the immune, respiratory, endocrine, reproductive and cardiovascular systems, weaken human resilience and capacity to respond to vaccines, or increase vulnerability to diseases. Exposure to these harmful chemicals is therefore a threat to human health.[39] Children, pregnant women, workers and the elderly are particularly vulnerable to risks arising from chemical exposure, and have higher probabilities of adverse health symptoms or diseases throughout their lives[40].

The Toy Safety Directive does not sufficiently protect children from risks posed by the most harmful chemicals. Children are exposed to harmful chemicals from different sources (indoor air,

[37] https://www.npd.com/news/thought-leadership/2021/whats-driving-online-toy-sales/

[38] The essential requirements of the Directive addressing other risks, supported by harmonised standards, have allowed to address or adapt the detailed technical specifications whenever new issues have emerged.

[39] See the CSS.

[40] European Commission, Study for the Strategy for the Non-Toxic Environment, p. 74

food, water, consumer products in general, for example, as well as toys) and it is difficult to establish a clear link between their exposure to these substances through one of these sources, such as toys, and immediate health consequences. The particular vulnerability of children to the harmful effects of hazardous chemicals is well documented[41]. There are physiological differences between children (especially those under 36 months of age) and adults, affecting the accuracy of certain exposure assessment methodologies (i.e. immature metabolic and immune system, proliferative tissues) [42][43][44][45]. Furthermore, the manner in which children interact with toys, in particular in their earlier years, makes them particularly exposed to any harmful chemicals that may be present in toys. Children exhibit specific habits and practices that may result in exposure scenarios not considered for other population groups. Under the age of 3, mouthing behaviour plays an important role regarding contact of children with toy materials[46]. As an example, the current migration limits for 19 substances or heavy metals in the Directive are based on the assumption that a child would ingest per day 100 mg of dry, brittle, powder-like or pliable toy material, 400 mg of liquid or sticky toy material, and 8 mg of scraped-off toy material. Studies show that children are currently exposed to known and unknown endocrine disrupting chemicals in toys[47], or to other chemicals that pose risks to children[48]. See annex 10. D. for an estimate of the potential harmful chemicals that could be currently present in toys. In particular, it has been mentioned by industry that toys like balloons, paints, modelling clays, glue or slime could be affected by the policy options proposed in this impact assessment.

CMR (carcinogenic, mutagenic or toxic for reproduction) substances are particularly harmful, and their effects can only be seen in the long term and are often irreversible. The Evaluation concluded that **the current requirements in the Directive for CMR substances are not effective and they do not sufficiently protect children from these substances in toys**. As will be explained below when describing the drivers of this problem (see section 2.2.1 below), the TSD contains generic bans for CMR substances subject to derogations, but these derogations still allow

[41] European Commission, Study for the Strategy for the Non-Toxic Environment,

[42] https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2019)29&docLanguage=en

[43] Environmental Chemicals and Children | Washington State Department of Health

[44] SWD(2019) 199.

[45] Carroquino, Maria J. et al. "Environmental Toxicology: Children at Risk." *Environmental Toxicology: Selected Entries from the Encyclopedia of Sustainability Science and Technology* 239–291. 4 Dec. 2012, doi:10.1007/978-1-4614-5764-0_11

[46] See the SCHEER opinion on the estimates of amount of toy materials ingested by children Estimates of the amount of toy materials ingested by children (europa.eu): Toys not intended to be mouthed were mouthed almost as frequently as toys intended to be mouthed.

[47] See for example "Potential endocrine disrupting properties of toys for babies and infants" available at: https://doi.org/10.1371/journal.pone.0231171; where nine of the 18 products showed significant oestrogenic activity. For seven of those, the source of the activity could not be accounted for by reference to a list of 41 known or suspected endocrine disrupting chemicals that had been compiled primarily from literature reviews of substances authorised for use in food packaging materials. See also the UN Environment Programme (UNEP) report that finds 25% of children's toys contain harmful chemicals "Chemicals of concern in plastic toys" available at: https://doi.org/10.1016/j.envint.2020.106194. Results indicate that a relevant amount of chemicals used in plastic toy materials may pose a non-negligible health risk to children, calling for more refined investigations and more human- and eco-friendly alternatives. Out of 419 chemicals found in hard, soft and foam plastic materials used in children toys, 126 substances that can potentially harm children's health either via cancer or non-cancer effects were identified, including 31 plasticizers, 18 flame retardants, and 8 fragrances. See also "CMR Substances in Toys – Market Surveillance and Risk Assessment", by the Danish Environmental Protection Agency, 2015 available at: https://www2.mst.dk/Udgiv/publications/2015/10/978-87-93352-79-7.pdf

[48] A Danish survey showed that 12 out of 12 tested squishies emitted chemical substances that posed a risk for children: Analysis and risk assessment of fragrances and other organic substances in squishy toys, https://www2.msl.dk/Ud£iv/Dub1ications/2oi8/o8/Q78-87-QT7io-64-i.ndf.

for too high a presence of CMRs in toys. Furthermore, the limit values currently set in the TSD for nitrosamines and nitrosatable substances, which are strong carcinogens, are deemed to be too high, and these limits cannot be amended by the Commission with its empowerments.

In addition, there are ongoing and emerging health concerns for **other most harmful chemicals** that **are not addressed by the Directive**. This is particularly the case for **chemicals that affect the endocrine system, the immune, neurological or respiratory systems or chemicals that are toxic to a specific organ**. In respect of these chemicals, the Fitness Check on Chemicals legislation excluding REACH[49] pointed to shortcomings in current legislation in meeting the objectives of protecting human health in particular as regards exposures to: neurotoxic substances; chemicals linked to cardiovascular and respiratory (CVR) disease; and endocrine disrupting chemicals. The possible **risks associated with the combination of chemicals** are also not addressed in the Directive. There are no specific legal requirements to ensure that risks from simultaneous exposure to multiple chemicals are effectively and systematically taken into account in toys. While it may not be currently realistic or economically feasible to specifically assess and regulate an almost infinite number of possible combinations of chemicals, scientific consensus is emerging that the effect of chemical mixtures needs to be taken into account and integrated more generally into chemical risk assessments[50].

Endocrine-disrupting (ED) chemicals require specific attention; these chemical substances can alter the functioning of the endocrine (hormonal) system and negatively affect the health of humans or animals. Endocrine disrupting properties have been the focus of increasing scientific research, and the accumulated knowledge identifies endocrine disruptors as a concern to public health[5152]. Given the essential role of the endocrine system during development, exposure to endocrine disruptors during vulnerable periods can induce long-lasting changes, with adverse effects in the short and long terms; some of these effects are expected at very low-doses[53]. Early exposure during critical periods of development can affect health at a later stage of life[54]. Many chronic health disorders have been clearly linked to endocrine disruptors[55]. These disorders include obesity and metabolic disorders, male and female reproductive disorders, reproductive cancers, thyroid disorders, neurodevelopmental disease and IQ loss [56]. It is not possible to quantify fully the impact on human health of chemicals with the most critical hazards. However, for illustrative purposes, a causal link of 70% to 100% between exposure to EDs and IQ loss and intellectual deficiencies was identified[57]. EDs are also suspected to cause male fertility troubles with a probability of causation between 40-69%. Researchers estimated that exposure to EDs leads to substantial health-related

[49] https://ec.europa.eu/info/publications/fitness-check-most-relevant-chemical-legislation-excluding-reach_en
[50] See section 2.2.2. of the CSS.
[51] United Nations Environment Programme, State of the Science of Endocrine Disputing Chemicals - IPCP-2012.
[52] L.N. Vandenberg & J.L. Turgeon, Endocrine disrupting chemicals: Understanding what matters. In L. N. Vandenberg, & J. L. Turgeon (Eds.), *Endocrine-Disrupting Chemicals*, 2021. Combined effects on two year old children (mst.dk)
[53] See also Prederi, Barbara, Alves, Crésio A.D. et Lughetti Lorenzo. "New insights on the effects of endocrine disrupting chemicals on children" *Jornal de Pediatria Volume 98, supplement 1, March-April 2022, p. S73.* https://doi.org/10.1016/j.jped.2021.11.003
[54] Fitness Check on endocrine disruptors and its Executive Summary, accompanying the Chemicals Strategy for Sustainability SWD(2020) 251 final.
[55] Endocrine-related disorders impact in particular the functioning of the thyroid, the immune system, the reproduction system and the overall human metabolism. SWD(2020) 249.
[56] Endocrine Disruptors: from Scientific Evidence to Human Health Protection (aesan.gob.es)
[57] Technical and Scientific Support to the Commission's Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP), to be published.

societal costs in the EU between 46 and 288 billion Euro per year[58]. **The TSD does not currently have provisions that allow to address EDs in toys in general and limit children exposure wherever this is necessary.**

Chemicals that affect the immune, neurological or respiratory systems or chemicals that are toxic to a specific organ are also amongst the most harmful chemicals. It is equally well documented that neurotoxic chemicals are particularly harmful to the developing brain of children, which is inherently more vulnerable to toxic injury than the adult brain[59]. Adverse effects of exposure to certain chemicals on IQ scores are well established and other disorders where the role of chemical exposure is suspected, include ADHD and autism. Recent research has focussed on links to depression, bipolar disorder, OCD, psychoses, dementia, Parkinson and Alzheimer's.[60] For example, it can be estimated that, in the EU, some 30,000 disability adjusted life years (DALYs) related to neurotoxic disease may be a result of chemicals exposure, with some 250,000 DALYs a result of chemicals exposure combined with underlying genetic predisposition. Developmental disabilities due to chemicals alone could cost the EU between €1.7 up to €4 billion per year directly and up to €14 – €33 billion per year taking into account chemical exposure and combined with genetic factors, depending on the valuation used[61]. Environmentally attributable childhood asthma (i.e. where the onset of asthma has been triggered by exposure to pollution and hazardous chemicals) was estimated in 2013 to cost the EU approximately €1.6 billion per year (inclusive of direct medical costs and indirect economic losses due to productive time lost by care for children with asthma).[62] **The TSD has specific limit values for some of the chemicals in these categories, but it does not address them in a general manner and new limit values for other substances in this category cannot be generally introduced either.**

Sufficient protection needs to be provided to children from potential exposure to those risks for human health when playing with toys. Risks coming from harmful substances are often only visible long term and parents are generally unaware of these risks in toys or of their potential severity; as opposed to mechanical risks, they cannot be avoided by parents being more or less vigilant of their children playing with toys. Increasing the requirements in the TSD for harmful chemicals is not expected to lead to less surveillance of children by their parents when playing with toys (i.e. the *Peltzman effect* is not expected to materialise).

REACH already regulates the environmental aspects of toys and the chemical substances in toys that pose a risk to the environment. Furthermore, the ESPR will also apply to toys. Therefore, the extent to which harmful substances to the environment may be limited in consumer products (such as substances which are persistent, bioaccumulative and toxic – PBTs and vPvBs), including in toys, will continue to be addressed under horizontal legislation such as REACH and the ESPR and not in the revision of the TSD.

2.1.2. Problem 2- A high number of toys on the Union market do not comply with the Toy Safety Directive and are unsafe

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 and, therefore, the exact share of non-compliant toys in the Union

[58] I. Rijk, M. van Duursen, and M. van den Berg, Health cost that may be associated with Endocrine Disrupting Chemicals — An inventory, evaluation and way forward to assess the potential health impact of EDC-associated health effects in the EU, Institute for Risk Assessment Sciences, University of Utrecht, 2016.
[59] The toxic truth | UNICEF
[60] Fitness Check of Chemicals legislation (excluding REACH).
[61] Study on the cumulative health and environmental benefits of chemical legislation - Publications Office of the EU (europa.eu)
[62] Study on the cumulative health and environmental benefits of chemical legislation - Publications Office of the EU (europa.eu)

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 found is consistently high.

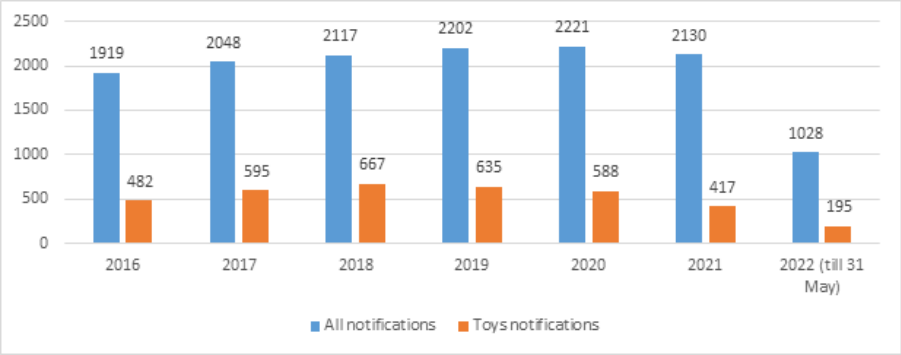

Figure 3: RAPEX notifications per year and toys notifications

First of all, as regards notifications in the Safety Gate for alerts of dangerous products (RAPEX notifications), **during the past years, toys were consistently one of the top categories of products with the highest number of notifications for dangerous products per year.**

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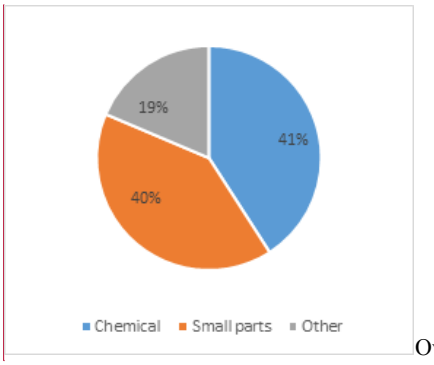

Overall, during the period 2016- May 2022, a total of 3579 dangerous toys were subject to an alert through the RAPEX system for exchange of information on dangerous products[63].[64] Around 40% of these notifications concerned chemical risks, which means that exposure to dangerous chemical substances through unsafe toys is a matter of concern, while another 40% concerned choking risks for younger children that can lead to fatal injuries.

[63] Each of these notifications affects a significant number of toys; for example, in 2020 there were 592 notifications of toys in RAPEX which affected as a minimum almost 1.100.000 individual items, with almost 50.000 items more in follow up market surveillance measures in other Member States. Similarly, in 2021 there were 438 notifications of dangerous toys in RAPEX which affected again almost 1.100.000 individual items, as a minimum, with an additional 120.000 in follow up measures. Not all RAPEX notifications include the number of individual items affected and this is why this information is the minimum.

[64] To note that RAPEX notifications only concern dangerous products (more or less serious risks) but not non-compliances that pose no risk for consumers (such as the wrong affixing of the CE marking, or lacking documentation…).

Market surveillance authorities are also required to enter into the information and communication system for market surveillance (**ICSMS**) **information** in relation to products made available on the Union market for which an **in-depth check of compliance** has been carried out, in addition to their obligation to alert of dangerous products under RAPEX. This obligation has become more explicit with the new Regulation 2019/1020 on market surveillance[65], which is fully applicable since July 2021. Data on the period 2016- May 2022 reveals that **43% of the toys subject to in depth inspections were found to be non-compliant and more than half of these relate to substantive safety risks**. Market surveillance authorities rely on risk management procedures to try and target their activities on toys with higher probabilities to be non-compliant. In-depth checks are carried out on toys which present such higher risks of non-compliance. While these data may show the effectiveness of such procedures, it still evidences the high number of non-compliant and unsafe toys that are present on the Union market.

Figure 4: Types of risks in dangerous toys notified in RAPEX

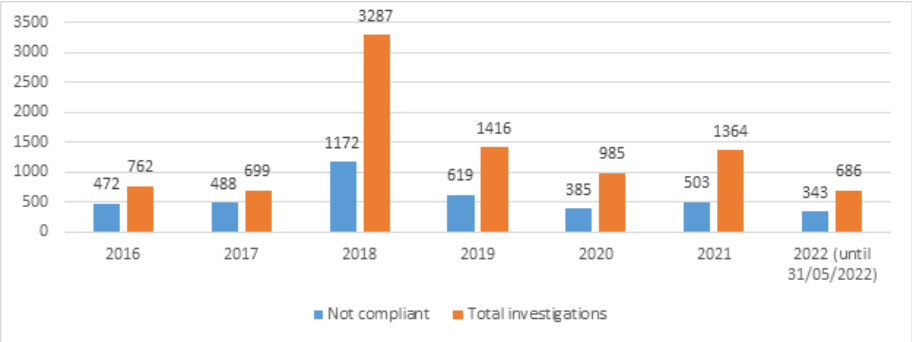

Figure 5: non-compliant toys and total number of in-depth toy investigations per year in ICSMS

Other recent but more targeted market surveillance joint actions focused on toys also confirm the high rates of non-compliance, see annex 11 for detailed results on coordinated activities on the safety of products (CASP)[66]. Data from the Evaluation based on the reports on market surveillance submitted by Member States[67] also shows a significant rate of non-compliant toys found on the Union market; **almost every third toy inspected in the reported period was non-compliant**.

The high number of non-compliant toys means that children in the EU can be exposed to risks when playing with these toys. Unsafe toys can cause injuries and even fatal accidents, for example risks of choking or from very serious injuries such as from magnets, or button cells batteries that children can swallow. Children may also be exposed to dangerous chemicals, for example from phthalates in soft plastics or too high quantities of boron in slime. Unsafe toys may undermine consumer trust in the safety of toys available in the EU. They are also a risk to the environment as the harmful substances they contain are ultimately released into waste.

[65] See article 34 of 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.
[66] For example, the *2021 CASP joint action on toys from non-EU workshops* focused on plastic toys and toys with plastic parts for children under and above 36 months collected online and originated from third countries and found that 84% of toys tested did not meet the applicable safety requirements.
[67] Article 48 of the Toy Safety Directive.

Non-compliant toys also lead to an uneven playing field for compliant companies. Complying with the stringent requirements is costly for companies, reputable manufacturers face the unfair competition of non-compliant toys from rogue traders who are able to sell their toys at lower prices. **The value of the non-compliant toys market has been estimated for 2019 to span from EUR 248 million to EUR 1.65 billion**[68].

At the stakeholder workshop organised on 26 April 2020, all the intervening stakeholders (consumer organisations, industry and market surveillance authorities) expressed strong concerns about the high number of non-compliant and unsafe toys, in particular made available through online sales, and the urgent need to take action at EU level to address this.

2.1.3. New risks in toys, in particular from digital technologies

The Evaluation also concluded on the TSD not being able to address new risks in toys linked to the use of digital technologies. The scope of the Directive is focused on health and safety and does not cover other issues such as privacy or information security. As a result, there were cases in the past where risks posed by cybersecurity or privacy concerns on toys could not be addressed. The application of the RED delegated act mid-2024 will address the cybersecurity and personal data privacy issues identified in the Evaluation. This delegated act requires radio toys to guarantee protection of privacy and data of the users, through cybersecurity features. Cybersecurity should be strengthened by the Cyber Resilience Act as well, once adopted[69]. Additionally, the incorporation of AI in toys may also lead to new risks. The Commission proposal on a regulatory framework for artificial intelligence, once adopted, will ensure that any AI systems incorporated into toys comply with the rules that safeguard the functioning of markets and the public sector, and people's safety and fundamental rights. Therefore, these risks have been addressed in legislation already adopted or under inter-institutional discussions and it does not appear that any significant legal gap remains that requires intervention through the revision of the TSD for the purposes of addressing cybersecurity, personal data privacy or AI.

2.2. What are the problem drivers?

2.2.1. Problem 1- Insufficient protection of children from harmful chemicals

a) The Directive allows for too high presence of CMR substances in toys

The Directive includes a **generic ban on the presence of CMRs in toys** subject to a number of derogations. The Evalution concluded that these **derogations** do not ensure sufficient protection of children from these harmful subtances. In particular, the Toy Safety Directive currently allows **three possibilities to derogate** from the generic ban to CMRs in toys: i) the TSD tolerates the presence of CMRs in toys or their components **up to the 'relevant concentrations' of the CLP Regulation for the classification of mixtures containing these subtances**. 'Relevant' are either the specific concentration limits assigned to specific substances in Annex VI, table 3.1 of the CLP Regulation or, if no specific concentration limits are indicated in that table, the generic

[68] Using the non-compliance rates identified through various market reports, the CLP Impact Assessment established three scenarios for the level of non-compliance with chemical-related requirements in the product 'Children toys or childcare items': a lower scenario of 3-4% non-compliance, a central scenario of 5-8% non-compliance, and an upper scenario of 10-20% non-compliance. These scenarios are primarily placed lower than the non-compliance rate identified above as the exercises used to generate the above rate target product types that are known for non-compliance. Using these scenarios, the value of the non-compliant toys market has been estimated as follows: considering turnover in the European toys market for 2019 was around EUR 8.3 billion, the non-compliant portion of this market could span from EUR 248 million (3%) to EUR 1.65 billion (20%). See the study supporting the revision of the Toy Safety Directive.

[69] Cyber resilience act – new cybersecurity rules for digital products and ancillary services (europa.eu)

concentration limits in Annex I of the CLP Regulation[70]. In addition, the TSD allows for the presence of CMRs ii) if they are inaccesible to children, including via inhalation and iii) if the Commission takes a decision to allow their presence if it is considered safe following a rigorous scientific evaluation and if they are not prohibited in consumer articles under REACH. For CMR substances of categories 1A and 1B which are of most concern, no suitable alternatives must exist for a Commission to take a decision granting the derogation. (For CMRs category 2, no analysis of alternatives is necessary.)

The Evaluation found the first derogation inadequate[71]. These 'relevant concentrations' have been set for the purpose of classification and labelling of mixtures containing hazardous substances, with the primary aim to ensure that the hazards of such mixtures are properly identified and communicated. They **do not take account of possible exposures and do not entail an assessment of risk related to the uses of a substance in an article such as a toy**. Whenever risk-based limit values for certain CMRs were introduced in the TSD through the empowerments to the Commission, these have been 15 to 1,000 times lower than the 'relevant concentrations' in the CLP Regulation. However, in accordance with the empowerements to the Commission for amending the Directive, these limit values could only be introduced for toys intended for children under 36 months, or to be put in the mouth (Apendix C). The Scientific Committee for Health, Environmental and Emerging Risks[72] (SCHEER) also identified a number of problems with this approach, due to the fact that classification limits set for mixtures are applied to articles (as the toys should be considered) [73]. This inadequacy of the CMR derogation based on the concentration limits for classification of mixtures from the CLP Regulation was referred to by public authorities (70% of public authorities responding – 22 out of 31 -disagreed or strongly disagreed with having this derogation) and by consumer organisations (75%- 46 out of 61) in the public consultation[74].

In addition, the Evaluation found that **the limit values in the Directive for nitrosamines and nitrosatable substances were too high[75].** Certain nitrosamines may be genotoxic and very strong carcinogens (CMRs). Nitrosatable substances can be converted into nitrosamines in the human body. The TSD sets migration limits for nitrosamines and nitrosatable substances in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth: 0.05 mg/kg for nitrosamines, 1 mg/kg for nitrosatable substances.[76] Germany however insisted on its lower national limits of 0.01 mg/kg for nitrosamines and of 0.1 mg/kg for nitrosatable substances in toys made of natural or synthetic rubber designed for children under 36 months and intended or likely to be placed in the mouth, which the Commission allowed[77]. Therefore, currently Germany has lower limits for these substances that do not correspond to the ones in the TSD. In their letter of April 2019 to the Commission,[78] 11 Member States considered that there was an urgent need to lower the limits for nitrosamines and nitrosatable substances. **The Commission is not empowered to amend these limit values in the TSD** via its possibilities for adaptation (see article 46 of the TSD and the

[70] These limits are 0.1% and 1% for carcinogens (table 3.6.2 of the CLP Regulation) and mutagens (table 3.5.2 of the CLP Regulation) of categories 1 and 2, respectively, and 0.3% and 3% for reproductive toxins (table 3.7.2 of the CLP Regulation) of categories 1 and 2, respectively

[71] See section 5.1.1.2 of the Evaluation

[72] The SCHEER, on request of Commission services, provides Opinions on questions concerning health, environmental and emerging risks, including in toys.

[73] SCHER Opinion on risk from organic CMR substances in toys, 18 May 2010.

[74] See annex 2.4 for further details on the replies to the public consultation.

[75] See section 5.1.1.2 of the Evaluation

[76] Annex II, Part III, point 8 of the Toy Safety Directive.

[77] Recital 88 of Commission Decision 2012/160/EU. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012D0160&qid=1571656440439&from=EN

[78] See letter of 25.4.2019 from the relevant Ministers of Denmark, Belgium, Sweden, Norway, Lithuania, The Netherlands, Hungary, Finland, Czech Republic, Luxembourg and France.

section below); these limit values can only be amended via a revision of the TSD by the co-legislators. In the open public consultation, 31% (28 out of 89) of industry representatives believed that these limits should be lowered and a further 25 % were neutral about it; while 77% (24 out of 31) of public authorities and 73% (45 out of 61) of citizens and consumer associations were in favour of lowering them. In practice, most manufacturers have indicated to comply already with the lower limit values applicable in Germany, but a problem with enforcing this limit remains[79].

b) The possibilities to adapt the Directive to new scientific knowledge on chemical substances are too limited

Having an effective and flexible system for adapting the protection from possible chemical risks in toys is crucial because scientific knowledge about chemical toxicity is constantly changing. Even chemicals with a long-known toxicity may turn out to be 'more toxic' when new knowledge arises[80]. In order to keep pace with latest technical and scientific developments, the Commission can amend certain parts of the Toy Safety Directive.[81] [82] In particular, the Commission may establish maximum limit values for any chemical in toys intended for children under 36 months of age and in all toys intended to be placed in the mouth, and it may also amend those limits (Appendix C to Annex II). However, **the Commission is not empowered to introduce new limit values for any chemical in other types of toys.** This does not ensure sufficient protection of children or that the Directive can be appropriately adapted to address emerging scientific knowledge[83].

The distinction between (1) toys for children under 36 months and toys intended to be taken in the mouth, and (2) other toys, takes account of the oral exposure to chemicals. Indeed, children under 36 months take 'everything' in their mouth, and toys such as a toy flute or a toy harmonica are by definition played in contact with the mouth. However, older children may also be exposed to chemicals via the skin or via inhalation. Experts in the Expert Group on Toys Safety repeatedly raised the need that older children be equally well protected for certain of these substances[84]. Examples are the sensitising preservatives benzisothiazolinone, chloromethylisothiazolinone and methylisothiazolinone for which specific limit values have been inserted in Appendix C to the Directive while SCHEER recommends that they are not used in toys[85]. In addition, the risk from

[79] Source: targeted survey and interviews. See annex 14 on the economic impacts and impacts on competitiveness from lowering the limit values on nitrosamines to the levels currently applicable in Germany.

[80] As an example, '[t]he toxicity of lead has been studied extensively in both animals and humans. On numerous occasions these data have been evaluated by expert committees.' (National Institute for Public Health and the Environment (RIVM), Chemicals in Toys). The limit values for lead in toys were proposed (and eventually adopted in the 2009 Toy Safety Directive) on the basis of scientific reviews from 1995 – 2005. However, in 2013, the European Food Safety Authority (EFSA) issued a scientific opinion on lead providing that lead is more toxic than known before. (EFSA Panel on Contaminants in the Food Chain (CONTAM), Scientific Opinion on Lead in Food. EFSA Journal 2010; 8(4):1570) Even the smallest intake of lead by children can harm their intelligence. It was therefore necessary to lower the limit values in the Toy Safety Directive almost 7-fold. In 2012 and 2013, the limit values for cadmium and barium had to be lowered, respectively, due to updated knowledge on their toxicity. For the same reason the limit values for bisphenol A and for aluminium had to be lowered, respectively, in 2017 and 2019; new information from EFSA suggests that the limit value for bisphenol A is still too high.

[81] Article 46 of the Toy Safety Directive.

[82] In the period 2012 – 2021, the Directive was amended 17 times to address newly identified chemical risks and to revise limit values for chemicals such as chromium VI, lead, phenol, bisphenol A. More particularly, eight amendments to the Toy Safety Directive have inserted specific limit values for a number of CMR substances and highly sensitising substances in Appendix C.

[83] See section 5.1.1.2 of the Evaluation.

[84] See also section 5.1.1.2 of the Evaluation.

[85] Scientific Committee on Health and Environmental Risks (SCHER), Opinion on "CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys", adopted on 29 May 2007, p. 8 and table 1 on p. 9.

chemicals may not be much different when comparing children under 36 months and older children based on bodyweight[86]. Finally, outside of Appendix C, all other chemical limit values in the Toy Safety Directive apply to all toys for children of all ages. In their letter of 25 April 2019, the 11 Ministers also stressed their concerns about the lack of possibilities in the Directive to add limit values for toys for older children. Over 93% of public authorities (29 out of 31) and 65% of industry (61 out of 89) responding to the public consutlation believed that the toy safety rules should allow for setting limit values for any toy when new scientific knowledge emerges.

A further limitation to the effectiveness of the adaptations of the Directive resides in the legal form of the toy safety rules, a Directive, which requires transposition in the national legal systems of all Member States to become applicable. Only then can all provisions be concurrently enforced in all Member States. This makes the overall process for adaptation of newly set limit values through the empowerments to the Commission lengthy. In addition, delays in the transposition in one or several Member States would be detrimental to the protection of children in those States. The Evaluation of the Directive concluded that national transpositions of amendments to the Directive often turn out to be excessively burdensome and time-consuming[87].

2.2.2. Problem 2- A high number of toys on the Union market do not comply with the Toy Safety Directive and are unsafe

a) Global supply chains: non-compliant toys from third countries and online commerce

Evidence shows that a significant proportion of non-compliant toys come from third countries and that they are particularly present online[8889]. **Only 4% of dangerous toys notified in RAPEX come from EU countries.** Online shopping is continuing to grow in the EU[90] and toys are among the most popular categories of products ordered online. For example, the 2021 Eurostat survey showed that 20% of people who bought online ordered toys or childcare articles.[91]

The value of online sales in total (not limited to toys) increased by 20% between 2010 and 2020[92]. The purchase of goods and services online has also increased the availability of products from

[86] The bodyweight of children under 36 months was estimated to be 7.5 kg[86] when calculating the migration limits for toxic 'elements' such as arsenic, cadmium or lead; for children of 36 months and over the bodyweight was assumed to be 15 kg.
[87] See section 5.1.4 of the Evaluation
[88] See above the results of the CASP joint action on toys from non-EU marketplaces, as well as TIE report on *EU Toy Safety: the problem of unreputable sellers on online marketplaces* TIE's EU Toy Safety report: The problem of unreputable sellers on online marketplaces - Toy Industries of Europe or the BTHA report "Still Toying with Children's Safety" which concerned products found in the EU market at that time BTHA-Online-Marketplace-Report.pdf (toysafety.co.uk). Also, BEUC March 2022 "Products from online marketplaces continue to fail safety tests – Compilation of research on unsafe products from online marketplaces from 2021 and 2022". Similarly, as an illustration Life-threatening children's toys easy to sell via Bol.com - Radar - AVROTROS' consumer program
[89] Recent joint actions and targeted campaigns illustrate that the rates of non-compliant toys available online are of particular concern, as investigations regularly reveal that these products remain available online even after being subject to bans or recalls. OECD 2015 sweep, 62% of non-compliance rate for toys, and the most commonly reported category of banned/recalled products that can still be found online. 5jlnb5q64ktd-en.pdf (oecd-ilibrary.org). The BTHA report signals that 69% of recalled toys could still be found online, albeit from other sellers.
[90] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=E-commerce_statistics_for_individuals
[91] 90% of people aged 16 to 74 in the EU had used the internet in the 12 months prior to the 2021 Eurostat Survey, 74% of whom had bought or ordered goods or services for private use. 20% of people who bought online ordered toys or childcare articles.
[92] Eurostat 2021.

outside the EU, with **almost one third (31%) of online shoppers having purchased goods or services from outside the EU.**[93] [94]

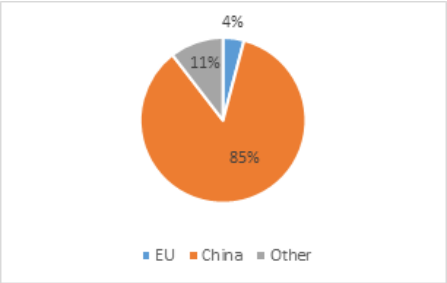

Figure 6: Country of origin of dangerous toys notified in RAPEX (2016- May 2022)

At the global level, online sales of toys were estimated to have increased markedly, by an estimated 20%, in 2020-2021.[95] In 2020, 44 % of large enterprises conducted e-sales, corresponding to an e-sales value of 27 % of total turnover in this size class[96]. E-commerce enables traders to introduce products that comply with the legal requirements of a non-EU country where they were manufactured, to be sold to other markets, where product safety and chemical legislation requirements may substantially differ[97]. New business models, including variety of intermediary services (e.g., social media, online marketplaces) that connect online sellers and buyers, increase the engagement in e-commerce of even more diverse players worldwide[98].[99]

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EU consumers are able to buy from non-EU websites toys which were never intended by the manufacturer to be placed on the Union market, but that had been directed to it by other third parties through global distribution chains and no economic operator clearly makes sure that the toy is compliant with the Directive. Non-EU economic operators may not know the requirements applicable in the EU or they may choose to ignore them. Non-EU sellers may only rely on the

[93] Eurostat 2021

[94] Many products ordered online are shipped across borders in individual consignments, in what is known as parcel trade. This trade has helped consumers access the goods they need in times of confinement and also allowed firms, especially smaller ones, to maintain economic activity. The types of parcels traded during confinement vary significantly; however, information available for EU countries shows that growth has been dominated by purchases of computers and related accessories; medical goods (pharmaceuticals); and leisure items such as books or games. Compared to 'traditional' container trade, parcel trade involves an even more complex network of interlinked actors and policies, and so ensuring that parcels get to where they are needed during confinement, as well as during gradual reopening, requires policy action across a diverse set of issues. See https://www.oecd.org/coronavirus/policy-responses/connecting-businesses-and-consumers-during-covid-19-trade-in-parcels-d18de131/

[95] https://www.npd.com/news/thought-leadership/2021/whats-driving-online-toy-sales/

[96] Eurostat 2021

[97] KEMI, Increased e-commerce – increased chemicals risks? A mapping of the challenges of e-commerce and proposed measures. Report of a government assignment, 2021.

[98] See KEMI (2021).

[99] The Study supporting the revision of the CLP Regulation (Technical Support to the Commissions Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP), page 113) assessed the compliance with chemical requirements detailed in the CLP and REACH Regulations for various product groups by analysing a wide range of market surveillance activities conducted by consumer associations, market surveillance authorities and other stakeholders. It concluded that 20% of the toys assessed across these reports and sold online were found to be non-compliant with regard to chemicals-related requirements. Furthermore, on the basis of reports from representatives of the same stakeholder groups assessing non-compliance with non-chemicals related requirements a wide range of compliance levels across toys sold online spanning from 3% to 90% was found, depending on the requirements and types of toys examined.

information provided by the manufacturer that the necessary steps have been taken to ensure that the toys are compliant with the applicable requirements. Rogue traders can benefit from these channels to sell their products at low prices avoiding the costs of complying with the legislation[100]. It has been found that many toys which have been recalled from the Union market because they are unsafe can still be found for sale online, sometimes from different online sellers. 70% (43 out of 61) of consumers/environmental groups, 80% (25 out of 31) of public authorities and 67% of industry and industry associations responding (61 out of 89) to the public consultation believed that the lack of specific rules on online sales hamper the effectiveness of the TSD.

b) Limits to market surveillance checks and customs controls

The data on non-compliant products set out above illustrates the ability of market surveillance authorities to target with their inspections non-compliant toys; the fact that toys are constantly one of the top categories of products subject to RAPEX notifications shows that significant efforts are put in market surveillance activities for toys. However, certain issues remain. The high rates of non-compliance show the limits to the effectiveness of market surveillance in ensuring that only compliant and safe toys are placed on the Union market.

In particular, the Evaluation concluded that the **compliance information** (EC Declaration of conformity) is **difficult to obtain** and equally often incorrect or of questionable quality and/or only drafted when requested by authorities[101]. Similarly, the safety assessment and the technical documentation also appear to be often incomplete, incorrect, difficult to obtain and only prepared on purpose when the authorities have asked for them. Parts of the technical documentation can be missing or even be faked. Re-launching a request for the obligatory documentation and the follow-up can cause considerable delays. In many cases, it is not possible to link the documentation to the toy, resulting in the documentation being of limited (or of no) value[102].

An effective way to ensure that unsafe or non-compliant toys are not placed on the Union market would be to detect such products before they are released for free circulation. Controls on products entering the Union market take place on a risk assessment basis and on a limited number of toys entering the Union market. The recent report on the current challenges for the Customs Union "*Putting more Union in the European Customs*"[103] notes that the explosion of e-commerce presents customs with an inflow of small consignments with new financial, counterfeit, compliance, safety and security risks. In 2019, the volume of international trade that was handled by EU customs offices, in terms of import, export or transit was of over 868 million items[104]. From July to December 2021, e-commerce represented more than twice the number of traditional customs transactions for only 0.4 % of the value.[105] For customs, e-commerce means an exponential and

[100] See the Europol 2021 campaign on identifying counterfeit toys online, and their operation LUDUS with OLAF and EUIPO between October 2020 and January 2021 which concluded in over 5 million counterfeit toys for a total value exceeding €16 million. How to recognise fake and hazardous toys | Europol (europa.eu) and Cute, but deadly: law enforcement seize over €16 million worth of fake toys | Europol (europa.eu). In 2019, revenue generated from counterfeit toys reached $32.3 billion in the US and $44.6 billion in Europe. Counterfeit toys are also very often non-compliant or unsafe, see Alarming consumer behavior with counterfeit toys (redpoints.com)

[101] See section 5.2.6 of the Evaluation.

[102] See section 5.2.6 of the Evaluation.

[103] Putting more Union in the European Customs - Ten proposals to make the EU Customs Union fit for a Geopolitical Europe – Wise Persons Group Report https://ec.europa.eu/taxation_customs/system/files/2022-03/TAX-20-002-Future%20customs-REPORT_BIS_v5%20%28WEB%29.pdf.

[104] That report notes that imports from third countries into the EU reached over EUR 2 trillion in 2019, rising from about EUR 1 trillion in 2004 and EUR 1.5 trillion in 2008. In recent years, a large proportion of these imports comes from e-commerce.

[105] From July to December 2021, the first six months of compulsory customs declaration for all goods imported into the EU irrespective of their value – traditional trade in goods represented over 220 million import declarations for a value of EUR 1,250 billion. In contrast, it is estimated that e-commerce represented 490 million customs declarations for a

unmanageable flow of millions of small individual consignments to be controlled and checked for fiscal and non-fiscal requirements, such as checking toys for compliance with the Toy Safety Directive. Data from European countries show the relevant importance of toys in cross border trade in individual parcels (10 % of small value parcels concerns toys), as well as the very high increase over the last period[106]. Evidence also suggests that the probability that small consignments will contain non-compliant or dangerous goods is very high[107].

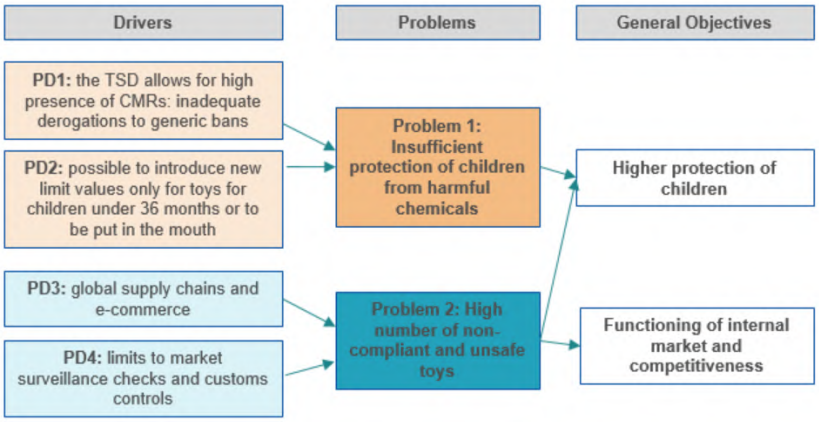

Figure 7: Problems and drivers

2.3. How likely is the problem to persist?

In the absence of EU action, the protection of children from chemical risks by the Directive will continue to be insufficient, and they will continue to face risks from non-compliant toys.

The most harmful chemical substances will continue to be harmful in the future. Their toxicity or hazard is not expected to decrease; on the contrary, as scientific knowledge of chemical substances progresses, new scientific evidence is expected to appear refining previous conclusions on the risks of harmful substances and identifying new substances presenting hazardous properties. As highlighted in the CSS, the sheer number of chemicals on the market represents an immense knowledge challenge, and the expected future rise in chemical production and use risks to further widen the 'unknown territory of chemical risks'. Children will remain a vulnerable population with specific exposure to chemicals in toys, and the need for them to benefit from swift protection from the most harmful substances will remain. The TSD in its current form will continue to be unable to ensure sufficient protection of children from these risks. It would only be possible to ban new harmful substances in toys for children under 3 years or to be put in the mouth.

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total value of EUR 4.8 billion. One of the aspects identified in urgent need of reform is the declaratory nature of most of the information presented at customs, often unrelated to commercial information or even reality and that can only be verified after specific checks at Customs. Source: DG TAXUD see the Wise Persons Report quoted above.

[106] An increase of over 500% took place from January to April 2020 compared with the same value the previous year. https://read.oecd-ilibrary.org/view/?ref=135_135520-5u04ajecfy&title=Connecting-Businesses-and-Consumers-During-COVID-19-Trade-in-Parcels

[107] See the Wise Persons Report. The WTO has also concluded that the increased number of small packages ordered directly to consumers has raised challenges with regard to compliance with health and safety regulations in importing countries https://www.wto.org/english/tratop_e/covid19_e/ecommerce_report_e.pdf

The high rates of non-compliant and unsafe products on the Union market are expected to remain. Market surveillance authorities will continue to perform checks on toys to remove non-compliant and unsafe toys from the Union market. However, e-commerce will continue to be used, probably increasingly, by EU customers[108], in particular cross-border trade will continue its upward trend and the current pressure on customs and market surveillance authorities will continue to grow. From 2020 to 2021 alone the proportion of online sales coming from outside the EU increased from 20% to 23%[109].

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The TSD is a 'total harmonisation' directive based on Article 114 TFEU (ex-Article 95 TEC) and follows the new legislative framework. As explained in Chapter 1, the TSD, like other EU product legislation, sets the 'essential safety requirements' which toys must satisfy to benefit from the free movement of products across the internal market.

3.2. Subsidiarity: Necessity of EU action

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

The TSD is key in ensuring protection of children in the EU. The main objective of the Directive is to ensure a high level of safety of children, and to allow the free circulation of toys in the EU. In particular, the TSD helps to reduce social costs by preventing accidents or harm to children that may be caused by the use of unsafe toys. A key rationale for an EU-level toy safety legislation is to provide harmonisation across Member States based on Article 114 TFEU. The TSD is a total harmonisation measure for the safety of toys, so Member States are not allowed to introduce additional safety requirements for toys; any changes to the scope or requirements of such a directive must be made at EU level.

3.3. Subsidiarity: Added value of EU action

In terms of toy safety and the creation of a large internal market for safe toys, the Evaluation has confirmed the EU added value of the Toy Safety Directive. In particular, without the Directive, Member States could set diverging limit values for chemicals, which would be to the detriment of the internal market. The Evaluation also concluded that all categories of stakeholders welcomed the existence of harmonised safety requirements across the EU, and companies valued the creation of a large market for toys and the simplification of trade as major achievements. Possibly diverging national rules were not considered as being more beneficial. Notified bodies in particular agreed that the Directive contributes to streamlining testing and standards, and public authorities welcomed the harmonisation of testing and standards and the opportunity to work together with authorities from other Member States.

A regulatory action at EU level would ensure coherent implementation of any new safety requirements for toys and thus a greater level of safety, and provide legal certainty and a level

[108] The COVID-19 crisis accelerated an expansion of e-commerce towards new firms, customers and types of products. Some of these changes in the e-commerce landscape will likely be of a long-term nature, in light of the possibility of new waves of the epidemic, the convenience of the new purchasing habits, learning costs and the incentive for firms to capitalise on investments in new sales channels. https://www.oecd.org/coronavirus/policy-responses/e-commerce-in-the-time-of-covid-19-3a2b78e8/#biblio-d1e705

[109] Impact Assessment study on a possible revision of the Toy Safety Directive 2009/48/EC, (2022) VVA, CSES and Asterisk, to be published.

playing field for industry. Regulatory action at EU level should lay down EU-wide requirements for ensuring the health and safety of children when playing with toys, and allowing market enforcement at the national level.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

The revision of the Toy Safety Directive would pursue two general objectives, corresponding to the general objectives of the current Directive:

- General Objective 1: Ensure a higher level of safety of toys so as to guarantee a higher level of protection of children

Children are amongst the most vulnerable population in the EU; they must continue to benefit from a high level of protection when playing with or enjoying toys. This general objective will also contribute to achieve another objective of the CSS: achieving safe products and non-toxic material cycles and directly to SDG#3: good health and well-being.

- General Objective 2: Continue to guarantee the functioning of the internal market for toys, limiting the number of non-compliant toys and preserving the competitiveness of EU industry

The objective of the functioning of the EU internal market is natural to a "total harmonisation" EU product legislation like the TSD. Toys complying with the Directive can circulate freely within the single market without further requirements. At the same time, it is essential to limit non-compliant products in the Union market, which put children at risk and create an uneven playing field for reputable companies. Manufacturers producing compliant toys must be protected from unfair competition, especially in online marketplaces.

4.2. Specific objectives

The initiative pursues the following specific objectives:

- SO 1: Adapt the rules to ensure protection of children against the most harmful chemicals
- SO 2.: ensure the necessary flexibility to be able to adequately address emerging scientific knowledge and risks

The toy industry is very innovative as this is essential to maintain a competitive position. At the same time, scientific knowledge on chemical substances is constantly evolving. It is essential that the rules can easily adapt to emerging knowledge and risks.

- SO 3: reduce the number of non-compliant and unsafe toys on the Union market

There is a significant number of non-compliant and unsafe toys on the EU market. To ensure the safety of children and facilitate the development of the internal market there is a need to reduce the number of these unsafe or non-compliant toys on the market. Given the growing prominence of online sales of products coming from outside the EU, there is a risk of seeing toy manufacturers following the requirements of the TSD having to compete with manufacturers producing toys which are not in conformity with the Directive.

- SO 4: streamline enforcement of the TSD

The work of market surveillance and enforcement authorities is crucial in ensuring the reduction of the number of non-compliant toys on the market and the internal market functions properly. Rogue traders can have an advantage against reputable manufacturers by exploiting the difficulties market

surveillance authorities have in enforcing the rules. As such, one of the objectives of the revision of the Directive should be to facilitate the work on enforcement by market surveillance authorities.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

The baseline assumes no change in the current TSD. Other legislative developments taking place in parallel are nonetheless considered in the baseline. On chemical protection, the revision of the CLP Regulation is expected to define new hazard classes for harmful chemicals, such as endocrine disruptors. However, the introduction of new hazard classes under the CLP Regulation will not have any effects in terms of the protection of children under the TSD: these hazard classes are not addressed in the TSD and the Commission is not empowered to introduce new limit values in all toys. The revision of the REACH Regulation has not been presented yet. It is expected to introduce generic bans on substances for the most harmful chemicals. It is also expected to address the risk management of consumer products containing chemicals classified under the most harmful hazard classes identified by the CLP Regulation. The REACH revision is not expected to introduce an upfront generic ban of the most harmful substances in the legislation but rather to provide for the legal means for the Commission to introduce such generic bans of the most harmful substances in consumer articles. However, the extent to which it will apply to consumer articles including toys, the hazard classes it may cover as well as the timing is yet unclear. A work plan to define how the most harmful chemicals will be addressed in REACH as well as the priorities is being prepared. So far, REACH has not been able to fully address the protection of children when playing with toys described in the problem definition. The protection from harmful substances that it will offer is not expected to be as comprehensive as the targeted approach in the TSD for toys. Nevertheless, toys will remain within the scope of REACH also concerning the risks on human health and if a substance is restricted under REACH in consumer articles, this can continue applying to toys.

Under the baseline, the Commission will continue to be able to amend the TSD with its empowerment under article 46. These regular amendments are expected to continue at the same pace as since the adoption of the Directive, and will continue to require economic operators to adjust to those. Economic operators will continue to face business-as-usual costs from complying with the current obligations of the TSD and its regular amendments.

In terms of ***administrative burden***, the total costs of the current TSD have been estimated at EUR 4000 per toy model both in case of large firms and SMEs in case of self-certification, and EUR 4500 in case of third-party certification. This includes drafting the technical documentation necessary to demonstrate compliance, the certification itself and labelling[110].

In terms of ***adjustment costs***, the key costs considered are i) costs related to chemical substitution or withdrawal and ii) testing. The analysis on adjustment costs makes a number of assumptions but acknowledges that there are a number of uncertainties which do not make it possible to provide a precise estimate for the baseline or each policy option. These underlying assumptions and uncertainties concerning the cost estimates are explained in detail below[111]. In respect of the dynamic baseline, the uncertainties concern particularly i) the specific substances for which a new limit value may be introduced in accordance with the existing possibilities to adapt the Directive, ii) the number of toy models which would be affected by the new restrictions; iii) the precise costs of replacing the particular chemical substance which would be restricted; iv) the capacity of the EU industry to shift production to alternative toys; and v) in cases of product withdrawals, the extent to which demand will shift to other toys which remain on the market, or will rather shift to other non-

[110] See more details for these calculations in Annex 14.
[111] See section 6 for the explanation on the underlying assumptions of these costs.

toy products. This is why a range of economic impacts is provided for the baseline and each policy option. Adaptation and withdrawal costs are one-off costs but would occur over time with the regular amendments of the Directive; for the purpose of the analyisis a 10 year timeframe can be considered.

As indicated above, in a dynamic baseline scenario the Commission will still be able to adapt the TSD's chemical restrictions, and new limit values for chemical substances will continue to be introduced in the Directive in accordance with the provisions of Article 46. Such changes would lead to product adjustment costs stemming from chemical substitutions and potential market withdrawals that would mostly affect toys intended for children under 36 months or to be put in the mouth. These costs, presented below, are considered business as usual compared to which costs of the different policy options should be presented. Assuming that the market for toys intended for use by children under 36 months and toys intended to be placed in the mouth accounts for around 20% of the total toys market, any new restriction could only apply to these toys, but any new limit value would not apply to all toys in that category, only to toys in which the restricted substance is used. It is estimated that the baseline scenario would require **one-off product adaptation or withdrawal costs in 0.6-1.2% of toy models[112] to comply with newly adopted limit values**. Approximately 0.4-0.8% toy models would be subject to adaptation, while a smaller segment of around 0.2-0.4% could no longer be made available on the market. While there are a number of uncertainties around these cost estimates depending on the specific substances that will be limited[113], adaptation costs to new limit values could range from EUR 6,700 per toy model produced by large firms and EUR 7,700 per toy model produced by SMEs to over EUR 15,000 per toy model[114]. Accordingly, the **total one-off costs associated with product adaptation (including chemical substitution) across the EU toys industry in the baseline scenario could range from around EUR 2 million to EUR 44 million over the period considered [115].** It is expected that the costs are closer to the lower range as these mirror the costs for complying with the updates of limit values calculated in the Evaluation.

In terms of market withdrawals, although the ultimate impact would depend on the value of the toy models affected, it is possible to indicate an estimate based on the turnover achieved by the European toys industry. The baseline scenario could affect **EUR 13.2 to 26.2 million worth of toys** (based on the percentage of toy models of 0.2-0.4 % which could no longer be made available on the market because of new limit values and based on provisional EU industry turnover of EUR 6.56 billion for 2020) over the period considered. In addition, given the time provided to accommodate such changes, the impact of such product withdrawals would likely be mitigated by: i) the ability for producers to shift resources to the production and sale of alternative toy products; and ii) the purchasing decisions of consumers, who, instead of choosing not to purchase a product, will in many instances purchase an alternative product and still contribute to the toys market.

The Toy Safety Directive puts the responsibility for the compliance of the toy on the manufacturer, in line with all EU product legislation. Beyond one-off adaptation costs to find alternative chemicals to those which are subject to restrictions or generic bans, any new toy model will need to

[112] Estimations by respondents to the SME survey.
[113] See Annex 14 for the precise description of the cost estimates. Data for the current administrative burden is calculated from the Evaluation, as well as interviews with industry and targeted SME survey in the framework of consultation activities.
[114] See the details for these calculations in Annex 14. The cost of adapting to new limit values introduced in the Directive have been calculated based on the information from the Evaluation on the basis of past adaptations (lower range), as well as interviews with industry and the targeted SME survey (higher range).
[115] This is based on 78,702 new toys models across all business sizes per year, and applying to that number the percentages of toy models that would be impacted by substitution costs and subsequently applying the costs for redesign or redevelopment that may be incurred.

be tested by the manufacturer for compliance with the applicable requirements. The manufacturer being responsible for the compliance of the toy, cannot simply rely on information provided by suppliers of raw materials for the toy, as he would not be complying with its obligations under EU product legislation. Testing costs for new toy models in the future will increase, as toys will have to be tested for more chemical substances. Testing of toys as part of assessing their compliance is estimated to cost currently EUR 2,200 per new toy model, but this is not considered to be administrative burden (testing per year for the overall EU industry under the baseline would be estimated at EUR 189.25 million[116]).

The regular amendments of the Directive should continue to introduce limit values for specific substances that will ensure better and targeted protection of children health but will be mostly limited to younger children or mouthing exposure in toys intended to be put in the mouth. This will lead to certain health benefits, targeted to those substances which have been limited, where there are specific and demonstrated risks. However, developing appropriate risk assessments for single chemicals has proven to be laborious, if not cumbersome in the past[117]. It will only be possible to introduce a reduced number of new limit values per year, as is the case now. The precise benefits on human health will only be realized after the introduction of such specific limit values and only for exposure to such substances. Furthermore, under the baseline, the increased protection of human health will only benefit younger children or children exposed to these substances through toys intended to be put in the mouth. This is because the current mechanisms to introduce new limit values in the Directive are limited to toys intended to be put in the mouth or intended for children under 3 years.

Under the baseline, the Commission together with members of the Expert Group on Toy Safety will continue to produce guidance on the application of the Toy Safety Directive which is helpful to economic operators in understanding how to comply with the Directive. Regulation 2019/1020 on market surveillance started applying fully on 16 July 2021. It is expected to improve the efficiency of market surveillance, including for toys, through more coordination and powers for market surveillance authorities; and to facilitate checks of toys coming from third parties and in particular online by being able to contact an economic operator established in the Union and responsible for the toy. The Digital Services Act will increase the involvement of online platforms in ensuring product safety by establishing the "know your business customer" principle. This legislative measure, together with the Regulation on General Product Safety should facilitate that non-compliant and unsafe products are withdrawn from online marketplaces when they have been subject to market surveillance measures (e.g. recalls). These initiatives should have positive effects on the rates of non-compliance, in particular concerning products sold online, but a high number of non-compliant products is expected to persist, damaging competitiveness of reputable manufacturers and the single market. E-commerce will continue to be used increasingly by EU customers[118], and the current pressure on customs and market surveillance authorities will continue to grow.

[116] Based on a total number of tests per year of 86,024 across all business sizes, from information by companies at the targeted survey.
[117] See section 5.1.1.2 of the Evaluation.
[118] The COVID-19 crisis accelerated an expansion of e-commerce towards new firms, customers and types of products. Some of these changes in the e-commerce landscape will likely be of a long-term nature, in light of the possibility of new waves of the epidemic, the convenience of the new purchasing habits, learning costs and the incentive for firms to capitalise on investments in new sales channels. https://www.oecd.org/coronavirus/policy-responses/e-commerce-in-the-time-of-covid-19-3a2b78e8/#biblio-d1e705

The **number of inspections in toys undertaken annually is estimated at a total of 25,259[119], and the average cost per inspection has been estimated at EUR 739** on the basis of the annual budget available. Customs authorities carry out controls on toys entering the Union market on a risk based manner. **Amendments to the TSD** will continue to take place on a regular basis, which will require the transposition of the new rules into national legislation leading to one-off costs per amendment of the Directive (**EUR 6,174 to EUR 18,522 per Member State**)[120].

In line with the strategic foresight approach, the baseline also takes into account relevant **megatrends[121]** identified. Growing consumption is relevant for this initiative, and in particular new trends such as sustainable consumption and digital, as well as previous covered trends such as eco-friendly products and e-commerce. Consumers are increasingly buying online, which will strengthen the role this channel plays in toys distribution, with the challenges that it poses for toy safety. The overall trend of digitalisation should support the companies' move towards digitalising product documentation. Other megatrends have also been factored in in the analysis, such as shifting health challenges and that new health burdens may appear and in particular the current trend towards a healthy environment. These megatrends strengthen the need to act as they show that the problem and the knowledge of hazardous substances will increase.

5.2. Description of the policy options

Three policy options were identified to address each of the problems 1 and 2. In order to address all problems that the initiative aims to tackle, option 1a, 1b or 1c (addressing problem 1 relating to strengthening the protection of children when playing with toys) would have to be combined with option 2a, 2b or 2c (addressing problem 2 related to the high number of non-compliant and unsafe toys). Addressing both different problems at the same time is essential, given that strengthening the requirements for toys will make compliance more costly, which will increase the incentives for rogue traders not to comply if the possibilities for detection are low. This risks damaging significantly competitiveness of industry if not accompanied with effective policy options to tackle non-compliance.

5.2.1. Policy options to strengthen the protection of children when playing with toys

Three policy options are presented, which are incremental, from minimum to highest level of intervention and with different approaches as regards risk management measures for harmful chemical substances. See annex 9 for the different risk management approaches in chemicals legislation and annex 9.4 for the description of the interaction between REACH and the TSD.

Option 1a – Minimum changes to the Directive

This option would keep the overall framework of the Directive unchanged, but would allow the Directive to adapt to emerging knowledge of chemical substances by imposing new limits for substances in any toy (and not only in toys intended for children under 36 months or to be put in the mouth, as in the current Directive). Therefore, more specifically, this option would:

- **Empower the Commission** to set, and amend, **limit values for any chemicals** and for toys for children of any age by introducing an **additional Annex for other toys that are not for**

[119] This information is based on summary of market surveillance reports provided by Member States in accordance with Regulation (EC) No 765/2008. See annex 14 for the detailed calculations and estimates.

[120] Data about the amount of person days needed for transposition considers the number of person days needed for transposition of a Directive to be between 20 and 60. Using the Member State daily labour cost (i.e. EUR 309- Data about labour costs comes from Eurostat's Labour Cost Survey, (2016), category 'public administration and defence, compulsory social security' per employee FTE and adjusted for inflation.), the overall cost of transposition is estimated to be in the range of EUR 6,174 to EUR 18,522 per Member State. Assuming the same number of amendments to the rules as in the last 10 years, this could amount to total costs of EUR 104,958 to EUR 314, 874 per Member State.

[121] Megatrends Hub; https://knowledge4policy.ec.europa.eu/foresight/tool/megatrends-hub_en

young children or to be put in the mouth. Substances would be scientifically assessed and banned from toys when they are deemed unsafe in a particular use (specific risk assessment). Therefore, the Directive would have the possibility of introducing limit values for any toy and to differentiate between toys intended for children under 3 years or to be put in the mouth (in the current Appendix C) and for toys for older children (in a new Appendix) if this would be warranted. This approach would not distinguish between chemical substances depending on the hazards they present, but would allow that any substance is limited in toys if an assessment of the substance's hazards and the exposure to those hazards in toys concludes that they pose a risk to children.

- **Reduce limit values for nitrosamines and nitrosatable substances** to align them with those in force in Germany
- Require manufacturers to assess the **known risks from the combination of chemicals** in the toy, by providing **guidance;**
- Finally, a fast-track mechanism will allow the Commission in consultation with national authorities to take exceptional measures against unsafe toys presenting sudden risks not specifically foreseen in the TSD[122].

This option would not revise the general prohibition of CMRs substances in toys nor the derogations to that prohibition; these would remain unchanged. However, specific limit values for such CMRs substances could be added for any toy. A differentiation in limit values for toys intended for children under 36 months/to be put in the mouth and toys for older children will be possible where this is warranted. Limit values for other chemical substances would also remain unchanged but could be amended. In this manner, this option would address all the problem drivers with minimum changes to the Directive.

Option 1b – Improved prevention: generic bans for the most harmful chemicals subject to derogations

This option would include the following elements:

- Extend the **generic approach to risk management** to other most harmful substances. This means that the existing general prohibition of CMR substances would be extended to **endocrine disruptors (a new hazard class recently introduced in the CLP Regulation), substances affecting the respiratory system[123], substances affecting the immune or neurological systems and chemicals toxic to a specific organ (currently under specific target organ toxicity – STOT - classes in the CLP Regulation)**. These substances would be automatically banned from toys as soon as they are classified under the CLP Regulation in these most harmful hazard classes. As these generic bans will concern the most harmful chemicals, they would apply to all toys without distinction, i.e. toys for children under 36 months or for older children as well as toys intended to be put in the mouth.
- **Derogations to these generic bans would be possible**. Derogations would be based on one of the current provisions for derogations to the CMR ban, and would apply when all the following conditions are met: i) when **the use of the specific substances in toys has been assessed as safe for children**, ii) when **there are no suitable alternatives** for that substance and iii) when that specific substance is **not prohibited in consumer articles under REACH**. In the current TSD, these derogations are adopted by the Commission following a scientific assessment and discussed with experts from Member States and

[122] Similar to the mechanism in Article 13 of the General Product Safety Directive 2001/95/EC.
[123] Classified as respiratory sensitizers in the CLP Regulation, see Annex 10.

industry. Under this option, the scientific assessment should be carried out by ECHA the European Chemicals Agency in Helsinki. ECHA would evaluate whether the substance, despite its hazard classification, would not expose the children to any health or safety risk in the manner in which it is used in toys. This chemical risk assessment would require the consideration of the inherent hazardous properties of the substance or a mixture and the extent of exposure to that substance or mixture in toys[124]. Derogations could only be granted where the scientific assessment concludes that the use of the substance in toys is safe and there are no alternatives. This is why derogations granted in this manner would ensure that the safety of children is not put at risk. The intention is to streamline this assessment as much as possible with other health and safety assessments done by ECHA for other EU safety legislation. The ECHA opinion would then serve as a basis for a Commission decision on the derogation request.

This option only retains one of the current derogations to the generic prohibition of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMRs) and is therefore more stringent than the current system**.** Accordingly, derogations will only be possible if the scientific assessment concludes that the use of the substance is safe. This means that where there are uncertainties about its safety in toys, a derogation should not be granted.

- Other derogations to generic bans in the current TSD, such as the possibilities of harmful substances to be present in toys up to the relevant concentration limits for classification established under the CLP Regulation will be deleted. The Evaluation concluded that this derogation still allowed for too much presence of CMRs in toys, posing a risk to children. The derogations proposed in this option 1b would not allow for this exposure. In addition, the derogation allowing for harmful substances in toys if they are inaccessible to children will be removed too. There were uncertainties in the past on the correct interpretation of this derogation. If they are inaccessible and they are safe, this should be scientifically assessed in the context of the remaining derogation. Lower limits or limits of quantification and/or detection would be set for the purposes of verifying compliance.
- In addition, this option would include all the elements of option 1a and would allow the introduction of specific limit values for specific chemicals if these are not covered by the generic bans.

With the introduction of generic bans for the most harmful substances and the removal of the derogation allowing the presence of such substances up to the 'relevant concentrations' of the CLP Regulation, this option is expected to address the problem drivers in a more preventive manner. As in option 1a, whenever scientific knowledge would point to the Directive still allowing for too high presence of other chemical that is posing a risk to children, specific limit values for such substance in any toy could be introduced[125]. A differentiation in limit values for toys intended for children under 36 months/to be put in the mouth and toys for older children

[124] Previous scientific opinions on hazardous substances in toys have assessed the possible ways in which children may be exposed to the substances (either via inhalation, ingestion or dermal contact) and whether there was any risk from that exposure. It may be that a substance is classified as hazardous via inhalation but it is only included in toys in metals containing that substance, so that the risk that children would be exposed to inhaling the substance is negligible. See the SCHEER opinion on nickel in toys: https://health.ec.europa.eu/document/download/af3a05ea-2f9f-4939-89c6-1637796d285b_en?filename=scher_o_163.pdf

[125] These limit values would be based, as is the case today for the limits in Appendix C of the TSD, on the experts views of the members of the Subgroup of Chemicals of the Expert Group on Toy Safety, as well as a relevant scientific opinion. Under this option, the scientific opinion is expected to be delivered by ECHA.

would be possible where this is warranted. However, in view of all the substances that would be covered by generic bans, these specific limit values should be less frequent than with the current TSD or option 1a.

Option 1c – Maximum protection from harmful chemicals: generic bans for the most harmful chemicals without derogations

This option would include all the elements in option 1a, it would also include the general bans of the most harmful substances in toys, as soon as these substances are classified under the CLP Regulation as presenting hazardous properties for human health in the most hazardous classes, as in option 1b. However, this option **would not allow for derogations to the generic bans for the most harmful substances**. As toys are intended for a vulnerable population group, this option would offer zero tolerance for the most harmful chemicals in toys. This would ensure the most preventive approach for children, and if new scientific knowledge emerged indicating that these harmful substances are even more harmful than considered before, exposure of children to those would have been prevented. As in option 1a and 1b, whenever scientific knowledge would point to a certain chemical that is posing a risk to children in toys and is not included among the hazard classes covered by generic bans, specific limit values for such substance in any toy could be introduced. A differentiation in limit values for toys intended for children under 36 months/to be put in the mouth and toys for older children would be possible where this is warranted. However, in view of the number of substances covered by generic bans, these specific limit values should be less frequent than under the current TSD or in option 1a.

5.2.2. Policy options to reduce the number of non-compliant and unsafe toys

Three policy options are presented, with a different focus in its intervention:

Option 2a – Extending third-party conformity assessment

To reduce the number of non-compliant toys on the European market, pre-marketing conformity assessment (**third-party conformity assessment**) would be **extended for certain toys**. The Directive currently requires third-party conformity assessment only under very specific circumstances. With the extension of third-party conformity assessment, the intervention of a notified body could be required for a) those types of toys which present higher risks, as well as b) for toys for which higher rates of non-compliance are found. As shown in section 2 above, the notifications of toys intended for children under 36 months which do not comply with the requirement not to have small parts which may cause a child to choke constitute around 40% of unsafe products notified under RAPEX. Notifications of toys non-compliant with chemical risks constitute around 40 % of notifications, too. While these may concern chemical risks on any toy, toys which are chemical substances or mixtures can lead to higher exposure of children to any harmful chemicals in them. Therefore, with this option, third-party conformity assessment would be extended to:

- Toys marketed at children under the age of 36 months old or designed to be put in the mouth. These toys are subject to the specific requirement not to include small parts which may cause the child to choke.
- Toys which are chemical mixtures or substances (i.e. such as slime, modelling clay or finger paint).

Option 2b – Facilitation of market surveillance checks and customs controls through digitalisation

To reduce the number of non-compliant and unsafe toys on the European market option 2b would include **post-marketing facilitation of market surveillance checks.** It would require the

introduction of a digital product passport (DPP) containing the EU declaration of conformity that could be immediately consulted by market surveillance authorities. In addition, the reference of this DPP would be presented at customs so that its presence can be automatically verified when the toy enters the Union market. Release for free circulation of such toys would not be granted if it is absent. This would be based on the Digital Product Passport under the proposal for Ecodesign for Sustainable Products Regulation[126], in order to avoid multiplication of digitalisation systems but this option is independent from the regulation of sustainability of toys under the ESPR. While toys are not currently included in the list of high priority sectors identified in the Circular Economy Action Plan, sustainability requirements under the ESPR may be imposed in the medium or longer term. Furthermore, it is expected that the DPP will become the vehicle to provide digital information on products in the future. The ESPR already foresees that the DPPs would be registered in a central registry which will be interconnected with the EU Customs Single Window Certificate Exchange System (EU CSW-CERTEX), which is the central module of the EU Single Window Environment for Customs[127]. Relying on the DPP under the ESPR and its registry for the revised toy safety rules will guarantee that these efforts are not duplicated. By means of this interconnection, when toys coming from third countries are presented at the borders, customs authorities will check that the DPP is referenced in the central registry. This will apply to any toy, either sold online or distributed through more traditional supply chains, and therefore cover also small or individual parcels containing toys and coming into the Union market from third countries. In order to be registered, the DPP for toys will have to include the EU declaration of conformity.

All commercial goods imported into the EU require a customs declaration for release for free circulation. The main benefit of the DPP as proposed in option 2b will be that a reference to it should be included in the customs declaration for every toy, and this includes online purchases by individual EU customers from third countries. The reference of the DPP, which for toys would include the product compliance information, will also have to be included in a central registry managed by the Commission, which will be interconnected with the IT customs environment to allow for its automatic verification. This will allow that **any toy which does not indicate a valid DPP reference in the customs declaration is automatically stopped at EU customs and is not released for free circulation.** Customs authorities will be able to carry out this automated control on all products entering the Union market, rather than controls on a risk-based manner on a limited amount of products as is the case today. Automated controls on every toy cannot take place today; a legislative change is necessary in the Toy Safety Directive to improve controls on toys in this manner.

With this option, the revised Toy Safety rules would require that the compliance information on the toy is presented at customs when it enters the Union market. The proposed measures under option 2b can take place independently from the revision of the UCC but they would support the general objectives of the revision of the UCC, including improved access to data to improve risk management at customs, to increase the capacity of customs to detect non-compliant toys. When both are adopted, there will be better controls at the border for toys.

[126] 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, COM(2022) 142 final

[127] Proposal for a Regulation of the European Parliament and of the Council establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013, COM(2020) 673 final

Option 2c – Extension of third-party conformity assessment and facilitation of market surveillance checks and customs controls through digitalisation

This option would combine options 2a and 2b.

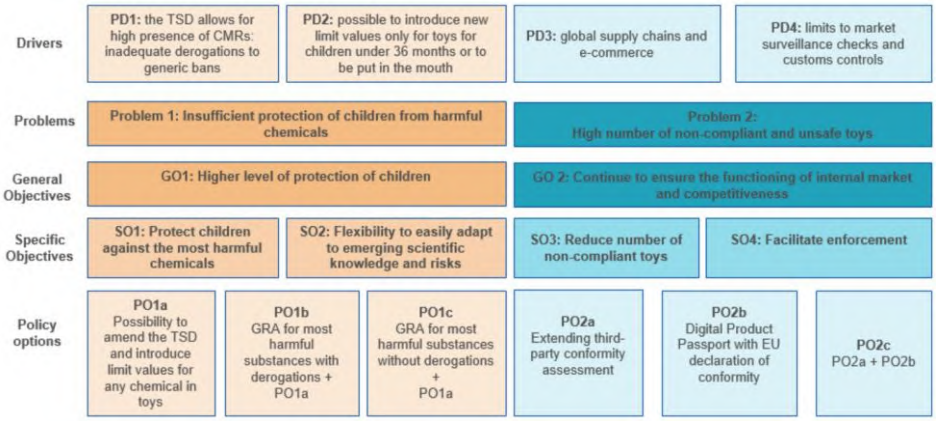


Figure 8: Intervention logic

5.3. Options discarded at an early stage

Several potential options were discarded at an earlier stage:

Introducing essential requirements for Internet-connected or other digital aspects of toys – The Evaluation had concluded that the issue of the security of internet-connected toys and the related protection of privacy (cybersecurity) emerged as a concern: the security threats that new technologies (including toys) pose cannot be addressed by the Directive in force, because of its limited scope, which focuses on health and safety, but not on privacy and security issues. Nevertheless, since the publication of the Evaluation, the RED delegated act[128] establishing essential requirements for the personal data protection and privacy as well as cybersecurity was adopted, covering radio toys within its scope. Similarly, a proposal for a Regulation on Artificial Intelligence[129] has been put forward and should address the specific risks that the integration of AI may pose on toys. Cybersecurity should be strengthened by the Cyber Resilience Act as well, once adopted[130]. With these initiatives, the risks for privacy, those concerning cybersecurity as well as artificial intelligence should be addressed and no remaining gap has been observed in the field of toys.

Derogations for "essential uses" to the generic bans of the most harmful chemicals

The Chemicals Strategy for Sustainability committed generally to extend the generic approach to risk management (preventive bans) to the most harmful chemicals in consumer products, while still allowing their use where proven essential for society. While the concept of essential use is still under development, including for its application under REACH and possibly other downstream

[128] Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive.
[129] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, of 21 April 2021
[130] Cyber resilience act – new cybersecurity rules for digital products and ancillary services (europa.eu)

legislation, it is not presented as an option or criterion for derogating from the generic bans under the Toy Safety Directive. First of all, toys will remain under the scope of REACH in the future, both for human health and environmental considerations. If a harmful substance would be banned under REACH in consumer articles (be it due to generic risk to human health or to the environment), for instance because it has no essential use, it can be prohibited for toys. If this is not (yet) the case, substances under the most harmful hazard classes will be covered by the generic bans under the TSD and subject to its derogations. As the main objective of the TSD is ensuring children safety, the assessment of the derogations under the TSD will remain based on the safety of the use of the substance in toys. Consequently, in PO1b presented in this Impact Assessment, derogations to the generic bans are considered possible if (i) the use of the chemical is safe, (ii) there are no alternatives to the presence of the chemical in the toy, and (iii) the specific substance is not prohibited for use in consumer articles under REACH[131]. The latter condition would continue to ensure consistency with REACH.

Creating an injury database

The Evaluation indicated that data on injuries or accidents caused by toys was not readily available. Nonetheless, addressing this issue identified in the Evaluation through the maintenance of a European injury database has not been considered as part of the options. First of all, since the publication of the Evaluation, Regulation 2019/1020 on market surveillance has become fully applicable. This Regulation requires market surveillance authorities to share information on all the in-depth checks of compliance that they perform, and the results of those investigations, in addition to any notification of dangerous products they may need to perform through RAPEX – Safety Gate. This information should provide a comprehensive picture of non-compliance of toys in the EU including on the specific type of non-compliance and the percentage of toys inspected which are not compliant. This information can also provide information on new risks emerging in toys. As such, these data provide more thorough information on the extent to which in the Union there are unsafe toys which do not comply with the applicable requirements of the legislation, and which may be putting children at risk. In addition, the General Product Safety Regulation includes a provision on mandatory accident reporting, which would be applicable to harmonised products such as toys. This obligation is primarily for manufacturers to notify accidents caused by products, within two working days from the moment they know about the accident, to the competent authorities of the Member State where the accident has occurred. This should already ensure greater availability of data regarding the accidents related to toys. Setting up and maintaining an injury database would be costly, and it would not provide sufficiently reliable information on toy safety in the EU. Information should be filled in by doctors when accidents happen, this may not be done consistently or in a comparable manner, or in a way that identifies the product at stake precisely enough and even when accidents concern toys, they may not relate to a safety issue of the toy or to a malfunction, as many accidents can be caused by safe toys (for example, injuries caused by falling from toy scooters). Furthermore, such an injury database should be addressed generally for all products in a manner that could provide additional sources of evidence for policy monitoring, but creating it only for specific toys injuries would not be efficient.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

The following sections provide estimations of the costs based on certain assumptions (see annex 14 for the detailed estimates) and address in particular economic impacts for economic operators, for public authorities, competitiveness and innovation, human health and the environment. Regarding **fundamental rights**, none of the policy options is expected to have significant impacts, but the first

[131] See Annex II, part III point 4(c)(iii) of the TSD.

three policy options should generally assist in the rights of children and their possibility to play. While the objectives of the revision of the TSD are focused on strengthening the protection of children health, the different policy options should have a limited positive impact on the environment. As such, the policy options devised respect the **'do not significant harm'** to the environment principle but do not address it specifically. In addition, the policy options do not have a relevant impact on the climate-neutrality objective of the Union. PO2b could, by means of digitalisation, lead to increased energy needs in terms of IT servers or cloud services by toy manufacturers, but these should be covered by the overall digitalisation of industry and balanced by energy efficiency efforts by the underlying IT infrastructure. On the other hand, it should reduce the use of paper.

Approach for the analysis of economic impacts and adjustment costs

This impact assessment considers the costs of **product adaptation** for economic operators, mainly toy manufacturers, stemming from possible new restrictions of chemicals in toys and based on the percentage of toy models to which those costs would apply in the different policy options under consideration. It also considers the sales value of the percentage of **toys that could no longer be made available on the market**, if alternatives to the chemical substances are not found and, in case of option 1c, if derogations are not available. These costs are relevant for a dynamic baseline scenario and the first set of policy options.

Adjustment costs have thus been estimated under a dynamic baseline scenario and for all the first set of policy options 1a, 1b and 1c of this impact assessment. The key costs considered as adjustment costs are i) costs related to chemical substitution or withdrawal and ii) testing. The analysis on adjustment costs of the baseline and compared to that, of the different policy options 1a, 1b and 1c makes a number of assumptions but acknowledges that there are a number of uncertainties which do not make it possible to provide a precise estimate for the baseline and each policy option. These uncertainties concern: i) the specific substances that may be banned in toys under option 1a; ii) the specific substances covered by generic bans in options 1b and 1c, and in particular the substances that will be classified as endocrine disruptors under the new hazard class proposed to be introduced in the CLP Regulation; iii) the number of toy models which would be affected by the new restrictions; iv) the precise costs of replacing the particular chemical substance which would be restricted; v) the extent to which derogations would be granted under option 1b; vi) the capacity of the EU industry to shift production to alternative toys; and vii) in cases of product withdrawals, the extent to which demand will shift to other toys which remain on the market, or will rather shift to other non-toy products. This is why a range of adjustment costs is provided as regards costs related to chemical substitution or withdrawal of products and testing costs. The different policy options 1a, 1b and 1c are presented with ranges of adjusment costs incremental to the baseline.

Adaptation and withdrawal costs are one-off costs but would occur over time with the regular amendments of the Directive in the dynamic baseline and in policy option 1a, and with the substances being classified under the relevant hazard classes covered by generic bans under policy options 1b and 1c. For the purpose of this impact assessment and comparison of the options and against the baseline, an overall figure corresponding to the total one-off adaptation or withdrawal costs over a 10 year timeframe has been considered.

6.1. Policy option 1a – minimum changes to the Directive

Economic impacts - Impacts on economic operators

In terms of ***administrative burden***, this option would not entail a direct increase of the administrative burden reported in the baseline since it does not involve any specific change in terms of information obligations or certification. In terms of ***adjustment costs***, the lowering of limit values for nitrosamines and nitrosatable substances to the levels already applicable in German law would have a minimal impact, as manufacturers are already complying with these lower values. Similarly, most manufacturers are already assessing and addressing the risks stemming from combination of chemicals[132] and therefore the need to consider known risks of combination of particular chemicals was not considered to lead to increased costs. The primary adjustment costs anticipated form this option are costs of chemical substitution and redevelopment resulting from new limit values which would apply to all toys (in contrast to the baseline in which new limit values only apply to toys intended for children under 36 months or to be put in the mouth). Should suitable chemical alternatives not exist, or product redesign not be possible, it may no longer be possible to make certain toys available on the market. The precise costs of product adaptation and product withdrawal will depend on the specific limit values that could be progressively introduced in the TSD and as such are difficult to quantify at this stage. Also, the scale of impact could differ based on the make-up of a manufacturer's portfolio and to what extent they manufacture toys using the restricted substance.

Potential impacts could be estimated to require **adaptation or withdrawal of 2.4-4.8% of toy models on the market in addition to the baseline[133].** In particular, it could be estimated that 1.6-3.2% of toy models would require redevelopment to identify and use safe, alternative chemicals, while the remaining 0.8-1.6% could no longer be made available on the market if no alternatives to the restricted chemicals are available[134]. Based on these estimates and the cost estimates for adjustments per toy model detailed in the baseline above which indicate that adaptation costs to new limit values could range from EUR 6,700 per toy model produced by large firms and EUR 7,700 per toy model produced by SMEs to over EUR 15,000 per toy model[135], the **total incremental one-off adjustment costs associated with product redesign and redevelopment to adapt to greater restrictions over the period considered could range from EUR 8.18 million to EUR 176.3 million compared to the baseline[136].** As this option would be similar to the current system of the TSD but allow that limit values are introduce for all toys, costs are expected to be closer to the lower range as these mirror the costs calculated in the Evaluation.

With limit values being added for new substances in toys, new toy models will need to be tested in order to ensure compliance. The increased complexity of testing for lower limit values would reportedly lead to increases in testing costs from EUR 2,200 to around EUR 3,300 per toy model when toys need to be tested for the substances subject to new limit values[137]. In view of the fact that products subject to adaptation efforts will be subject to these increased testing costs, **yearly testing**

[132] See Annex 14 for further details. Source: Study on the possible revision of the Toy Safety Directive, 2022, VVA, CSES and Asterisk, to be published.

[133] Estimates from manufacturers in the targeted survey are that this option would affect 3-6 % of toy models (compared to the baseline of 0.6-1.2%).

[134] This is based on a number of assumptions considering information provided by industry, and that this option will lead to the introduction of limit values that may affect all toys rather than only toys intended for children under 36 months or toys to be put in the mouth, as is the case today. See Annex 14 for further details on these calculations.

[135] See the details for these calculations in Annex 14. The cost of adapting to new limit values introduced in the Directive have been calculated based on the information from the Evaluation on the basis of past adaptations, as well as interviews with industry and the targeted SME survey.

[136] This is based on an estimation of 78,702 new toys models put at the market yearly across all business sizes, out of which the percentage of those impacted by substitution costs is calculated, and on the range of costs that redesigning each of those affected toy models could represent.

[137] Estimates by businesses interviewed in the framework of the supporting study.

costs are estimated to incrementally increase compared to the baseline by around EUR 1.89-3.79 million[138].

These are overall estimates for the EU market, given that the specific number of substances that will be addressed with future limit values for chemicals is not currently known. Depending on which substances are addressed by new limit values, companies will have to determine which products in their portfolios are affected and need to be redesigned. This is why precise cost estimates per type of company could not be calculated. Nevertheless, **SMEs** account for a fourth of turnover in the sector so they will bear a proportionate amount of these costs; they are also expected to have higher costs per new toy model than larger firms, as they face higher unit costs. As it was reported in the Evaluation, while large companies have had adaptation costs of EUR 6,700 per toy model, these cost are of EUR 7,700 per SME. SMEs were concerned about facing higher unit costs than large manufacturers in particular for testing[139]. Specific differences per size of SMEs were not available either.

In terms of product withdrawals, although the ultimate impact would depend on the value of the toy models impacted, it is possible to indicate an estimate based on the turnover achieved by the European toys industry. Accordingly, this option could affect **EUR 52.47 to 104.9 million worth of toys in addition to the baseline (**based on provisional EU industry turnover of EUR 6.56 billion for 2020). As detailed under the baseline, these impacts would be mitigated by the time provided to adjust to the updated rules, which would allow producers to shift resources to the production and sale of alternative products, and the fact that, in many instances, consumers would choose to purchase an alternative toy product, rather than not purchasing anything, thereby ensuring the revenue to the toys market remains.

Impacts on public authorities

It is likely that there would not be any additional costs for national authorities. The budget available is expected to remain the same, as well as the number of inspections. Even if the number of substances subject to limit values would increase, market surveillance authorities are expected to conduct testing only for certain types of products inspected, as is currently the case.

Impacts on innovation, competitiveness and the internal market

It has been estimated that for a number of restricted chemicals, alternatives may not be found and certain toys could no longer be made available on the market (around 0.8-1.6%). This would be mitigated in terms of the impact on the toy industry overall as consumers may instead purchase alternative products that remain on the market and that meet more stringent limit value thresholds, as well as the possibility for producers to adapt production through a sufficiently long transition period. The impacts on competitiveness will depend strongly on the specific substances concerned by a change in the limit values. Regarding the impacts on innovation, no evidence was identified that there are alternative substitutes to many chemicals used in toy production and therefore, if major changes to limit values are introduced, this could incentivise producers to search for alternatives, which could spur innovation.

This option is not expected to have net impacts on employment, as it is expected that companies will require more man hours dedicated to research of alternative chemicals and product redesign. Overall, complementing this option with another option to effectively address the high number of non-compliant toys on the Union market was considered essential by industry to preserve its

[138] Based on the percentage of tests per year (from the total 86,024 test per year) that would be more complex (1.6-3.2%) and for which the costs will be higher. See annex 14 for more detailed estimates.
[139] Source: interviews. See Annex 14 for further details.

competitiveness[140]. There would be positive impacts on the single market for having uniform limit values for all substances in toys, and responding to consumer expectations regarding the safety of chemicals in toys.

Social impacts - Impacts on human health

The available evidence on potential human health impacts of PO1a was limited mainly due to the lack of detail on which limit values would be updated or introduced (apart from nitrosamines). Most manufacturers already comply with the lower limits for nitrosamines[141], but this option would ensure enforceability of those lower limits if this may not be the case and thus lead to better protection from these strong carcinogens. For other specific limit values, this option will lead to better and targeted protection of children health by ensuring that only those cases based on scientific evidence of hazards and risks would be addressed, with due account of mouthing exposure by younger children, as appropriate. This will guarantee a targeted approach for the protection of specific and demonstrated risks. However, developing appropriate risk assessments for single chemicals has proven to be laborious, if not cumbersome in the past[142]. The time between the identification of a hazard for children or from the classification of a chemical as hazardous under the CLP Regulation until it is banned in toys is likely to be too long (around 2 years in past instances), leaving children unprotected for a certain period of time and requiring prioritisation of substances to be tackled in toys. For these reasons, it may only be possible to introduce a limited number of new limit values per year. The precise benefits on human health will only be realized after the introduction of such precise limit values.

In terms of consumer welfare, as this option is only expected to have limited impacts on product redesign and adaptations, it should not lead to lower choice of products or increased prices. A certain improvement of toy safety and trust could be expected but, like the benefits for human health, these are expected to be limited.

Environmental impacts

PO 1a will not address chemical substances that are harmful to the environment as such. It will address specific chemical substances that would pose a risk to children's health. Nevertheless, this PO could still have a minor positive effect on the environment, as it would lead to less harmful substances from toy materials once they are banned in toys. This means that less harmful chemicals would reach the environment by means of end-of-life toys in waste or recycling.

Stakeholders' views

92% of consumers/environmental groups (56 out of 61), 94% (29 out of 31) of public authorities and 68% of industry (61 out of 89) agreed or strongly agreed that the Commission should be empowered to amend the Directive to set new requirements for chemicals in any toy.

6.2. Policy option 1b – Improved protection: generic bans of the most harmful substances with derogations

Economic impacts - Impacts on economic operators

Similar to PO1a, this option would not entail a direct increase of the ***administrative burden*** since it does not introduce any specific change in terms of information obligations or certification. Nevertheless, if industry intends to request a derogation from generic bans, it will need to submit a dossier with this request, justifying that the specific substance is safe and that there is no alternative. This cost is considered as administrative burden even if it will only be incurred if

[140] Source: interviews and targeted survey. See annex 14 for further details.
[141] Source: interviews and targeted survey. See annex 14 on the economic impacts and impacts on competitiveness.
[142] See section 5.1.1.2 of the Evaluation.

manufacturers want to continue using substances subject to generic bans in toys. This administrative burden will depend on the specific derogations that will be requested. In the past, requests for derogations have been made by industry associations, which means that the administrative cost for requesting a derogation could be expected to be shared among industry rather than born by a specific company. Past derogation requests have been estimated by the toy industry at roughly EUR 50.000 per derogation request (per industry association, not per company), including the work that manufacturers incur in verifying whether a derogation appears necessary, formally requesting the derogation through industry associations and commissioning a study on the scientific aspects. Other industries which need to request derogations for continued use of chemicals under generic bans, through similar procedures, have indicated a rough estimate of EUR 150.000 to EUR 200.000 per derogation request in the most complex cases. Based on this information, it could be estimated that the cost per derogation request could range from EUR 50.000 to EUR 150.000 per derogation request, and that there could be a maximum of two derogation requests per year, which would represent a total administrative burden for the overall industry of EUR 100.000 to EUR 300.000 per year. Derogations would be requested by companies as a means to mitigate the adjustment costs.

As for PO1a, the primary ***adjustment costs*** anticipated under PO1b are the costs of chemical substitution or product redesign and redevelopment resulting from greater restrictions on the use of chemical substances in toys. Should suitable chemical alternatives not exist, or product redesign not be possible, or derogations are not possible, certain products could no longer be made available on the market. The challenge in providing specific cost estimates is the uncertainty about the precise number of substances that might be included in extension of the generic bans[143]. The specific substances that may be covered in future hazard classes of the CLP Regulation is not yet known. Furthermore, manufacturers will need to assess the extent to which their portfolio is affected. In addition, if similar generic bans are applied to substances themselves under REACH, it will be much less costly for the toy industry to comply with this option as chemical substitution will already be carried out by chemical producers. It could be estimated that the number of substances covered by generic bans under PO1b might increase by about 10-30%. This could affect a significant number of toy models, but derogations would limit the toy models that would 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 additional to the baseline may be impacted under PO1b and for which a derogation may not be possible[144], with 4.6-7.2% subject to product adaptation efforts (including chemical substitution efforts) and 3.8-5.6% could no longer be made available on the market if no alternatives to the restricted chemicals are available. Using the same data on cost estimates for product adaptation and redevelopment detailed above for the baseline (from EUR 6,700 for large firms and EUR 7.700 for SMEs per toy model to over EUR 15,000 per toy model), the estimated impact on 4.6-7.2% of all EU new toy models could result in total **incremental one-off adjustment costs associated with product redesign and redevelopment of EUR 23.5 to 396.66 million compared to the baseline[145].** With more substances being subject to general bans, as well as limit values added for new substances in toys, new toy models will need to be tested in order to ensure compliance with such limit values. Due to the need to have more complex and sensitive testing for the toy models that may be impacted by the new requirements for chemical substances, the costs of testing may increase from EUR 2,200 to EUR 3,900 per toy model. In view of the products subject to adaptation efforts will be subject to these increased testing costs, **yearly testing**

[143] See annex 10 for a more detailed estimate of substances that could be covered by generic bans.
[144] Based on information by manufacturers in the targeted survey.
[145] Applying the relevant percentages of toy models affected to the estimate of 78,702 new toys, and based on the range of costs that such redesign may require.

costs are estimated to incrementally increase compared to the baseline by around EUR 7.31-11.70 million[146].

As in PO1a, these are overall estimates but the specific costs of this option and the precise impacts depending on the size of the company could not be quantified. Nevertheless, as mentioned for PO1a above, SMEs are expected to have higher costs per new toy model than larger firms, as they face higher unit costs. Also, as SMEs account for one fourth of the turnover in the sector, they are expected to bear costs in proportion to that.

In terms of product withdrawals, although the ultimate impact would depend on the value of the toy models impacted, it is possible to indicate an estimate based on the turnover achieved by the European toys industry. This option **could thus affect EUR 249 to 367 million worth of toys in addition to the baseline**[147]. As mentioned throughout, this would not lead to a direct market contraction of that size, given 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.

There would be additional costs for companies to request a derogation insofar as they will need to prepare a dossier justifying the request. These costs could not be quantified with precision at this stage, as it will depend on the specific derogations that will be requested and on whether a number of derogations are requested at the same time, in particular in the initial application of GRA. In the past, derogations have been requested jointly by industry, and sometimes for a number of substances at the same time, which helped generate savings.

Impacts on public authorities

As in PO1a, it is likely that there would not be any additional costs. The budget available is expected to remain the same, as well as the number of inspections. Even if the number of substances subject to limit values would increase, market surveillance authorities are expected to conduct testing only for certain types of products inspected, as is currently the case.

Impacts on innovation, competitiveness and the internal market

The extension of the GRA to other harmful chemicals could have certain negative impacts on competitiveness. It has been estimated that if alternatives to restricted chemicals cannot be found, 3.8-5.6% of toy models could no longer be made available on the market. The impacts of market withdrawals may be limited to a certain extent by transition periods, shift of production to alternative toys and consumers purchasing an alternative safer product. While some industry stakeholders noted that most toy manufacturers already adopt a risk management approach centred on exposure risk and do not use the substances that would be subject to restrictions under the extension of the GRA, others highlighted the potential scale of the substances that could be banned and stated that there would be a potentially significant impact on their product portfolio[148]. There are a number of concerns among industry (especially SMEs) regarding adverse impacts on competitiveness, as SMEs have less resources to allocate for research and innovation[149]. These negative impacts may be limited by the discussed implementation of the GRA in REACH. If the same hazard classes and substances are banned under REACH, it will be much easier for the toy

[146] Based on the percentage of tests per year (from the total 86,024 test per year) that would be more complex (4.6-7.2%) and for which the costs will be higher.
[147] Based on provisional EU industry turnover of EUR 6.56 billion for 2020.
[148] Source: interviews. See Annex 2 for the results of the consultations and in particular annex 14 for the detailed explanations on impacts on competitiveness.
[149] Source: interviews. See Annex 2 for the results of the consultations and in particular annex 14 for the detailed explanations on impacts on competitiveness.

industry to be compliant as chemical manufactures themselves will need to adapt their practices. Innovation could be stimulated e.g. through investment in R&D&I for alternative chemical substitutes. In order to preserve competitiveness of EU industry, measures under the second set of policy options to address the high number of non-compliant products are essential and which would harm even more compliant manufacturers which face these adaptation costs. PO1b is not expected to have net impacts on employment, as it is expected that companies will require more man hours dedicated to research of alternative chemicals and product redesign and that the toys that may no longer be made available on the market should not lead to loss of turnover for the overall sector. In terms of working conditions, it could lead to certain benefits in terms of reduced exposure to harmful substances of workers for toy manufacturers.

Social impacts - Impacts on human health

The human health impacts of an extension of the GRA and the removal of the derogation up to the concentration limits of the CLP regulation would bring high benefits for the protection of children health. The health benefits would be immediate for children, as the generic bans will apply as soon as substances are classified in one of the relevant most harmful hazard classes in the CLP Regulation. The study analysing the extension of the GRA in REACH[150] is looking into the overall damages that endocrine disruptors in particular are causing. It is not possible to establish the precise contribution of toys to exposure to such harmful substances. However, certain indicative health benefits are presented from the introduction of generic bans based on the value of the avoided health damage from exposure to harmful chemicals in toys, in particular to endocrine disrupting chemicals, taking into account currently identified health outcomes from exposure to these chemical substances. The estimate considers a number of assumptions and relies on the study analysing the extension of the GRA in REACH. As indicated, the precise chemical substances that would be covered under the generic bans in the TSD, as well as their current presence in toys are not known at this stage. Therefore, the precise exposure that children have today to these harmful chemicals in toys is not known either. Due to these uncertainties, the value of the health damage is estimated for endocrine disrupting chemicals only, as it is known that children are particularly vulnerable to the harmful effects of those. Exposure during childhood and puberty, even at low doses, has been found to lead to significant health damage that can only be observed at later stages. Even if the contribution of toys to the exposure to harmful chemicals is not known with precision, specific limit values in the current TSD are based on the fact that toys should only contribute to 10% of tolerable daily intakes of harmful chemicals, and 5% for particularly toxic metals[151]. Furthermore, the limit values are also based on the assumption that a child would ingest per day 100 mg of dry, brittle, powder-like or pliable toy material, 400 mg of liquid or sticky toy material, and 8 mg of scraped-off toy material. These assumptions are based on a number of studies on children exposure scenarios and mouthing behaviour and have been validated by the relevant scientific committee[152].

On this basis, it is considered that from 1 up to 5% of health damage can be avoided due to reduced exposure to endocrine disruptors in toys. For other classes of harmful substances, the precise contribution that toys could have to the health damages and the benefits that could be expected from the proposed policy options were considered more uncertain and could not allow for

[150] See annex 14 for detailed explanations on the health benefits. The REACH study is not yet published.

[151] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on "Assessment of the bioavailability of certain elements in toys", June 2004, Opinion on bioavailability of certain elements in toys, CSTEE plenary, written procedure (europa.eu)

[152] SCHER (Scientific Committee on Health and Environmental Risks), Final Opinion on estimates of the amount of toy materials ingested by children, 8 April 2016 Estimates of the amount of toy materials ingested by children (europa.eu)

reasonable estimates. Even **if only 1-5% of the exposure could be attributed to toys**, banning those substances from toys would have considerable **health benefits (EUR 240 million to EUR 1.2 billion per year)** [153] in terms of avoided health damage. This is compared to limited benefits under the baseline in terms of reduced exposure to specific substances in toys intended for children under 3 years or to be put in the mouth and which will only happen after a certain time after the substance has been found to pose a risk to the endocrine system and a limit value for it has been added to the Directive. It is worth noting though that comparing them with the cost estimates is very difficult as the benefits would accrue over the life time of a child exposed (or not exposed) to endocrine disruptors now which means that the time span can be over several generations far exceeding standard appraisal periods of 20-30 years, while industry will face adaptation costs after the entry into force and start of application of the TSD and thus in an earlier timeframe[154]. As derogations will be allowed only when it has been considered that the use of that chemical in toys is safe, derogations to general bans should not compromise the health benefits of this option. In addition, by removing the derogation that allows substances subject to generic bans to be present in quantities below the concentration limits for classification under the CLP Regulation, this minimum exposure will also be eliminated. Requiring regular reviews of the derogations granted, it will ensure that any new scientific knowledge that may have emerged is duly considered. In addition, as is required by the current derogation procedure, derogations granted should be reassessed every five years to ensure that their use remains safe. Product withdrawals estimated would result in corresponding reduction of exposure to the most harmful substances. This should lead to direct health benefits, in particular as these substances may cause harm at very low doses, and to a vulnerable population which is particularly sensitive to such harmful effects.

In terms of consumer welfare, this option may have certain impacts on the choice of products or increased prices, though these should be moderate, as the possibility to have derogations should limit the impacts on categories of products. Improvements in toy safety and trust could be expected, in line with the significant benefits for human health that can be expected from this option.

Impacts on the environment

PO1b would address substances that are hazardous for human health. It would introduce generic bans on substances classified as hazardous for human health under certain hazard classes in the CLP Regulation, as well as additional limit values for other substances that may pose a risk to children health. However, this option would have certain benefits for the environment too. The CLP Regulation includes different hazard classes for hazards to human health or the environment. However, harmful substances can be classified under several such hazard classes at the same time. Substances which can be harmful both for human health and for the environment, such as EDs and CMR would not be present in toys, as they would be subject to generic bans due to their hazardous classification for human health. This would lead to certain benefits for the environment. If fewer harmful chemicals are included in toys, there would be less harmful substances that would reach the waste stream or recycling. Derogations to generic bans will still be possible under this option, limiting these benefits on environmental protection.

Stakeholders' views

Over 85% (between 50 and 55 out of 61, depending on the specific harmful substance) of consumer groups and environmental associations would like to see the most harmful substances banned preventively. Also while 58% of public authorities (18 out of 31) would like to see certain of

[153] See Annex 14 for the calculations of human health benefits, based on the avoided health damage currently caused by endocrine disruptors. Source: Study for the revision of the Toy Safety Directive. Calculations in the REACH study would reflect overall health benefits from reducing exposure to endocrine disruptors in all products jointly considered.
[154] See annex 14 for the detailed estimates. Source: Study for the revision of the Toy Safety Directive.

endocrine disruptors preventively banned by the TSD, 40% (13 out of 31) considered that generic bans should also cover other harmful substances such as substances affecting the immune or neurologic systems. Only 10% (8 or 10 out of 89, depending on the substance) of industry supported this option.

6.3. Policy option 1c – Maximum protection: generic bans of the most harmful substances without derogations

Economic impacts - Impacts on economic operators

Concerning ***administrative burden***, as for PO1a and PO1b, this option would not entail direct costs because it does not affect information obligations, labelling or certification. In terms of ***adjustment costs***, the removal of all derogations under PO1c would implement further adjustment costs on industry stakeholders. In particular, this option could lead to a significant number of toys that could no longer be made available on the market. Indicative estimates of the potential adjustment costs related to PO1c could lead to a **total of 19.4-28.8% of toy models in addition to the baseline**[155] that will be impacted under PO1c, with **9.6-14.2% subject to product adaptation efforts** (including chemical substitution) **and 9.8-14.6% that could no longer be made available on the market**. Using the same data on cost estimates for product adaptation and redevelopment detailed above in the baseline (from EUR 6,700 for large firms and EUR 7.700 for SMEs per toy model to over EUR 15,000 per toy model), the estimated impact on 9.6-14.2% of all EU toy products could result in total incremental one-off adjustment costs associated with product redesign and redevelopment of **EUR 49.1 – 782.3 million compared to the baseline**[156]. As in PO1b, due to the need to carry out more complex and sensitive testing, testing costs would increase from EUR 2,200 to around EUR 3,900 per new toy model. In view of products subject to adaptation efforts will be subject to these increased testing costs, **yearly testing costs are estimated to incrementally increase compared to the baseline by around EUR 14.62-21.94 million**[157].

In terms of product withdrawals, although the ultimate impact would depend on the value of the toy models impacted, an estimate based on turnover would imply that this option **could affect EUR 642 to 957 million worth of products** (based on provisional EU industry turnover of EUR 6.56 billion for 2020). As mentioned throughout, this would not lead to a direct market contraction of that size, given 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. However, the lack of derogations will render it very difficult to find alternatives for certain categories of products. Derogations under option 1b would set out permitted uses in toys which have been considered safe for prohibited substances. As such, they would be included in the legislation itself, benefitting the whole industry and not only the applicant. Since the adoption of the Toy Safety Directive including a generic ban for CMR substances, only 3 derogations have been requested. Even if the number of derogations requested under PO1b is not expected to be high, the absence of specific derogations for certain substances may mean that an entire category of toys could no longer be available in the Union market. For example, nickel is classified as a carcinogenic substance and as such is not allowed in toys in accordance with the provisions for generic bans of CMRs of the current Toy Safety Directive. Nevertheless, it is allowed in toys and toy components made of stainless steel or in those toy components which are intended to conduct an electric current, and it actually prevents

[155] Based on the information provided by manufacturers in the interviews and SME survey.
[156] Based on applying those percentages to 78,702 new toy models and also based on the range of costs that redesign could represent.
[157] Based on the percentage of tests per year (from the total 86,024 test per year) that would be more complex (9.6-14.2%) and for which the cost will be higher.

corrosion of metals. Nickel is allowed in toys because it has been scientifically assessed in the past that nickel present in toys as set out above does not pose a risk for children[158]. According to the scientific opinion of the predecesor of SCHEER, nickel only causes tumours in the respiratory tract after inhalation exposures to nickel-containing dusts and fumes, but not after oral intake. Since inhalation of nickel from toy materials intended to transmit the electric current is extremely unlikely, SCHER concluded that a tumor risk due to nickel exposure when handling toys is not present[159]. Nickel in these uses has thus been considered to be safe and that it does not expose children to the hazardous properties of the substance. Nevertheless, without a derogation to allow for the presence of nickel in the materials described above, electric toys would not be allowed on the Union market. This is why the adjustment costs and product withdrawals in PO1c are significantly higher than in PO1b.

As in PO1a and PO1b, the number of specific substances that will be covered by the generic bans, as well as the precise number of products impacted and the availability of alternatives are not possible to quantify with precision. Thus, data on the detailed impacts on the different sizes of company is not available. However, as in PO1a and PO1b, SMEs are expected to have higher costs per new toy model than larger firms, as they face higher unit costs and, as they account for a fourth of the turnover in the EU market, they are expected to bear costs in that proportion.

Impacts on public authorities

It is likely that there would not be any additional costs for national authorities. The budget available is expected to remain the same, as well as the number of inspections. Even if the number of substances subject to limit values would increase, market surveillance authorities are expected to conduct testing only for certain types of toys inspected, as is currently the case.

Impacts on innovation, competitiveness and the internal market

This option would have a negative impact on competitiveness due to the inability of manufacturers to rely on derogations to generic bans. If there are no viable alternative substitutes, it has been estimated that a number of products could no longer be made available on the market (9.8-14.6%). This would be unlikely to be fully mitigated as consumers would not be able to purchase alternative products not containing these chemicals if they are necessary for production in the specific product concerned across the whole product category. There could therefore be loss of revenue for the overall toy sector. The removal of the derogations related to the use of nickel (which is a CMR substance) in certain forms for example would lead to a significant withdrawal of toys across different product lines, as its use is necessary in toys and toy components made of stainless steel and toy components which are intended to conduct an electric current[160]. Therefore, the non-availability of a specific derogation for this substance would have impacts on an entire category of toys.

The vast majority of SMEs responding to the public consultation disagreed with the option not to have derogations to general bans (67.4 % - 31 out of 46). SMEs view this option as having significant adverse impacts on firm and sectoral level competitiveness, as the impacts of the option on product categories will be significant and SMEs would have less resources available to invest on research and development of products which would not contain these chemicals. This option could

[158] https://health.ec.europa.eu/document/download/af3a05ea-2f9f-4939-89c6-1637796d285b_en?filename=scher_o_163.pdf

[159] Scientific Committee on Health and Environmental Risks SCHER Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys, 25 September 2012, https://health.ec.europa.eu/system/files/2016-11/scher_o_163_0.pdf

[160] See annex 14 for the detailed explanation on these concerns on competitiveness. Source: targeted survey and interviews.

have some positive impacts on innovation. As with the other options, PO1c should be accompanied by measures under PO2 to address the high number of non-compliant toys, and which would harm even more competitiveness of compliant manufacturers which face these adaptation costs.

This option could lead to certain negative impacts on employment. Even if, as in the previous PO1a and 1b, it is expected that companies will require more man hours dedicated to research of alternative chemicals and product redesign, the extent of the restrictions could lead to loss of turnover for the overall sector. In terms of working conditions, it would limit exposure of workers for toy manufacturers to harmful chemicals, and this limitation would be higher than in PO1b in view of the lack of derogations.

Social impacts - Impacts on human health

The extension of the GRA and the removal of derogations on CRM substances would have strong benefits to human health. Exposure of children to such harmful substances would be significantly reduced, similar to PO1b. The health benefits would be immediate for children, as substances would be banned from toys as soon as they are classified in one of the relevant most harmful hazard classes in the CLP Regulation. The product withdrawals estimated would be due to the presence of these harmful chemicals in such toys. Their withdrawal will result in a corresponding reduction of exposure of children to the most harmful substances (only toys containing these harmful substances will be withdrawn from the market). The measures envisaged in this option to address chemical substances will lead to direct health benefits, in particular as these are the most harmful substances that generally cause harm at very low doses, and exposure will be reduced for a vulnerable population which is particularly sensitive to such harmful effects. If the criteria for the derogations under PO1b are sound and the risks can be clearly limited with the conditions to grant such derogations, PO1c would not provide significant additional health impacts but similar **health impacts as PO1b (EUR 240 million to 1.2 billion EUR per year)[161],** based on the assumptions and estimates as explained under that policy option. Derogations should only allow uses of substances subject to generic bans for which safety can be scientifically concluded. Generic bans will cover hundreds of substances while derogations are expected to cover only a limited number of them and for limited uses. Derogations under PO1b would be of general application to allow certain uses of substances in toys, but only where this has been considered to be safe for children in terms of exposure to the substances. In addition, derogations should be reassessed every 5 years.

The estimated health benefits stem from the introduction of generic bans for the most harmful chemicals. Generic bans are proposed in both options 1b and 1c and will apply to a significant number of substances and will protect children from exposure to these harmful chemicals. Based on the explanations above, derogations should not allow for exposure to the harmful effects of these chemicals and this is why the estimates for health benefits in both option 1b and 1c should be quantitatively similar. If derogations are only granted for a use that has been evaluated as safe and there are no alternatives, it should not diminish the overall estimated health benefits achieved by reducing exposure of children to these substances. The overall health benefits in option 1c should not be significantly higher than in PO1b. However, derogations could affect entire categories of products; see the example of nickel explained above which could affect all electric toys on the Union market. This is why, while the health benefits of PO1c are expected to be substantially the same as in PO1b, the economic impacts in terms of adjustment costs in PO1c are expected to be much higher than in PO1b.

In terms of consumer welfare, this lack of possibility for derogations is expected to limit significantly the choice of products and possibly lead to higher prices. Improvements in toy safety and trust could be expected, but comparable to those under PO1b.

[161] See annex 14 for detailed calculations on health benefits. Source: Study on the revision of the Toy Safety Directive.

Impacts on the environment

Similar to PO1b, PO1c would introduce generic bans on harmful substances classified as hazardous for human health under certain hazard classes in the CLP Regulation, as well as additional limit values for other substances that may pose a risk to children health, this option would have certain benefits for the environment. The CLP Regulation includes classification of harmful substances as hazardous for human health or the environment. Chemical substances can be classified under several such hazard classes at the same time. Where substances are considered as hazardous not only for human health but also to the environment and are subject to generic bans in toys, this option will have positive impacts on the environment. This option will bring more benefits to the environment than the previous options, given that substances which can be harmful both for human health and for the environment, such as EDs and CMRs, would not be present in toys at all. If there are no derogations to the generic bans, this should mean that less harmful substances will be present in the waste stream, which would thus have a positive impact on the environment. Less harmful substances would be present in recycled materials from toys, which could then be used more safely. In addition, this option may have other indirect positive impact on the environment; by leading to higher prices of toys, there may be less consumption and waste.

Stakeholders' views

A number of respondents to the public consultation believed that there should be no derogations to the general bans: most support came from consumer and environmental groups (50% - 31 out of 61- of respondents) while only 35% (11 out of 31) of public authorities supported that there would be no derogations. 73% (66 out of 89) of industry respondents disagreed with removing derogations from general bans. Consumer and environmental groups believed that maximum protection should be offered to children, while public authorities and industry were concerned about the impacts on competitiveness and choice of toys that the lack of derogations would have.

6.4. Policy option 2a: extending third-party conformity assessment

Economic impacts: Impacts on economic operators

This option would lead to additional costs in terms of ***administrative burden*** for companies. The proportion of new toys undergoing third party conformity assessments would increase from currently 3% to about 20%[162]. The current administrative burden has been estimated at an average of EUR 4,000 per new toy model in case of self-certification and EUR 4,500 in case of third party conformity assessment. Applying this extra cost to the percentage of additional toy models which would be required to go through third party conformity assessment, it has been estimated the yearly increase of the administrative burden for the EU market would amount approximately to **EUR 7.8 million[163]**. No differences in the administrative burden were identified depending on the type of company, as these costs are associated with the amounts that Notified Bodies charge for their services. There would be no ***adjustment costs*** stemming from this option.

For notified bodies, the number of EU-type examinations would be expected to increase, leading to benefits. Notified bodies may incur costs relating to the increase in the testing capacity required to undertake these additional tests, since only around 3% of the toys in the EU market are currently subject to third-party testing.[164] These costs are not expected to be borne by notified bodies but rather to be passed on to manufacturers who will pay for the additional EU-type examinations.

[162] Estimates by businesses interviewed in the framework of the supporting study and on 78,702 new toy models per year.
[163] Based on an estimation of 78,702 new toy models placed on the market every year. See annex 14 for detailed calculations on the economic impacts.
[164] Information from the Notified Bodies-Toys group.

Impacts on public authorities

It can be estimated that this option will reduce the time necessary to collect information for market surveillance authorities, as the time needed to collect information from a notified body is significantly lower than economic operators. It can be estimated that PO2a would result in a 5% time saving for the average inspection by market surveillance authorities which would translate into a 5% increase in the number of inspections[165], as it could be assumed that the budget allocated to market surveillance activities in toys will remain the same and that the efficiency gains will be redirected to additional toy inspections. The **number of inspections** in the EU is expected to **rise to a maximum of an additional 1000 per year** (from 25,259 to 26,522) leading to a reduction of the **cost per inspection from EUR 738.52 to EUR 703.35[166]**. There would also need to be more efforts, and costs, to control conformity assessment bodies' quality by public authorities.

Impacts on innovation, competitiveness and single market

The main negative impacts on competitiveness were considered by industry to include: the higher costs of mandatory third-party conformity assessment for toys, and increased lead times to market. In particular, while the costs of lead times to market are difficult to quantify, mandatory third-party conformity assessment could add an additional 4-6 months to the process of placing a product on the European market, with an adverse impact on competitiveness. The reduction of non-compliant toys on the single market would lead to positive effects on competitiveness for EU and other compliant industry, as they will face less competition from rogue traders selling non-compliant products, often at cheaper prices. However these positive effects on competitiveness will not be very significant, as the improvements on the number of non-compliant toys are expected to be limited. This is because this option will facilitate enforcement by market surveillance authorities to a limited extent, and therefore it will not significantly increase the incentives to comply for rogue traders. It may be expected that those manufacturers that already comply with the requirements of the TSD will also comply with the obligation to perform third party examination, but those rogue traders which already ignore the rules will continue to do so. Nonetheless, these limited positive effects will likely not offset the costs for EU industry (in particular SMEs) who will continue to face unfair competition from rogue traders to a significant extent. SMEs were particularly concerned by this option, as they were of the opinion that this would adversely affect their competitiveness.

This option is not expected to have impacts on employment by toy manufacturers, but a slight increase in employment by Notified Bodies would be likely, as they would need to ensure additional capacity to provide conformity assessment services.

Social impacts - Impacts on human health

The available evidence suggests that only a limited improvement in the number of illicit toys is to be expected from this option, as explained in the previous sections on impacts on public authorities and on competitiveness, innovation and the single market. Accordingly, the risks of illicit toys would only decrease slightly and this option would only have limited benefits on children's health. Similarly, as the reduction of non-compliant toys is expected to be limited, this option is not expected to have significant impacts on consumer welfare and trust.

Impacts on the environment

[165] Based on assumptions of experts consulted in the framework of the supporting study.

[166] The extent to which the efficiency gains will translate into a precise increase in the number of inspections may vary in practice depending on the specific time and resources saved as well as the precise toys subject to inspection. As such, this analysis presents certain estimates to illustrate the impact of the policy options in the increase of number of inspections, but the precise increase in practice would probably be lower.

This option is not expected to have positive impacts on the environment. Illicit toys could be more harmful to the environment as they could contain more dangerous substances, therefore, a reduction of the number of such toys would mean less pollution. Less harmful substances would be present in recycled materials from toys, which could then be used more safely. However, it is expected that this option will only lead to minor reductions on the number of non-compliant toys, thereby yielding limited benefits to the environment.

Stakeholders' views

In the public consultation, 83% (51 out of 61) of consumer/environment groups and 75% (23 out of 31) of authorities supported the extension of third-party conformity assessment while 75% of industry was against it (67 out of 89). Industry believes that it will impose additional costs without bringing a significant improvement to the problem of a high number of non-compliant toys.

6.5. Policy option 2b: facilitation of market surveillance through digitalisation

Economic impacts - Impacts on economic operators

This option requires the introduction of a digital passport that would include the EU declaration of conformity so that it is digitally accessible (via a machine-readable code) and the registration of the reference in a central registry. This will be based on the Digital Product Passport proposed under the ESPR. Toys may be covered in the longer term by one of the delegated acts setting sustainability requirements, however they are currently not included in the list of high priority sectors identified in the Circular Economy Action Plan (CEAP) adopted by the Commission in March 2020. This is why the impacts for economic operators are considered under PO2b and not part of the baseline. In terms of administrative burden, this option can lead to one-off costs (such as development of required IT tools, new procedures for the preparation of the product documentation, and potentially additional IT services) and recurrent costs (e.g. the FTE required to collect and provide electronically the required documentation). For the calculation of the overall market costs, **SMEs have been assumed to incur in yearly costs of EUR 3,000 per company, while for larger companies, up to EUR 140,000**[167], but the specific breakdown of these costs into one-off and recurring costs for the toy sector was not available. Previous research in other markets has found a split of 80% one-off vs 20% annual costs for large firms, and 62% one-off vs 38% annual costs for SMEs[168]. Applying this breakdown to the estimates for toys[169] would suggest **a total one off cost of EUR 18 million in addition to an annual recurring cost of EUR 10.5 million**. It is therefore expected that companies will incur in significant initial costs, but that these would be lower in subsequent years thanks to economies of scale and the fact that after the systems are set up and most initial data entered, there are only expected to be additional costs related to updating and maintenance costs.

The Digital Product Passport will contain the compliance documentation that economic operators must possess and be able to present upon request in any case. This option is also expected to lead to savings as compliance information that economic operators currently need to create will only be provided digitally. The digital passport under option 2b will replace the EU declaration of conformity that manufacturers have to produce currently for every toy. Previous studies have suggested a benchmark of about 10-15% savings in administrative costs from the full digitalisation

[167] Estimations of respondents from different SME sizes participating in the SME survey.

[168] Study to support the Impact Assessment on the use of digital labelling for EU fertilising products, European Commission's DG GROW, 2022

[169] The range 3000 – 140,000 per company reflects the range of prices per administrative action of producing non-labelling information between EUR 300 and 1100 per toy model. Further calculations are based on a cautious estimation of EUR 325 per action per toy.

of product information (not only compliance but also user-related information)[170]. These studies also estimate the cost of the provision of compliance information at 0.4% of turnover of the sector.[171] Accordingly, savings could be estimated at around **EUR 2.62 to EUR 3.93 (EUR 3.275 on average) million per year** only from moving to the digital provision of compliance information.

In addition, there would be savings from the immediate availability of information when dealing with market surveillance authorities for specific inspections. These are independent from the savings on the digitalisation of compliance information that are detailed above; these savings will happen when toys are subject to inspections. The Evaluation provides an indication of the average cost – per new toy for an average importer or distributor – to *"ensure that the toy is accompanied by the required documents"*.[172] The average cost of such activities per new toy model are estimated to be between EUR 548 and EUR 651. This can serve as a basis to estimate the amount of time and relative cost a company would incur in retrieving all the necessary information for a toy model and supplying it to market surveillance authorities when inspections are conducted[173]. With the implementation of the DPP, this cost would likely disappear for companies, since relevant documentation would be available online for market surveillance authorities, as well as the supply chain information. Since the annual number of inspections in Europe is calculated to be around 25,000 (and may rise to 30,000 in case of implementation of the DPP), and each inspection would concern a specified toy model, it can be estimated that the average **annual saving for EU companies could be between EUR 13 million and EUR 16 million in case inspections remain at the same levels or increase slightly, or even up to EUR 20 million in case of increased number of inspections**.

It is reasonable to assume that in the long term the internal costs for companies to implement the DPP will diminish, and the benefit of less burdensome inspections for compliant companies will lead to a visible economic benefit in terms of reduction of administrative burden. Efficiencies are expected from having all the information about a given toy available via a single QR code or a similar machine readable item, which is how the DPP will be implemented in practice.

Impacts on public authorities

While it is difficult to assess the exact scale of the reduction by this option in the time needed to undertake inspections, it is estimated that it could range between 10% to 20%, which could translate into an equivalent percentage increase in the number of inspections which could be undertaken with the resources available[174]. The **number of inspections** in the EU is expected to **rise to a maximum of an additional 2500 to 5000 per year** (from 25,259 to between 27,785 and 30,311) assuming that the overall budget for market surveillance authorities for toys will remain the same and that efficiency gains will be reinvested in additional toy inspections, thus lowering the

[170] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Supporting study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2873/625443

[171] 0.4% of turnover of EU toy industry in 2020 was EUR 26.2 million. The share of 0.4% is the result of a multiplication of the total cost of compliance (2% of annual turnover, based on previous literature) by the share of the total cost compliance related only to the cost of indicating compliance with EU harmonisation legislation (20%, based on stakeholder consultation in the study supporting the Evaluation of the New Legislative Framework).

[172] Evaluation of Toys safety Directive, p. 64

[173] The Evaluation also estimated costs for "getting supply chain information" of EUR 700 per toy model.

[174] Based on assumptions of experts consulted in the framework of the supporting study. See annex 14 for the detailed explanations on these estimates.

cost per inspection from EUR 738.52 to between EUR 671.37 and EUR 615.42[175]. There would be one-off costs relating to market surveillance authorities adapting their information systems and procedures to the digitalised information but this would already be covered by the ESPR[176]; additional costs are not expected to be attributed to the revision of the TSD. The ESPR also foresees that the reference to the DPP will be included in a central registry, managed by the Commission, as well as the interconnection with the underlying IT infrastructure for customs purposes, in order to allow for the automatic verification of the existence of a DPP at the time of import. In terms of customs controls, this option would entail the submission of the required documentation by the importer at a stage before the actual shipping of the toy, which will apply to any toy entering the EU. This would lead to potential savings for customs with less shipments on hold at the border[177]. Customs authorities would check through automated systems the provision with the imported shipment of the DPP, thereby ensuring a minimum automatic check of the existence of the DPP on any toy entering the EU, either in small consignments or in higher volumes. The actual content of the DPP and the toy itself could still be subject to checks by the relevant national market surveillance authorities. Carrying out automatic controls would allow customs to reduce their costs and likely allow more effective and targeted controls.

Impacts on innovation, competitiveness and single market

This option is expected to lead to significant benefits for the competitiveness of companies. Firstly, the digitalisation of product information (including regulatory compliance aspects) could lead to greater efficiencies and cost savings. Once toys are subject to the ESPR, relying on the DPP already for compliance under the toy safety rules will lead to important savings for the toy industry. In addition, the information that could be mandatorily required under the ESPR in the DPP could bring synergies if it helps contribute both towards meeting toy safety compliance requirements, for example, and information on specific chemicals. Furthermore, this option is expected to lead to important reductions in the number of non-compliant toys in the EU. This is because, first of all, it will allow market surveillance authorities to be more efficient in their inspections and target products without the DPP which may be more likely non-compliant. In addition, currently toys entering the Union market from third countries are subject to controls at the border on a risk- based approach. Under PO2b the presence of the DPP in toys will be automatically verified at customs when toys are presented for release for free circulation. These will apply to any toy entering the Union market, either bought online or through other distribution channels. Toys without the DPP will be prevented from being released for free circulation in the Union market. These automatic controls at customs are expected to have significant impacts in reducing the number of non-compliant toys entering the Union market. This will prevent that toys not intended for the Union market reach EU customers. It will only be possible to create the DPP if a valid EU declaration of conformity exists for the toy. All toys imported into the Union market will have the EU declaration of conformity, and this will be easier to verify when market surveillance authorities inspect them.

The overall reduction of the number of non-compliant toys will have a positive impact on the competitiveness of compliant manufacturers by improving the level playing field and curtailing illicit competition. A shift in demand to compliant products in the EU can also occur. SMEs were concerned about the impacts of this option on their competitiveness as they are less able to invest in

[175] The extent to which the efficiency gains will translate into a precise increase in the number of inspections may vary in practice depending on the specific time and resources saved as well as the precise toys subject to inspection. As such, this analysis presents certain estimates to illustrate the impact of the policy options in the increase of number of inspections, but the precise increase in practice would probably be lower.
[176] Commission staff document SWD(2022) 82 final, p.61.
[177] See annex 14 for the detailed explanations on the impacts for authorities. Source: study for the revision of the Toy Safety Directive.

digitalisation compared with large firms. Despite this, this option was still seen very positively by industry, both by large firms and SMEs[178]. Digitalisation of product information was therefore welcomed by industry as a means of modernising the provision of regulatory compliance and supply chain information, despite certain concerns on costs by SMEs. This in turn could improve the functioning of the single market as digitalisation of certain information is being actively considered and is close to being introduced in other EU legislation (e.g. fertilisers, chemicals and detergents) and other global jurisdictions that have also embraced digital labelling.

This option could have certain positive impacts on employment, as toy manufacturers will need to dedicate resources to ensure the digitalisation of information. There might be a shift in demand towards IT skills and qualifications.

Social impacts - Impacts on human health

The introduction of a DPP could have significant impacts on the number of illicit toys and in protection from the health risks of those. Controls at customs of the presence of the DPP would be rendered automatic in the first place, facilitating that a significant percentage of non-compliant toys are prevented from being released for free circulation in the Union market. In terms of consumer welfare, it will lead to positive impacts on product safety and consumer trust, and should not affect the choice or price of toys.

Impacts on the environment

As explained in PO2a, non-compliant and dangerous toys are more harmful to the environment, therefore, a reduction of the number of such toys would mean less pollution. As this option is likely to significantly reduce the number of non-compliant toys, the benefits on the environment may also be relevant. Less harmful substances would be present in recycled materials from toys, which could then be used more safely. Additionally, the digital passport for toys could help reduce the number of papers used by economic operators and national authorities; however this impact could not be quantified.

Stakeholders' views

59% of consumer/environmental groups (36 out of 61), 96% of public authorities (30 out of 31) and 52 % of industry (47 out of 89) supported that toys should have a DPP with compliance information to improve enforcement.

6.6. Policy option 2c: Extending third party conformity assessment and facilitation of market surveillance through digitalisation

Economic impacts - Impacts on economic operators

The costs and savings of this PO2c will be the sum of costs and savings estimated for PO2a and PO2c. No additional adjustment costs are expected.

Impacts on public authorities

While it is difficult to assess the exact scale of the reduction in the times needed to undertake inspections under PO 2c, the effects of option 2a and 2b are expected to be aggregated. As such, the

[178] Source: targeted survey and interviews, see annex 2 on the consultation activities and annex 14 on detailed impacts on competitiveness.

time savings for inspections would be in the range of 15% 25%[179]. The average **number of inspections** in the EU is expected to rise to a maximum by an **additional 3500 to 6000 per year** (from 25,259 to between 29,048 and 31,573) assuming the budget allocated for market surveillance in toys will remain the same and that the efficiency gains will be reinvested in additional toy inspections **thus lowering the cost per inspection from EUR 738.52 to between EUR 642.18 and EUR 590.83[180].** Other impacts for market surveillance and customs were already highlighted in the analysis of PO2b.

Impacts on innovation, competitiveness and single market

The impacts on innovation, competitiveness, the single market and employment were already highlighted in the analysis of PO2a and PO2b. However this option will lead to a stronger reduction of the number of non-compliant toys thereby strengthening the competitive position of compliant manufacturers.

Social impacts: Impacts on human health

This option will have strong impacts on improving human health, as it will lead to significant reductions of the number of non-compliant toys. The two PO2a and 2b combined in PO 2c will reinforce each other. A real improvement in market surveillance could be achieved with more certainty on the assessments coming from third party conformity assessments and the information more easily available with the DPP. The impacts on consumer welfare in terms of increased product safety and trust will also be high.

Impacts on the environment

Both measures combined would lead to less non-compliant toys in the EU market, and thus more benefits for the environment. Less harmful substances would be present in recycled materials from toys, which could then be used more safely. Digitalisation should lead to less paper consumption.

7. HOW DO THE OPTIONS COMPARE?

7.1. Effectiveness of the proposed policy options

The following table presents the effectiveness of the proposed options against the relevant specific objectives.

	SO1: Higher protection of children from harmful chemicals	SO2: Flexibility to adapt to new scientific knowledge	SO3: Reduce the number of non-compliant and unsafe products	SO4: facilitate enforcement
Option 1a	++	++	+-	+-
Option 1b	+++	+++	+-	+-
Option 1c	+++	++	+-	+-

[179] See annex 14 for detailed explanations on these estimates. These calculations are based on interviews with market surveillance authorities and the efficiency in conducting inspections they have declared if the DPP would be available.
[180] The extent to which the efficiency gains will translate into a precise increase in the number of inspections may vary in practice depending on the specific time and resources saved, the reallocation of those resources to toy inspections, as well as the precise toys subject to inspection. As such, this analysis presents certain estimates to illustrate the impact of the policy options in the increase of number of inspections, but the precise increase in practice would probably be lower.

Option 2a	+	+-	+	++
Option 2b	++	+-	+++	++
Option 2c	++	+-	+++	+++

Legend: +- no relevance; + limited effectiveness; ++ effective; +++ very effective

Introducing generic bans for chemicals classified under the most harmful hazard classes[181] as proposed in options 1b and 1c **is the most preventive approach for regulating chemical substances**. This is because substances are preventively banned in toys as soon as they are classified without having to assess whether their use in toys poses a risk to children (as required in option 1a). These specific risk assessments in toys have proven to be laborious and time consuming in the past, although ensuring tailor-made protection. The time between the identification of a hazard for children or from the classification of a chemical as hazardous under the CLP Regulation until it is banned in toys is likely to be too long (around 2 years in past instances), leaving children unprotected for a certain period of time and requiring prioritisation of substances to be tackled in toys. This is why PO1a is not considered as effective in ensuring protection of children from harmful chemicals.

PO1a will ensure that the TSD can adapt to emerging scientific knowledge though in a less streamlined manner than PO1b and PO1c. This is because under PO1b and PO1c, as soon as substances are classified in one of the most harmful hazard classes under the CLP Regulation, they will be banned in toys. PO1a will require the identification of specific substances that are found to pose a specific risk in toys, substance per substance, and carry out a detailed risk assessment of their use in toys, before they are actually regulated.

PO 1b and PO1c will be similarly effective in ensuring SO1 and the protection of children from the most harmful chemicals, as substances will be preventively banned in toys as soon as they are classified under the most harmful hazard classes in the CLP Regulation, and derogations will only be possible in PO1b if substances are safe for use in toys. **The possibility for derogations proposed under option 1b would constitute the main possibility for costs mitigation**. If there would be an absolute ban of the most harmful substances without the possibility to have any derogation, the consequences for the toys industry and for entire categories of toys would be extremely severe, without corresponding benefits in the protection of children. For example, as explained above, nickel is classified as a carcinogenic substance. Nevertheless, it is allowed in toy and toy components made of stainless steel or in those toy components which are intended to conduct an electric current, and it actually prevents corrosion of metals. It has been scientifically assessed in the past that nickel present in toys as set out above does not pose a risk for children[182]. Without a derogation to allow for the presence of nickel, electric toys would not be allowed on the Union market.

As regards the objectives to reduce the number of unsafe toys and facilitate compliance and enforcement, PO2a will be less effective in reaching the objectives than PO2b, as PO2a is expected to allow a moderate increase in the number of inspections, while option PO2b is expected to lead to more significant efficiency gains and be more effective in increasing inspections. All commercial goods imported into the EU require a customs declaration for release for free circulation. The main benefit of the DPP as proposed in option 2b will be that a reference to it should be included in the customs declaration for every toy, and this includes online purchases by individual EU customers

[181] The so-called generic risk approach for chemicals (GRA).

[182] https://health.ec.europa.eu/document/download/af3a05ea-2f9f-4939-89c6-1637796d285b_en?filename=scher_o_163.pdf

from third countries. The reference of the DPP, which for toys would include the product compliance information, will also have to be included in a central registry managed by the Commission, which will be interconnected with the IT customs environment to allow for its automatic verification. This will allow that **any toy which does not indicate a valid DPP reference in the customs declaration is automatically stopped at EU customs and is not released for free circulation.** Customs authorities will be able to carry out this automated control on all toys entering the Union market, rather than controls on a risk-based manner on a limited amount of toys as is the case today. Automated controls should have a significant impact on the number of non-compliant toys reaching the Union market. It will prevent that toys not intended for the Union market reach EU customers. All toys imported into the Union market will have the compliance information, and this will be easier to verify when market surveillance authorities inspect them.

Furthermore, PO2a will not be as effective in addressing rogue traders who deliberately ignore the rules to gain a competitive advantage, as it will not increase the probability of getting caught and these traders will probably not carry out the third-party conformity assessment. PO2c is however the most effective as it will cumulate the impacts of PO2a and PO2b in achieving the objectives. Nonetheless, most of the effectiveness in PO2c is attributable to PO2b.

7.2. Impacts of policy options

The following table summarises the costs and benefits, for each policy option, quantified and presented in section 6.

Costs & Benefits summary table[183]

	Incremental benefits compared to baseline		**Incremental costs compared to baseline**							
			Incremental adjustment costs – one-off		**Incremental product withdrawals one-off**		**Incremental testing costs (recurrent)**		**Incremental administrative burden**	
	Low end	High end	Low end	High end	Low end	High end	Low end	High end	One-off	Recurrent
PO1a	N/A	N/A	€8.18m	€176.3 m	€52.47 m	€104.9 m	€1.89m per year	€3.79m per year	N/A	N/A
PO1b	€240m per year	€ 1.2b per year	€23.5m	€396.66 m	€249.21 m	€367.25 m	€7.31m per year	€11.7m per year		€ 100.000 to €300.000 per year
PO1c	€ 240m per year	€1.2b per year	€49.11 m	€782.3 m	€642.69 m	€957.47 m	€14.62m per year	€21.94m per year	N/A	N/A
PO2a	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	€7.8m per year
PO2b	€ 15.62 m per year	€ 23.93 m per year	N/A	N/A	N/A	N/A	N/A	N/A	€18m	€10.5m per year
PO2c	€ 15.62 m per year	€ 23.93 m per year	N/A	N/A	N/A	N/A	N/A	N/A	€18m	€18.3m per year

Summary of incremental costs per policy options. See annex 14 for details.

[183] While the benefits of policy options 1a, 1b and 1c refer to benefits for human health, the benefits of policy options 2a, 2b and 2c refer to savings in administrative burden. Similarly, the costs in policy options 1a, 1b and 1c refer to adjustment costs while the costs of options 2a, 2b and 2c refer to increase of administrative burden.

The aim of the assessment is to provide ranges of the magnitude of potential impacts generated by each policy option. While costs are borne by industry and the benefits of PO2b and 2c are also savings for industry, PO1b and 1c present overall health benefits for citizens and society. The following table summarises the quantitative and qualitative assessments, presented in section 6, on the potential effects of policy options to industry, consumers, internal market, and competitiveness as well as on the environment.

Summary of Economic, social and environmental impacts

Policy option	Economic impact[184]	Social impact	Environmental impact
Option 1a	-	+	+
Option 1b	--	+++	+
Option 1c	---	+++	+++
Option 2a	-	+	+
Option 2b	+++	+++	++
Option 2c	++	+++	++

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ significant positive impact; - minor negative impact; -- negative impact; --- significant negative impact

The scale of the negative economic impacts will increase with the level of intervention. In contrast, however, the policy options with high levels of intervention are anticipated to have potentially significant positive social impacts on the protection of health of children.

PO1a would have certain negative impacts for industry and competitiveness but slight positive impacts on innovation the functioning of the internal market and the environment. It would also have limited impacts on the protection of children. PO1b and 1c would have strong positive impacts on the protection of children due to the more preventive approach towards the most harmful substances in toys. These options would entail important costs for industry, higher in PO1c than in PO1b. While PO1b would mitigate to a certain extent the negative consequences in costs and competitiveness for companies by allowing derogations to the generic bans, PO1c would lead to very important number of product withdrawals which will lead to high costs for industry and hinder innovation. If derogations are granted only where safety and protection of children is not compromised, there will not be substantial differences in terms of benefits for human health between PO1b and PO1c.

PO 2a would have some benefits for the internal market and minor impacts on competitiveness and innovation. However, it would have important costs for the industry while not clearly yielding very high impacts on reducing the number of non-compliant products in the EU. Under policy option 2b, a certain economic impact is to be expected to adjust to digitalisation, with a potential for savings over the longer run in producing compliance information as well as in simplifications of contacts with the market surveillance authorities. The incremental benefits of option 2c in comparison with 2b alone are not evident, while this option represents higher costs for the reputable manufacturers who are complying with the TSD. PO2a and 2c would be particularly burdensome for SMEs.

Policy options face greater opposition from the industry as the level of intervention increases, while receiving greater support from consumers.

Stakeholder support

[184] The scoring of the economic impacts takes account not only of the costs and savings of the different policy options but also the impacts in terms of competitiveness of companies and the single market.

	Stakeholder support		
	MS	Industry	Consumers
Option 1a	+++	++	+
Option 1b	+++	+	++
Option 1c	+-	+-	+++
Option 2a	+	+-	++
Option 2b	++	++	++
Option 2c	++	+-	+++

Legend: +- no support; + limited support; ++ support; +++ strong support

In particular, industry stakeholders supported that new limit values could be added in the TSD for all toys, but voiced strong opposition in particular to removing derogations to generic bans. The main concern was that removing derogations completely would have strong consequences by requiring the removal from the market of a significant number of toys (for example electric toys). Industry was also opposed to extending third party conformity assessment in PO2a, but supported the digitalisation of compliance information. Member States expressed clear support for revising the TSD and strengthening the chemical requirements, both with specific limit values and with additional generic prohibitions for certain substances. There was also support to digitalising product information as well as for extending third party conformity assessment but to a lesser extent. Consumers favoured the options with stricter chemical requirements for products for children and the more limited derogations.

7.3. Summary of policy options assessment

The table below summarises the assessment presented so far, providing an overview of the effectiveness, efficiency and coherence with the EU law for each of the policy option analysed.

Summary table

	Effectiveness	Efficiency	Coherence with EU law
Option 1a	+	+	+++
Option 1b	+++	+++	+++
Option 1c	+++	++	++
Option 2a	++	+	++
Option 2b	+++	+++	+++
Option 2c	+++	++	+++

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ significant positive impact;

For the first set of policy options, PO1b and PO1c will more effective in strengthening the protection of children (SO1), as they will introduce generic bans to the most harmful chemicals. While all three PO1 will allow for adaptations to new scientific knowledge (SO2), PO1b and PO1c will be more effective as substances will be banned in toys immediately after they are classified under the most harmful hazard classes in the CLP Regulation, while in PO1a a specific assessment for each substance will be required. In achieving both objectives, PO1b will be the most efficient. PO1a will require resources to analyse each substance that may pose a risk in toys, and this has proven in the past to be a laborious process. By not allowing for derogations, PO1c will be less efficient as it will achieve the same results as PO1b with higher costs for industry.

For the second set of policy options, PO 2a will be the least effective and efficient in achieving the related SO: it will lead to limited improvements in the number of non-compliant toys (SO3) and

limited facilitation of enforcement (SO4), but with significant costs for compliant industry. PO2b and 2c will be more effective in achieving the reduction of non-compliant toys in the Union market, including for online sales, as they will prevent that any toy which is presented at customs and does not have a DPP is placed on the Union market and lead to significant efficiency gains for market surveillance authorities. PO2c will be more effective in facilitating enforcement and lead to higher efficiency gains for market surveillance authorities, as it will cumulate the benefits of PO2a and PO2b. However, it is not clear that PO2c would lead to significantly lower levels of non-compliance than option 2b, while having higher costs for industry. PO2b is considered to be the most efficient, as it will achieve the objectives in an effective manner without disproportionate costs on industry.

PO1a and 1b are considered to generally be coherent with wider EU policy and regulatory developments, in terms of future and ongoing regulatory actions following the Chemicals Strategy for Sustainability. PO1b will introduce generic bans for the most harmful hazard classes, coherent with other measures EU chemicals legislation and in particular those considered under the REACH Revision. Option 1c would be the least coherent, though, as it would not allow for derogations to generic bans which are currently possible in all chemicals legislation where generic bans are present. Derogations to generic bans are expected to continue to be possible under EU chemicals legislation in the future.

PO2a is coherent with the New Legislative Framework and other EU product legislation which requires the intervention of a notified body for assessing the compliance of certain products. PO2b is also be coherent with priorities and current trends towards digitalisation by default, the conclusions regarding digitalisation of product information in the Evaluation of the New Legislative Framework, which also covers the TSD as well as the recent proposed ESPR. Considering that the digital passport will contain the documentation that economic operators must possess and be able to present upon request in any case, it will be coherent with the existing relevant obligations under EU product and market surveillance legislation. As PO2b follows the current and future trends towards digitalization, it is scored as more coherent than PO2a. For the same reasons, the coherence of PO2c is considered to be high as it contains the measures included in both PO2a and PO2b.

8. PREFERRED OPTION

Based on the comparative assessment of policy options above, the preferred combination of policy options consists of PO1b and PO2b. They scored well across a range of criteria (positive social and environmental impacts, with less important economic costs, effective, efficient and coherent). PO2b also responds to the **"digital-by-default"** principle, by providing for a move towards the digital provision of compliance information.

Impacts of the combination of PO1b and PO2b

Economic impacts – Impacts on economic operators: The economic impacts will correspond to the sum of PO1b in terms of product adaptations and withdrawals and relevant administrative costs (in respect of applications for derogations), as described above, and PO2b in terms of administrative burden and savings for the implementation of the DPP.

The number of substances covered by generic bans under PO1b might increase by about 10-30%. A total of 8.4-12.8% of products additional to the baseline may be impacted under PO1b and for which a derogation may not be possible, with 4.6-7.2% subject to product adaptation efforts and 3.8-5.6% could no longer be made available on the market if no alternatives to the restricted chemicals are available. The estimated impact on 4.6-7.2% of all EU toy products could result in total **incremental one-off adjustment costs** associated with product redesign and redevelopment

of additional **EUR 23.5 to 396.66 million**. **Yearly testing costs** are estimated to incrementally increase compared to the baseline by around **EUR 7.31-11.70 million**. In terms of **product withdrawals,** this option **could affect EUR 249 to 367 million worth of products**[185], which should be mitigated by an appropriate transition period in which manufacturers 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. Administrative burden incurred if derogations are requested could amount to EUR 100.000 to EUR 300.000 per year. Derogations would be requested as a means to limit the adjustment costs that the restrictions on chemical substances could lead to.

For the introduction of the DPP under PO2b it is estimated that the cost for the EU manufacturers could be around **EUR 18 million of one –off costs and EUR 10.5 million per year** due to the incidence of initial costs, and decrease after the systems are set up and most initial data entered, there are only expected to be additional costs related to updating and maintenance costs. PO2b could lead to **savings of around EUR 2.62 to EUR 3.93 million per year** only from moving to the digital provision of compliance information. In addition, savings from no need to prepare for dealing with inspections by market surveillance authorities could range **from EUR 13 million up to EUR 20 million per year**.

Impacts on public authorities: PO2b will lead to significant efficiency gains for market surveillance authorities (if reinvested in toy inspections, the number of inspections is expected to increase by a maximum of 2,500 to 5,000), that are not expected to be lowered by the increased number of chemical substances banned in toys under PO1b. This is because market surveillance authorities do not necessarily test all toys inspected, nor for all substances concerned. In many cases they conduct documentary checks only, in other cases they identify the toys that would need to be subject to testing, as well as the chemical substances are most relevant for the specific toy at stake.

Impacts on innovation, competitiveness and single market: The impacts on innovation and the single market for both 1b and 2b will cumulate. However, PO1b and 2b will have synergistic impacts in improving competitiveness. While PO1b will impose costs on industry for the compliance with new requirements on chemical substances, it will be accompanied by effective measures under 2b to significantly reduce unfair competition from non-compliant toys. This will help preserving the competitiveness of compliant industry. Without PO2b, PO1b may lead to more rogue traders benefitting from selling non-compliant (and often cheaper) toys.

Social impacts – impacts on human health: Although PO1b and PO2b each address a distinct problem, they will complement each other in terms of protection of human health. The human health benefits estimated in PO1b (**EUR 240 million to EUR 1.2 billion per year**) will be reinforced by ensuring under PO2b that non-compliance will be significantly reduced.

Environmental impacts : While the protection of the environment is not part of the SO pursued, the preferred combination of options will lead to certain benefits for the environment, due to the reduction of harmful substances in toys as well as the significant reduction of non-compliant toys. It is also consistent with the objectives of the Climate Law[186]. This is detailed in the analysis of each of these options.

[185] Based on provisional EU industry turnover of EUR 6.56 billion for 2020.

[186] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law')

Stakeholders' views: Industry stakeholders supported that new limit values could be added in the TSD for all toys in all policy options, but did not support the extension of generic bans to other harmful substances (PO1b). Industry supported the digitalisation of compliance information in PO2b. Member States expressed clear support for revising the TSD and strengthening the chemical requirements, both with specific limit values and with additional generic prohibitions for certain substances (PO1a and PO1b). There was also support to digitalising product information (PO2b) as well as for extending third party conformity assessment (PO2a) but to a lesser extent. Consumers favoured the options with stricter chemical requirements for products for children (PO1b) and the more limited derogations (PO1c). Consumers also favoured the introduction of the DPP (PO2b) as well as the extension of third party conformity assessment (PO2a and PO2c).

Conclusion on the preferred option: In terms of protection of children from harmful substances, PO1b strikes a more appropriate balance between the negative impacts for industry which should be limited by providing for appropriate derogations to generic bans, and significant reduction on children exposure to these harmful substances. It will also ensure that the toy safety rules can continue to adapt to new scientific knowledge. PO 2b will ensure that toys presented at customs without the declaration of conformity included in the DPP would be automatically prevented from being released for free circulation in the Union market. This, together with the efficiency gains for market surveillance authorities will have a potential to reduce the number of non-compliant toys. In this manner, PO2b better addresses the drivers of the problem.

The preferred option will contribute achieving Sustainable Development Goals: to SDG 3 due to its positive impacts on children health and well-being, to SDG 6 by reducing harmful substances in toys that may become waste, to SDG 9 by providing incentives for businesses to innovate in substitution of harmful chemicals and digitalisation and to SDG 12 by enhancing that toys and children health are protected in a more sustainable manner.

8.1. Legal instrument: converting the Directive into a Regulation

A directive leaves Member States to choose which means they will use to comply with the legislative objectives. As the TSD is a 'total harmonisation' directive it does not allow the Member States to impose more restrictive obligations. The existing legal instrument being a Directive means that every amendment to the text (of which there has been 17 to date) must be transposed by all Member States. Therefore, to increase efficiency, the legal text would fit better with a regulation approach rather than with a directive approach[187]. There was a broad consensus across all stakeholder groups on the benefits of this conversion. A large majority of public-consultation respondents (85% of all respondents including 80 % of public authorities, 82% of businesses and business associations and 88% of consumers, consumer organisations and NGOs) expressed support for this change. Finally, PO2b requires that the underlying legal instrument be a Regulation to ensure a harmonised enforcement of the Regulation in the Union and, in particular, at the EU external borders.

With a Regulation the costs of transposing any amendment to the Directive would disappear. The transposition of each amendment to the Directive is estimated to be in the range of EUR 6,174 to EUR 18,522 per Member State. The **annual savings** of the policy measure for public authorities in the EU would therefore be **EUR 435,979**[188]. A Regulation will also lead to savings for the industry

[187] See also section 5.1.4 of the Evaluation

[188] See annex 14 for the detailed calculations of these estimates, based on an estimate of the amount of person days needed for transposition to be between 20 and 60. Using the Member State daily labour cost (i.e. EUR 309 - Data about labour costs comes from Eurostat's Labour Cost Survey, (2016), category 'public administration and defence, compulsory social security' per employee FTE and adjusted for inflation.), the overall cost of transposition is estimated to be in the range of EUR 6,174 to EUR 18,522 per Member State.

and benefit the single market, as it will enter into force simultaneously across the EU, as well as any subsequent amendment to it.

8.2. REFIT (simplification and improved efficiency)

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

The option to move to digital in the compliance information will lead to simplification and improved efficiency in the contacts between economic operators and market surveillance authorities. This is supported by outcomes from the public consultation for the Evaluation of the New Legislative Framework, 79.2% of the respondents (54.2% to a great extent and 25% to some extent) 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 for simplification of 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 TSD 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 will also lead to savings to the industry when producing the labels but these cannot be quantified with precision.

8.3. Application of the 'one in, one out' approach

As indicated in the previous sections, the first set of policy options is only expected to lead to an increase in the administrative burden as compared with the business as usual costs of the baseline 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 to a maximum of EUR 150.000 per derogation request, and that there would be a maximum of two derogation requests per year, which would lead to a recurrent cost of EUR 100.000 to a maximum of EUR 300.000 per year (with an average of EUR 200.000 per year). Option 2b would entail administrative costs for businesses and benefits. Based on current market structure and expected average production per enterprise, the overall **additional administrative burden** has been estimated at approximately **EUR 18 million one-off and EUR 10.5 million recurrent, per year**.

In terms of benefits, option 2b is likely to bring some reduction of the administrative burden on companies and authorities: the introduction of the DPP, while it would lead to initial costs for companies, it has the potential to reduce the administrative burden on public authorities, in particular customs, when importing toys from third countries since the DPP would allow for more automatic documentation checks and prevent the import of non-conform toys that would be held on border premises and subject to physical controls. PO2b could lead to **savings for companies from moving to digitalised information of around EUR 2.62 to EUR 3.93 (EUR 3.275 on average) million per year**. In addition, **a cost reduction** would also incur for manufacturers **during inspections** by market surveillance authorities but these are not savings that are accounted for offseetting under the 'one in, one out' apporach.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The Commission will monitor the application of the future Toy Safety Regulation and its implementation in the Member States, possibly 5 years after the start of application. It will monitor that when new substances are classified under the most harmful hazard classes under the CLP and covered by generic bans, all the relevant stakeholders are sufficiently informed and testing methods are available in advance. The Commission will also monitor the requests for derogations to these generic bans and their regular evaluation, and any derogation granted should be reassessed every 5 years, as is the case in the current TSD.

The Commission will continue to follow with experts emerging scientific knowledge in the field of chemical substances to determine whether additional or stricter limit values should be introduced in the future Toy Safety Regulation. The Commission will continue to produce guidance documents in cooperation with Experts in the Expert Group on Toy Safety, to ensure that stakeholders have the best possible understanding of the obligations under the Toy Safety Regulation so that compliance is facilitated.

The coordination of notified bodies in the relevant NB group for toys will inform of the types of toys for which an EU type certificate is requested, and risks that may appear in novel toys.

As regards the evolution of the rates of non-compliance and possibly the number of toys stopped at the border, the Commission will monitor the implementation by Member States of their obligation under article 34 of Regulation 2019/1020 on market surveillance to notify under ICSMS information on the inspections they conduct on toys, and on the results of those inspections. First of all, the Commission will monitor the number of inspections carried out by market surveillance authorities, which is expected to grow. The information on the results of investigations should report as far as possible if the toy is available online or not. This information, together with the notifications performed under the RAPEX-Safety Gate on dangerous toys, should allow for a more complete picture on the evolution of non-compliance for toys in the EU, and the percentage of toys inspected which are compliant or not, and the extent of the non-compliance including online sales. It is expected that the number and share of non-compliant toys will be reduced. Furthermore, information on the number of toys which are not released for free circulation because the digital product passport including the declaration of conformity was absent, will also allow for evaluating the success of that measure in preventing that non-compliant toys are placed on the Union market.

Objective	Indicator
Strengthen the protection of children from harmful chemicals	Number of derogations to generic bans requested Notifications of measures taken againts toys containing harmful substances
Flexibility to adapt to emerging scientific knowledge	Number of specific limit values introduced for other harmful substances Time taken for the adoption of such additional limit values
Reduce the number of non-compliant toys	Number of non-compliant toys found, if possible with a breaking down as to the sales channels used and origin of products Number of non-compliant toys stopped at the border without a DPP
Facilitate enforcement	Total number of inspections on toys

ANNEXES

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

Lead DG: DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

Directorate: Directorate F – Ecosystems I: Chemicals, Food, Retail

This impact assessment corresponds to the initiative with the *Decide* reference PLAN 2021/11623, for the revision of the Toy Safety Directive.

2. ORGANISATION AND TIMING

The inception impact assessment feedback period ran from 5 October to 2 November 2021.

The public consultation period ran from 2 March 2022 to 25 May 2022.

An inter-service steering group was convened and chaired by DG GROW. The following Directorates-General participated: SG, JUST, GROW, CNECT, SANTE, ENV, TAXUD. The ISSG met 8 times. The last meeting on the final draft impact assessment report was held on 23 September 2022.

3. CONSULTATION OF THE RSB

The RSB was consulted in an informal upstream meeting on 22 February 2022. This impact assessment was submitted to the RSB on 28 September 2022. The meeting with the RSB took place on 26 October 2022.

Following the opinion of the RSB from 28 October 2022, changes were made to the IA in order to reflect the recommendations of the Board. The table below presents an overview of the RSB's recommendations and how these have been addressed.

Opinion of the RSB	How the comments have been addressed
Summary of findings (1) The report does not provide sufficient information about the process to grant derogations for the most harmful chemicals under the preferred option. It does not explain how this process will ensure that children's safety is not compromised.	A better description of the process to grant derogations has been included in section 5.2.1. The report also includes explanations on how once a chemical has been classified in one of the most harmful hazard classes the derogation process should look into whether there is children exposure to it and only uses which are considered to be safe for children and pose no risk should be allowed.
(2) The report is not sufficiently clear about the robustness of the cost and benefit estimates. It does not explain sufficiently why granting	The report now includes explanations concerning how the costs and benefits have been calculated and the limitations of this

derogations does not have any impact on the expected health benefits.	assessment, for the dynamic baseline as well as for all policy options. A better description of the derogation process has been included in 5.2.1. indicating that derogations can only be granted where children exposure to the harmful chemical and the risk can be excluded. If derogations are only granted for a use that has been evaluated as safe and there are no alternatives, it should not diminish the health benefits achieved by reducing exposure of children to these substances. Further explanations are provided in section 6 as well.
What to improve	
(1) The report should provide additional information about the scientific assessment to be carried out by the European Chemicals Agency to grant derogations for harmful substances. It should discuss to what extent this approach is future-proof in view of the experience with certain substances, which new scientific knowledge found more toxic than known before. The report should also consider the expected costs of requesting and assessing derogations under the preferred policy option.	A better description of the process to grant derogations has been included in section 5.2.1., making reference to the scientific assessment to be carried out by the European Chemicals Agency. Section 6.2. considers in the analysis that there are likely to be administrative costs from requesting a derogation, with an approximate order of magnitude based on past experience from this and other sectors. Section 6.2. also includes explanations on how the approach in this option is expected to ensure health benefits.
(2) The report should better explain the evidence base, reliability and robustness of the estimates of costs to businesses. In particular, it should explain why the industry would bear high costs in case derogations are not allowed, considering the low number of derogations on Carcinogenic, Mutagenic or toxic for Reproduction substances having been requested and granted under the current Directive. It should also clarify how the business- as-usual costs are taken into account in the estimates.	Section 5.1. has been modified to include a better explanation of the business-as-usual costs which are taken as the baseline against which the other policy options are compared. In addition, the introduction to section 6 now includes more detailed explanations as to the methodology of the cost estimates, the evidence base and the limitations and uncertainties of the assessment. Section 6.3. gives further information on the impact that not having specific derogations could have on the market.
(3) The report should clarify the analysis of the expected health benefits. It should better explain the methodology used (in particular, whether the estimates are only based on the value of the avoided health damage from exposure to endocrine disruptors) and what the limitations of these estimates are. It should also explain why the overall health benefits for the options with derogations and without are quantitatively the same given that a derogation could	Sections 6.2. and 6.3. have been amended to include better explanations of the estimates for the health benefit, the fact that they are based on avoided health damage and why they are only based on exposure to endocrine disruptors. The limitations of this assessment are also explained in those sections. These sections, as well as section 7.1. explain the role of the derogations and why they would not compromise the health

potentially allow for minimum exposure to a specific substance.	benefits of that policy option.
(4) The report should further elaborate on the articulation between this initiative and other related proposals. It should clarify that this initiative builds on the forthcoming inclusion of new hazard classes in the Classification, Labelling and Packaging Regulation but is independent from the revision of the REACH Regulation, the revision of the Union Customs Code and the proposal for a Regulation on Ecodesign for Sustainable Products. It should also clarify the role of the existing CE label in this initiative.	Section 1.2. and section 5 on the description of the policy options has been amended to include better explanations of the articulation with these initiatives.
(5) The report should explain how a Digital Product Passport under the preferred option would address the problems related to an exponential increase in small individual parcels containing toys and the incorrect and questionable quality of the EC declaration of conformity.	Section 5.2. and 6.5. have been amended to provide a better explanation of this policy option and how it would address the problem identified including in relation to small individual parcels.

4. EVIDENCE, SOURCES AND QUALITY

The Evaluation of the Toy Safety Directive[189] identified the key areas for the revision. It was supported by a study by an external contractor[190] .

This impact assessment is also supported by a study undertaken by another external contractor[191], who carried out dozens of interviews, analysed data from public and targeted consultations and complemented this through desk research.

[189] 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
[190] 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
[191] VVA with CSES and Asterisk (2022) Impact Assessment study on the revision of the Toy Safety Directive

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

1. CONSULTATION STRATEGY

The objectives of the consultation were to collect evidence and views from a broad range of stakeholders, on the identified problems and the potential solutions concerning the TSD. The activities included a 12-week dedicated public consultation (PC) concluded in May 2022, a Stakeholder Workshop held on 26 April 2022, discussions with Member States at the Administrative Cooperation formation of the Expert Group on Toy Safety and feedback collected in response of the Commission's inception impact assessment. Also, as part of the impact assessment study, an external contractor 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.

Summary table on the numbers and type of activities

Stakeholder group	Consultation methods		
	Interviews	SME Survey	OPC
Companies and business associations	15	201	89
Authorities and notified bodies	23	-	31
Consumer associations	3	-	12
Other (NGOs, individuals etc.)	-	-	64
Total	**41**	**201**	**196**

2. INCEPTION IMPACT ASSESSMENT (IIA)

The Inception Impact Assessment for this initiative was launched in 2021, with a feedback period running from 5 October to 2 November 2021. There were a total of 34 responses, of which 12 from business associations, 6 from companies/business organisations, 5 from non-governmental organisations, 6 from public authorities, 3 from consumer organisations, 1 from an environmental organisation and 1 from an EU citizen. Responses from industry argued that the TSD is currently sufficiently protective and that there was no need to strengthen its requirements. Conversely, public authorities, consumer and environmental organisations strongly advocated for a revision of the TSD which would ensure that children are protected from the most harmful chemical substances.

3. STAKEHOLDER WORKSHOP

The Stakeholder Workshop on 26 April 2022 brought together approximately 120 representatives of EU-level consumer, business and industry organisations, manufacturers, standardisation and notified bodies, as well as Member State authorities. The objective of the workshop was to present the state of play on the impact assessment work and to discuss ways to adapt the TSD to ensure a higher protection of children from the most harmful chemicals, and to reduce the number of unsafe products in the Union. Consumer groups and public authorities considered that the requirements for chemical substances should be strengthened, while industry and business associations were more sceptical. There was consensus among all participants that it should be possible to add new limit values for toys for any children in the TSD, and not only for children under 36 months or to be put in the mouth, as is the case today. On the other hand, all participants agreed that it was necessary to tackle the high number of non-compliant toys on the Union market, in particular those sold online.

While consumer associations and notified bodies were in favour of extending the third party conformity assessment under the TSD, the option to require the EU Declaration of conformity in digital form as part of a Digital Product Passport, to be presented at customs too, gathered the most support.

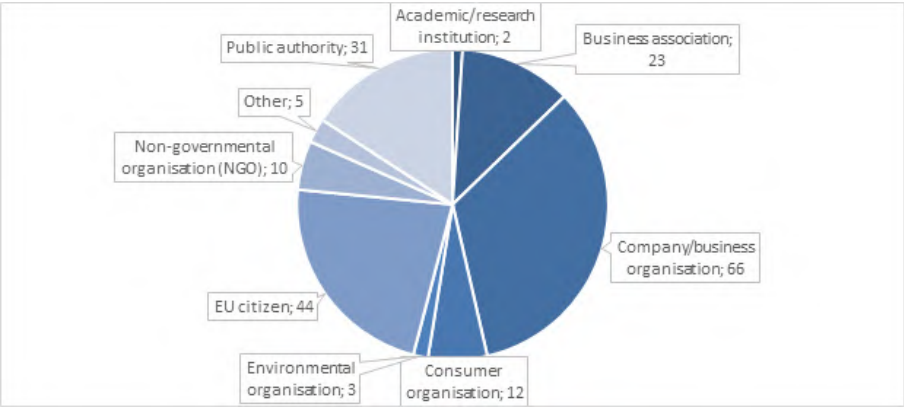
4. PUBLIC CONSULTATION

The consultation was open during 12 weeks between 2 March and 25 May 2022, via the EU Survey online system in 24 EU languages. A total of 17 position papers were attached by stakeholders to the consultation.

4.1. Respondents by Stakeholder category

All in all, 196 responses were submitted, the biggest represented group (34%) was of companies and business organisations, but EU citizens (22%), public authorities (16%) and business associations (12%) were also represented. Albeit in smaller proportion, NGOs, environmental organisations and academic, research institutions also shared their insights on the topic. Out of the 31 responding public authorities 48% is national, 32% is regional, 13% is international and 7% is local.

Figure 1: Respondents by category of their organisation



4.2. Respondents by country of origin

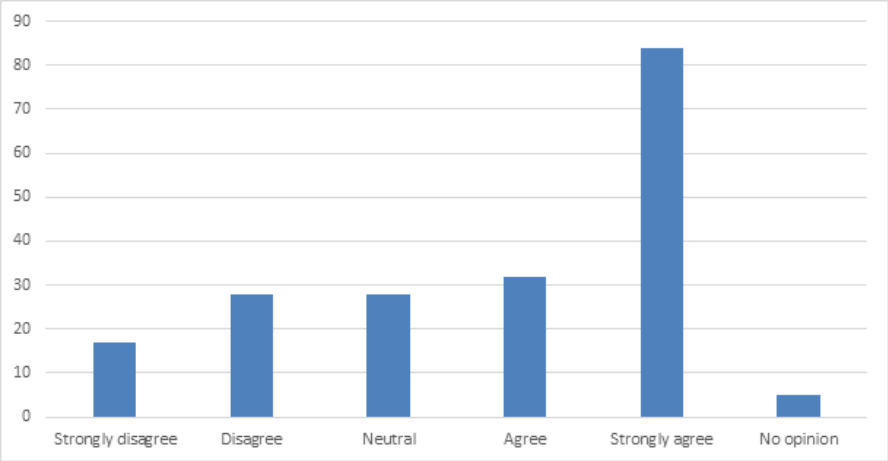
The 196 respondents are coming from 24 different countries, most from EU Member States, but there are respondents from Mexico, Singapore and the United Kingdom too. From Germany, an outstanding number of answers were received (59), but Spain (21), France (19) and Belgium (19) can also be considered as well represented.

4.3. Setting stricter requirements for chemical substances

The participants of the consultation were asked whether they agree or disagree that the EU rules on toy safety should set stricter requirements for chemicals in toys. The sample shows a support for stricter rules with 43% strongly agreeing and an additional 16% agreeing with setting stricter rules.

The other end of the scale appears to be much less committed, as those who strongly disagree only amount to 9%.

Figure 2: Ratio of respondents supporting the stricter EU rules on toy safety



If the type of organisation is also taken into consideration when analysing this question, it becomes evident that those who (strongly) disagree are representatives of business associations and companies (47%), while all the environmental and consumer organisations agree to some degree with the statement (over 90%). Similarly, 90 % of public authorities agreed or strongly agreed with the statement.

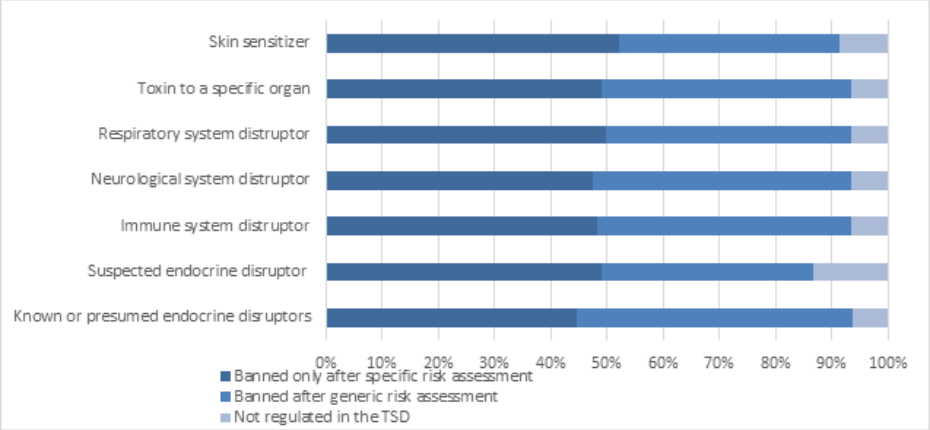
- **Specific chemical substances and regulatory approach**

The respondents were asked how the TSD should handle the different substances that pose health risks. The answers show that the option of the TSD not regulating the harmful chemicals presented was preferred to a much lesser degree. From the sample, it seems that the respondents were most worried about the substances that are endocrine disruptors or immune system disruptors and they would like to see these substances banned. Over 85% of consumer groups and environmental associations would like to see them banned preventively. Also over 85% of public authorities would like to see these substances addressed by the TSD, but the specific approach to address them (specific risk assessment or generic risk assessment) is balanced. Over 70 % of industry believed that they should only be banned after they have been scientifically assessed as unsafe in toys.

The respondents also had the possibility to give further comments on the subject. Several of them underlined the importance for the revised Toy Safety Directive to ban certain categories of chemicals (rather than individual substances), in line with the "Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment" of the Commission published in October 2020, which foresees to use generic bans ("generic approach to risk management") not just for endocrine disruptors but also for CMRs, substances of very high concern (SVHCs) or sensitizing substances as default approach.

Industry argued that harmful substances could be regulated through REACH restrictions and that the form or specific route in which the substance has been classified (for example, causing cancer by inhalation) should be taken into account.

Figure 3: Ratio of the preferred action for the substances posing different health risks



- **Use of derogations**

The participants were asked whether they agree or disagree that the Toy Safety Directive should, by way of exception, allow the presence of chemicals which are subject to current and new general bans. While a number of respondent think that there should be no derogations to the general bans (35% public authorities and 50% of consumer and environmental groups), 73% of industry respondents disagreed with this statement.

The use of derogations is perceived differently by the participants of the PC depending on the reason behind the given derogation. The biggest support is visible in those cases when the used chemicals are found to be safe for human health for that particular use in toys and there are no alternatives or when the used chemicals are found to be safe for human health (as evaluated by a scientific committee) for that particular use in toys (91% of industry, 68% public authorities and 39% of consumer and environmental groups).

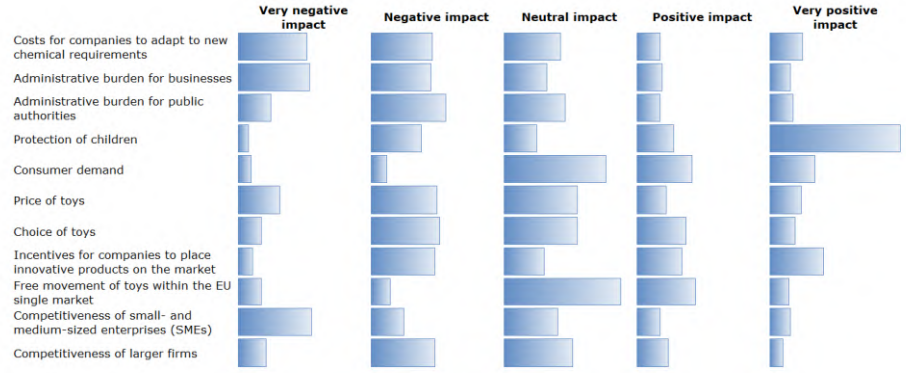
The participants of the PC were asked about their opinion on the likely overall impact of introducing general bans for the most harmful chemicals with some limited derogations if necessary. The answers were collected in 5 different categories (in addition to "no opinion" or "I don't know" answers), where the higher numbers represent an expected very positive impact and a lower number means very negative impact.

From the diagram below, it is visible that the respondents expect that the general bans will have a different impact on different aspects. While industry respondents indicate that it will affect very negatively (42%) or negatively (26% answers) the costs of companies which have to adapt to the new requirements and it will also have a predominantly negative impact (in the same percentages) on the administrative burden for businesses, it is expected to have a very good impact on the

protection of children (84% of public authorities, 80% consumer and environmental groups, and 30% of industry).

Out of the different aspects, most respondents thought that the most positive impact will be on the protection of children and on the appearance of innovative products on the market. Positive impact is expected mainly on free movement of toys within the EU single market and on consumer demand. At the same time, industry and in particular SMEs were concerned about costs, administrative burdens and loss of competitiveness for SMEs.

Figure 4: The ratio of the respondents expecting different impacts for the different aspects



When prompted to explain their opinions, industry feared that the result will be more non-compliant toys in the market and less compliant toys offering for consumers.

- **Requirements for toys intended for children under 36 months or to be put in the mouth**

Firstly, stakeholders were asked whether the toy safety rules should continue to allow different requirements to be set for chemicals in toys for younger children (under 3 years) compared to older children. Almost half of the respondents (90% industry, 50% public authorities and 48% of consumer/environmental groups) (strongly) agree with the statement. The same trends in the responses per different group appear when asked if the TSD should continue to allow for different requirements to be set for chemicals in toys intended to be put in the mouth.

When asked whether the toy safety rules should allow new requirements to be set for chemicals in any toy should new scientific knowledge emerge, 92% of consumers/environmental groups, 94% of public authorities and 68% of industry agreed or strongly agreed.

- **Requirements on nitrosamines**

32% of industry, 77% of public authorities and 73% of consumer/environmental groups agree to some degree that limit values in the Directive for nitrosamines and nitrosatable substances should be lowered.

- **Labelling of chemicals in toys**

When asked whether the toys should be labelled with their chemical composition or not, the answers are painting a quite divided picture where 53% thought it would be a good idea and 39%

does not support it. Companies (50 answers) and business associations (18 answers) are those who predominantly oppose labelling the products. The vast majority of answering EU citizens (86%) however would like to see the chemical composition on the label.

4.4. Protecting children from other risks in toys

Consumer and environmental organisation were supporting that the TSD addresses privacy breaches (88%), cyber security (90%) and protection from psychological harm (83%). Public authorities were slightly less supportive of the TSD handling these aspects (54% privacy breaches, 58% cybersecurity and 54% for protection from psychological harm). Least of support came from industry respondents (28% for privacy, 27% for cybersecurity and 29% for protection from psychological harm).

Among the additional comments, it was mentioned by industry that as children usually have access to "other" (non-toy) digital equipment like mobile phones, tablet computers, video consoles etc. which potentially pose comparable risks for children. Therefore, cybersecurity and data protection need to be regulated horizontally and not be treated differently than other products used by children and already covered by GDPR, GPSR, RED, Cyber Resilience Act, AI etc (52% indicated this as their preferred option). In contrast, 51% of public authorities and 52% of consumer/environmental groups chose as their preferred option to ensure that the TSD would protect not only the physical but also the psychological wellbeing of children.

4.5. Single Market

- **Factors hampering the application of the TSD**

The participants of the public consultation were also asked to what extent five different issues hamper the application of the directive. The most problematic issue identified by all different respondent groups was the lack of specific requirements for online sales (70% consumers/environmental groups, 80% of public authorities and 67% of industry). Industry considered to a much smaller extent that the need to transpose the adaptations of the Directive into national law could hamper the effectiveness of the Directive (37% to a (very) large extent and 27% to a moderate extent, or chemical values being set in different pieces of legislation (31% to a (very) large extent and 24% to a moderate extent). Public authorities and consumer/environmental groups rather referred to other factors such as the fact that conformity assessment is carried out without the intervention of a NB (58% of authorities and 70% of consumer/environmental groups considered this affected the effectiveness of the TSD to a (very) large or to a moderate (20% for authorities) extent). Similarly, the fact that documentation is provided only upon request affected to a (very) large extent for 58% of public authorities and 65% of consumer/environment groups and to a moderate extent for an additional 19% of authorities and 13 % of consumer/environmental groups.

- **Third-party conformity assessment**

When asked whether the participants think the toy safety rules should extend the obligation of third-party conformity assessment to more toys (EU-type examination) the results are quite balanced depending on the interest group. 83% of consumer/environment groups and 75% of authorities support it while 75% of industry is against. Out of those who were in favour of extending this obligation, 44% of consumer/environment associations and 32% of authorities thought it should apply to all toys, while close to 40% of authorities and consumer/environment groups supported that it covers chemical mixtures and an additional 25% of public authorities and 37% of consumer/environment groups believed it should cover toys intended for children under 36 months.

In terms of impacts of the measures, consumer groups rather believed that it would have a very positive impact in the protection of children (63%) and in compliance of toys (50%). Similarly, public authorities considered it could improve the protection of children (54%) and the compliance of toys to a high or moderate extent (80%). Conversely, industry was concerned about the negative impacts on their costs and administrative burden (over 60%) and on price of toys (52%). Negative impacts on the competitiveness of SMEs was also raised as a strong concern (55%). In general, industry did not believe this option would have a strong positive impact on the protection of children or on compliance.

- **Digital tools**

The participants to the open consultation seem to agree that it would be a mistake to have certain information available only digitally in the case of name and address of the manufacturer, instruction for use, safety information and information on chemical substances; there are no significant differences in the different responding groups. Industry supports that the EU declaration of conformity (56%) and EU-type examination certificates (54%) are enough if published digitally. For the EU declaration of conformity, public authorities agree that it can be provided digitally (35%) or which basic information on paper (61%). Consumer groups rather support that this documents are either made available on paper (EU declaration of conformity 44% and EU type certificates 31%) or with basic information on paper and more details provided digitally (EU DoC 47% and EU type certificates 49%).

Public authorities and consumer/environmental groups considered that this measure would have the most important impacts in terms of protection of children, compliance of toys with the TSD and efficiency of market surveillance. Similarly, industry respondents also considered that the measure could have benefits for the protection of children (40%) for the compliance of toys (47%) and for the efficiency of market surveillance (59%). However, they were also concerned to a certain extent about possible costs (43%) and administrative burden (45%). SMEs were concerned to a certain extent of the possible negative impacts on their competitiveness (43%).

- **Compliance and enforcement**

The respondents were asked whether they would like to see the Toy Safety Directive converted into a Regulation. 85% agrees with the conversion without significant differences across respondent groups (82% industry, 80% of public authorities and 87% of consumer/environment groups.
From the additional comments, it turns out that some of the respondents from industry think that the conversion of the Directive into a Regulation should only be carried out with a view to clarifying a number of provisions in the current framework, and not to increase in any way the burden on manufacturers. It was also pointed out that the same rules must apply everywhere. Either way, a Regulation would allow for stronger enforcement of the provision and guarantee a harmonized implementation of the provisions across the EU, guaranteeing the same level of protection for all children.

When asked about their preferred measures to be included in the Directive to improve compliance and enforcement, the respondents could select multiple replies simultaneously. Public authorities were strongly in favour of a digital passport (96%) of converting the Directive into a Regulation (74%) and of extending third party conformity assessment (67%). Consumer/environmental groups were strongly in favour of converting the Directive into a Regulation and extending third-party conformity assessment (78% for each response) and also to have a digital passport (59%). Industry was also quite in favour of converting the Directive into a Regulation (67%) and of the digital passport (52%) but in a much smaller percentage of extending third party conformity assessment (19%).

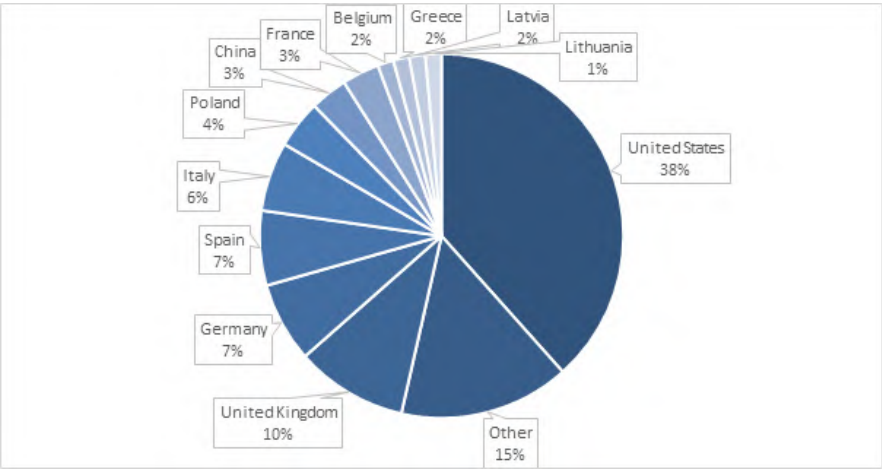
5. TARGETED SURVEY FOR SMES

5.1. Number and basic characteristics of the respondents

A targeted online survey was carried out to collect as many views from the representatives of SMEs as possible. In total, 201 completed responses were received.

Most of the answers were received from the United States (65), the United Kingdom (21), Germany (15), Spain (14) and Italy (13). Out of the 32 represented countries, 19 were based in one the European Union Member State with 40% of the companies in the sample.

Figure 5: Ratio of the respondents' States where they are based[192]



In terms of the **size of the organisations**, most of the respondents (73.6%) were categorised as micro-organisations employing 1 to 9 employees. Small enterprises employing 10 to 49 employees and medium ones employing 50 to 249 employees were represented in a more balanced way, having 11.9% and 14.4% respectively.

5.2. Costs related to the revision of the TSD

- **Administrative burden**

In connection with **bureaucracy and extent of requirements,** the respondents stated that the biggest burdens are rooted in the **testing obligations**. Also, it is quite burdensome that companies have to continuously update the documents, especially the Declaration of Compliance. Others referred to costs in relation to keeping the technical documentation up to date as all data from purchased parts and raw materials (for each batch), all test reports (from both raw-materials as finished products), all the updating of DOC's and every additional document are required to have a

[192] Under the category "other" those countries are aggregated from where less than 3 responses were collected (such as Austria, Bulgaria, Czech Republic, Denmark, Estonia, Finland, Hungary, India, Romania, Sweden, The Netherlands) and those responses who selected originally the option "other" wishing not to specify the country they are based in.

complete and complying dossier. Furthermore, there are specific challenges such as the length of the custom process in certain countries; the strict fire safety testing requirements; or storing the documentation for 10 years.

Another administrative burden stems from the **need for specific knowledge, skills and extensive human resources for following the changing requirements**.

In terms of **staff costs** expressed in number of working days per new SKU, for the costs of making available the declaration of conformity on the website 59 companies assigned a greater number of working days than zero, the majority estimating it to be between 1 and 10. To adapt the labels indicating the chemical content of a product 56 estimations greater than 0 were received. The least resource intensive intervention would be to register the link to the DoC on the website, this only receiving 39 votes. The vast majority of respondents estimated that all of the interventions could be carried out in 1-10 working days per new SKU.

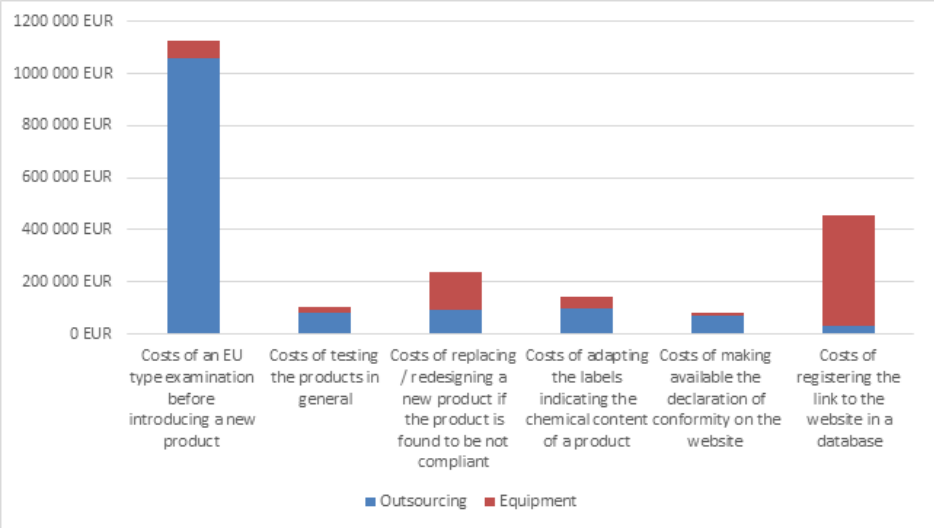
***Table 1**: The number of companies that estimated that each intervention would require the given number of working days*

Number of working days per new SKU / Interventions	**0**	**1-10**	**11-20**	**21-45**	**46-200**	**>200**
Costs of an EU type examination before introducing a new product	7	38	7	7	1	0
Costs of testing the products in general	8	35	6	5	5	0
Costs of replacing / redesigning a new product if the product is found to be not compliant	9	22	11	6	8	6
Costs of adapting the labels indicating the chemical content of a product	9	39	4	4	5	4
Costs of making available the declaration of conformity on the website	5	42	5	6	3	3
Costs of registering the link to the website in a database	11	29	2	1	4	3

The outsourcing costs and equipment costs were also assessed by the respondents[193]. According to the answers, from the point of view of outsourcing, the costs of an EU type examination before introducing a new product would be the highest (most of the companies estimating that it would cost between 201 and 1 000 EUR per new toy model, while the lowest would be the costs of registering the link to the website in a database (around 30 000 EUR in total). From the point of view of the equipment costs, the picture is quite different as the costs of registering the link to the website in a database would require the largest sum (around 420 000 EUR) in total, together with the costs of replacing / redesigning a new product if the product is found to be not compliant (around 145 000 EUR in total) and the cheapest would be to make available the declaration of conformity on the website (around 13 000 EUR) in total.

[193] Even though a data cleaning process was completed, the data analysed here primarily relies on the responses of the SMEs who filled out the survey, consequently any distortion is a result of their indications, which in turn can result from not having the proper sources of information.

Figure 6: The outsourcing and equipment costs according to the respondents



The respondents were also asked to assess the **total costs of process in relation to the total expected revenues**. In connection with the EU type examination, 16 companies claimed that they would lose anywhere between 11-50% of their expected revenues, with an additional 8 saying they would lose between 51-100% and another 8 claiming that it would seriously question the sustainability of their respective companies. The interventions connected to the websites are considered to cause the least loss from the expected revenues.

- **Impacts of potential policy measures**

The first policy measure envisions to introduce new limit values for toys or lowering the limit values following the newest scientific evidence. The responding SMEs were asked to assess this policy measure's impact on their competitiveness. The responses show that almost half (41,8%) claimed that the competitiveness will decrease as a result and only a mere 8% expected that as a result of this measure the competitiveness of their company will increase to some degree.

The second policy measure is the ban on specific substances. Based on the newest scientific evidence on chemical risks, some substances might be banned from toys altogether or only allowed using derogations. The ban on specific substances would have an adverse effect on their competitiveness. 44,8% considers that their competitiveness would deteriorate. The number of those who are unsure or do not want to share their opinion was relatively high, however, the ratio of those who consider that this measure will help their competitiveness is quite low (7,5 and 4% respectively). Each tightening of chemical requirements causes a significant increase in costs (tests, searching for materials, documentation etc.) and this is why they feel that they are losing competitiveness with companies that do not comply with these requirements, if enforcement of the TSD is not improved.

Another proposed policy option is to extend third-party conformity assessment for certain toys. Only 7,5% of respondents considers that their competitiveness compared to imports outside of the

EU will increase and 5,5% thinks similarly optimistically in connection with large manufacturers, in particular if nothing is improved in relation to the enforcement of the Directive.

The last proposed policy option is the introduction of a digital product passport containing the EU declaration of conformity which can be presented at customs and used by market surveillance authorities could be based on the Digital Product Passport under the ESPR. This option is the most supported, as 10% and 5% of the respondents think that their competitiveness would increase thanks to this. Nonetheless, SME companies fear they will be less competitive compared to larger companies, since the administrative and economic burdens will be bigger for them.

6. INTERVIEWS

All in all 41 interviews were carried out with authorities, notified bodies, companies and business associations as well as consumer associations.

ANNEX 3: WHO IS AFFECTED AND HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The preferred policy package would lead to policy objectives related to strengthening the protection of children from harmful substances and ensuring that the toy safety rules are flexible to adapt to updated scientific knowledge. Furthermore, it would achieve a significant reduction of non-compliant toys in the EU and facilitate enforcement of the rules. The TSD's legislative revision would contribute towards the achievement of EU policy objectives in strategic areas for the future of the EU economy such as green and digital economy.

Impacts on businesses

The preferred PO will lead to adaptation costs of product redesign and product adaptations to substitute the harmful chemicals which will be subject to generic bans. There will be product withdrawals of products in which the chemical substances cannot be substituted but this should be mitigated to a certain extent by a shift in demand to other products that will remain on the market. With the preferred PO, businesses will be required to include a Digital Product Passport on their products containing the EU declaration of conformity. The reference of this Digital Product Passport will be included in a central registry and indicated at the time of import into the Union. While this will lead to costs for businesses, it will also lead to benefits in streamlining the provision of compliance information, updating such information and replying to requests from authorities. Furthermore, it will yield significant benefits in terms of competitiveness of reputable companies which now face unfair competition by rogue traders.

Impacts on consumers

The preferred PO will lead to significant health benefits in terms of strengthen protection of children from the most harmful substances. These are substances such as CMRs, endocrine disruptors or substances which are toxic for the immune, neurological and respiratory systems. These substances are particularly harmful for children who are a vulnerable population group, and can produce adverse effects sometimes at very low doses. In addition, a significant reduction of non-compliant toys on the Union market can be expected from relying on the Digital Product Passport, thus reducing also the possible risks that children face from non-compliant toys.

Impacts on public authorities

The preferred PO will lead to significant efficiency gains for public authorities in tackling non-compliant toys in the Union. Non-compliant toys come particularly from non-EU countries. Customs controls of the existence of the Digital Product Passport can be rendered automatic on all toys coming into the Union market, rather than risk-based, which will stop a significant number of non-compliant toys which do not have this Digital Product Passport from being placed on the Union market. In addition, checks by market surveillance authorities will be rendered more efficient by allowing immediate access to the compliance information of the toy via a machine readable code on the toy. This will allow for an increase in the number of inspections between 10 to 20%.

2. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Improved well-being and health	Total amount not quantifiable with precision but generated from the improved protection from harmful chemicals and the reduction of non-compliant toys on the market. Estimates €240 million to €1.2 billion per year materialising within 30 years at least	Consumers and in particular children
Efficiency gains in market surveillance and customs controls	Facilitation of checks for market surveillance authorities leading to lower costs per inspection, generated by the DPP, as the information will be readily available. Automated customs controls will ensure more efficient checks at the border of toys. Estimated increase of inspections by a maximum of 2500- 5000 per year.	Market surveillance authorities Customs authorities
Efficiency gains in providing compliance information	Savings generated from digitalisation of the compliance information and the possibility to quickly update it, which could range from € 2.62 million to € 3.93 (€3.275 on average) million per year. There will also be savings from dealing with inspections on products by market surveillance authorities; estimates range from € 13 million to € 20 million	Businesses
Indirect benefits		
Competitiveness in the Single Market	Total amount not quantifiable but generated by the introduction of the DPP with compliance information and its verification at customs.	Businesses
Administrative cost savings related to the 'one in, one out' approach		
direct	Savings in producing information digitally only, which could range from € 2.62 million to € 3.93 million (€3.275 million on average) per year.	Businesses

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct adjustment costs	N/a	N/a	€23.5m to €396.66m in product adaptations	€7.31m to €11.70m per year in increased testing	N/a	N/a
	Direct administrative costs	N/a	N/a	€18m on setting up the DPP	€100.000 to €300.000 yearly if derogations are requested €10.5m yearly costs for DPP	N/a	N/a
	Direct regulatory fees and charges	N/a	N/a	N/a	N/a	N/a	N/a
	Direct enforcement costs	N/a	N/a	N/a	N/a	N/a	N/a
	Indirect costs	N/a	N/a	€249.21m to €367.25m worth of toys that could no longer be made available on the market	N/a	N/a	N/a
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	N/a	N/a	€ 23.5m to €396.66m	€7.31m to €11.70m per year		
	Indirect adjustment costs	N/a	N/a	€249.21m to €367.25m worth of toys	n/a		
	Administrative costs (for offsetting)	N/a	N/a	€18m	€10.5m per year €100 000 to €300 000 per year if derogations are requested		

3. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG #3 Good health and well-being	Reduction of exposure of children in toys to the most harmful substances as meeting one of the relevant hazard classes under the CLP Regulation should lead to a reduction of the mortality rate attributed to cardiovascular disease, cancer, diabetes or chronic respiratory disease.	Specific Target 3.4 'By 2030, reduce by one third premature mortality from non- communicable diseases through prevention and treatment and promote mental health and well-being' and Specific Target 3.9 'By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination'
SDG #6 Clean water and sanitation	The reduction in toys of the most harmful substances will lead to less amounts of these substances ending up as waste.	Specific Target 6.3 'By 2030, improve water quality by reducing pollution, eliminating dumping and minimising release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally'
SDG #9 Industry, innovation and infrastructure	The introduction of a digital passport for the compliance information will foster digitalisation of companies and innovation. A more stringent regulation of chemical substances will enhance innovation and substitution of the most harmful chemical substances.	Specific Target 9.4 'By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities'
SDG #12 Ensure sustainable consumption and production patterns	A higher protection of children in toys through more stringent requirements for the most harmful chemicals will reduce significantly exposure of children in toys and will also ensure that less harmful substances end up as waste.	Specific Target 12.4 'By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimise their adverse impacts on human health and the environment'

ANNEX 4: ANALYTICAL METHODS

In order to support the Impact Assessment, a study was carried out using a set of dedicated data collection and analytical tools to maximise relevance of the results and minimise the limitations of the study.

See annex 11 for further details on the methodology for calculation of number of non-compliant toys in the Union, and annex 14 for details on the methodology for the assessment of the different impacts of the policy measures.

1. OVERVIEW OF THE METHOD

The study was carried out between January 2022 and October 2022. The work was structured around three phases, each of them with various sub-tasks. This section summarizes the work under the key evidence-gathering and analysis activities.

Intervention logic and identification of the key problems

To prepare the work for the development of the policy options, the study first established the intervention logic and mapped and assessed the 1) key drivers, 2) problems and sub-problems, and 3) consequences of these problems to consumers, national regulatory authorities, the internal market and businesses. The intervention logic was regularly updated based on evidence gathered from the various data collection tasks.

1) Literature review

The study included a review of relevant documentation and literature. The review covered a broad catalogue from a variety of EU and Member State sources, including legal and policy documents, statistical data, studies and academic papers, position papers and other publications from relevant stakeholders.

2) Development and appraisal of the policy options

Based on the analysis carried out in the legal gap analysis, literature review and analysis of the consumer journey and on the feedback collected from stakeholders, 6 different policy options for the future of the TSD were identified:

Policy option 0: no change (baseline)

Policy option 1a: minimum changes

Policy option 1b: improved protection

Policy option 1c: maximum changes

Policy option 2a: extending the conformity assessment

Policy option 2b: facilitation of control through digitalisation

Policy option 2c: extending the conformity assessment and facilitation of control (combination of options 2a and 2b)

3) Consultation with EU and national-level stakeholders

The stakeholder consultation aimed to collect information and feedback for the assessment of impacts and on the different policy options. The stakeholder activities included:

- Scoping interviews with notified bodies, business associations and consumer associations to gather preliminary information on the topic and assess key issues and challenges;
- SME survey: the survey was shared with SMEs, SME associations and business associations to ensure that specific input from SMEs was gathered, especially on impacts;
- Semi-structured interviews with EU-level and national stakeholders, particularly from the following stakeholder groups: businesses and business associations, national regulatory authorities and notified bodies, and consumer associations. The key aim of the semi-structured interviews was to receive feedback from the stakeholders on potential improvements of the Toy Safety Directive, and insight to feed into the assessment of impacts and comparison of policy options;
- Open public consultation questionnaire: the PC ran for 12 weeks from the end of March 2022 to May 2022 and gathered information and views on how the Toy Safety Directive can better protect children, and to collect information on how to improve the Directive.

Table 2: Summary table on the number and type of consultation activities

Stakeholder group	**Consultation methods**			
	Scoping	**SME survey**	**Interviews**	**OPC**
Businesses and business associations	2	201	15	89
National Regulatory Authorities and notified bodies	2		23	31
Consumer associations	2		3	12
Academic institutions				2
Environmental organisations				3
Other (NGOs, individuals etc.				59
Total	**6**	**201**	**41**	**196**

2. LIMITATIONS ENCOUNTERED AND MITIGATION MEASURES

The key limitation of the study was the shortened timeline of the data collection which made the setup of the data collection tools extremely challenging and left no time for further probing into the evidence and reconnecting with stakeholders after the data collection had been done. Some limitation in the assembled evidence was therefore unavoidable and will be addressed as soon as possible:

- The overall number of third-party conformity assessments both in the baseline option and in option 2a was not available to stakeholders. Further discussions with stakeholders on this specific topic will continue to revise the estimate as appropriate.

- Cost estimates for all of the options under 1 but especially 1a were very uncertain as the details of the chemical substances may only be determined later on. It is not clear which limit values would be introduced or how many toy relevant substances would be affected by an extension of the GRA.

- Information on toy specific health risks were also scarce. On the one hand, information on illnesses or accidents with toys is patchy at best while, on the other hand, there is ample evidence of dangerous substances still present in toys on the EU market. The study could not fully resolve that gap in the data.

To mitigate these deficiencies, the study triangulated the information from the SME survey, the interviews and the literature to develop robust estimates for each of the options. For some topics knowledgeable stakeholders were asked for further input to fill the gaps.

3. STRUCTURE OF THE ANALYSIS

The analysis followed a step-by-step approach, where each step built on the outcome of the previous step. The steps mirrored the different elements mapped in the intervention logic, from the drivers to the problems and consequences and then to policy objectives and policy options. In terms of the impact assessment of the options, first a baseline assessment of the toys market was carried out. The policy options were then assessed with regard to their impacts and compared, based on feedback collected from stakeholders through the online survey. The following impacts were assessed:

- Administrative burden
- Cost for companies
- Impacts on competitiveness and the single market
- Costs for authorities and notified bodies
- Human health impacts
- Environmental impacts

4. LEGAL ANALYSIS - METHODOLOGY

A legal comparative analysis was conducted to see possible overlaps, duplications and gaps between the TSD and other relevant EU legislation (both legislation in force and proposed). The legal analysis did not intend to repeat the comprehensive legal analysis performed for the 2020 evaluation of the TSD, therefore it was focused on the legislation adopted or proposed since then. Nonetheless, to understand the overall approach to product safety, including toy safety, many of the older legal acts were reviewed as well. All legal acts were reviewed in the latest consolidated version.

The following legislation (in chronological order) was reviewed:

- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11 of 15.01.2002

- 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

- Regulation 1907/2006, 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

- 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

- 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

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006Directive 2011/65/EU, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

- Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys

- Regulation No 1223/2009 on cosmetic products

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

- 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

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC

- Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013

- 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

The following proposals for legal acts (in chronological order) were reviewed:

- Proposal for a Regulation of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM(2020) 825

- Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, COM(2021) 206

- Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council, COM(2021) 346

- Commission Delegated Regulation (EU) …/… of 29.10.2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that directive, C(2021) 7672

- 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, COM(2022) 142

To put legal developments in context, several policy documents were analysed:

- Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment, COM(2020) 667

- New Consumer Agenda, COM(2020) 696

- Cyber Resilience Act, Call for evidence for an impact assessment (2021)

- European Parliament resolution of 16 February 2022 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)

The analysis of the legal documents was supported by the literature review of the relevant scholarship and other studies. All publications are referenced in the text of the report.

5. GLOBAL AND EUROPEAN TOYS MARKET

Descriptive statistics on the European toys industry draw mainly on Eurostat Structural Business Statistics (SBS), C32.4 – Manufacture of games and toys (NACE Rev 2). The analysis focuses on data covering the EU-27 and EFTA countries, while highlighting the respective shares of leading countries in the European toys industry. Detailed data tables presenting disaggregation for all Member States and EEA / EFTA countries where Eurostat SBS data is available are provided below.

It is important to highlight data gaps and shortcomings in the quality of data. The statistical analysis was partly hampered by data gaps in Eurostat SBS data in some Member States and EEA / EFTA countries, especially for some variables, such as turnover and the number of people employed. In some cases, there were insufficient data for Eurostat to estimate the total for the EU-27, while those estimates that are available are marked as low reliability by Eurostat. The most recent year for which data was available was 2020 for some variables, but there were provisional estimates only and remained gaps.

Regarding mitigation measures, the methodology focuses on reporting the sum of the available data across the EU-27 and EEA/EFTA countries, rather than the overarching Eurostat EU-27 estimates. This allows increased traceability and analysis between the overarching figures and the country data. To ensure this is transparent, it is clearly stated in each case the number of countries whose data is included in the estimate. Furthermore, where appropriate, data imputations have been calculated for certain missing data points based on average market changes year on year. More detail on the data gaps and the approach to mitigating these challenges is provided throughout the analysis of the different elements.

Supporting data tables with full disaggregation

This section contains supporting data with full disaggregation by country and year. It should be noted that in Eurostat SBS, the majority of 2020 data is provisional only – marked by a (p) below. Furthermore, the data does not cover all countries across all years and all variables; for instance, no data on the number of toy industry enterprises is provided in Ireland, Malta and Liechtenstein for the entire period 2016-2020, while no data on this indicator exists for Cyprus in 2016-2017. To mitigate this challenge, data imputations have been developed for certain countries and years, but only where they can be based on robust assumptions. The methodology for developing the imputations is detailed in the box below.

Method for developing data imputations

In the absence of relevant supporting data, the methodology for developing data imputations was based on the assumption that the changes in a particular country for a particular variable will follow average market changes year-on-year; i.e. that missing 2020 data for a particular variable can be estimated based on overall market changes in that variable from 2019-2020. This is particularly relevant given the unique and challenging nature of the market in 2020, which resulted from the COVID-19 pandemic. Furthermore, most of the data imputations developed were for 2020.

On this basis, the following three steps were conducted to estimate each missing data point:

i. For each country that has data, we calculated the absolute change and percentage change in the relevant variable from year n to year n+1 (e.g. from 2019 to 2020).

ii. Calculate the average percentage change across all countries for year n to year n+1.

iii. Apply the average percentage change to the data from year n in the country without data to develop a value for year n+1.

Data for countries which had no data across the examined time period was not estimated due to the inherent lack of baseline data on which any data imputations could be developed.

Each table first presents, where available, the Eurostat composite figures for the EU-27 and former EU-28. However, in most cases, these figures are marked by Eurostat as low reliability due primarily to the use of different definitions in some countries. As such, each table also provides the sum of the available data for the EU-27 and the EU-27 + EEA/EFTA countries. However, as data is missing for certain countries and years, these overarching figures are accompanied by notes detailing the number of countries for which data is available.

In the main body of the analysis, the combined EU-27 + EEA/EFTA figures for each year are presented; this is due to the limited reliability of the composite EU-27 figures and the increased traceability and comparability provided by the EU-27 + EEA/EFTA figures in combination with the country-specific data.

***Table 3**: No. of enterprises in the European toys industry (disaggregated among EU-27 and EEA/ EFTA countries)*

	2016	2017	2018	2019	2020 (p)
European Union – 27 countries (from 2020)	**5,300**	**5,400**	**5,800**	**6,000**	
European Union – 28 countries (2013-2020)	**5,900**	**6,000**			
Belgium	42	162	71	88	103
Bulgaria	45	43	42	47	52
Czechia	554	520	529	513	506
Denmark	95	96	97	103	105
Germany (until 1990 former territory of the FRG)	579	568	605	697	683
Estonia	29	30	19	22	25
Ireland					
Greece	74	77	83	81	79
Spain	379	386	401	404	409
France	787	641	729	771	848
Croatia	47	50	44	71	73
Italy	359	374	382	327	338*
Cyprus			3	4	4
Latvia	71	75	88	103	112
Lithuania	60	92	108	119	139
Luxembourg	2	3	4	4	4
Hungary	198	207	222	232	235
Malta					
Netherlands	417	432	478	495	536
Austria	92	94	93	101	92
Poland	732	771	872	870	904
Portugal	67	67	72	69	78
Romania	119	143	183	194	207
Slovenia	40	43	42	40	42
Slovakia	211	218	315	362	398
Finland	31	35	35	33	32

	2016	2017	2018	2019	2020 (p)
Sweden	224	241	239	243	242
Total EU-27	**5,254**	**5,368**	**5,756**	**5,993**	**6,246**
Total EU-27 (# of countries with data available)	24	24	25	25	25
Iceland	14	13	10	10	10*
Liechtenstein					
Norway	32	37	32	34	25
Switzerland	32	30	28	30*	31*
Total EU27 + EEA/ EFTA	**5,332**	**5,448**	**5,826**	**6,067**	**6,313**
Total EU-27 + EEA/EFTA (# of countries with data available)	27	27	28	28	28

Source: Eurostat SBS.

* Data imputations developed for the following data points and years: IT (2020), IS (2020), and CH (2019-2020).

Table 4: *Turnover generated in the European toys industry in million EUR (disaggregated among EU-27 and EEA/ EFTA countries)*

	2016	2017	2018	2019	2020 (p)
European Union - 27 countries (from 2020)					
European Union - 28 countries (2013-2020)					
Belgium	128.7	119.0	144.0	137.0	134.5
Bulgaria	210.7	236.7	228.6	287.9	175.0
Czechia	850.9	790.8	850.5	861.6	898.2
Denmark					
Germany (until 1990 former territory of the FRG)	2,939.5	3,067.1	4,191.8	3,915.2	2,608.2
Estonia	1.3	1.1			0.8
Ireland					
Greece	14.6	13.9	13.9	15.0	13.6
Spain	552.1	548.2	574.7	592.4	546.4
France	448.7	357.0	457.3	447.1	421.5
Croatia		11.0	7.4	7.3	5.4
Italy	674.9	581.1	516.6	589.1	560.1
Cyprus			4.7	4.5	2.6
Latvia	5.5	6.2	5.9	6.0	7.7
Lithuania	3.0	3.5	4.1	6.1	6.3

	2016	2017	2018	2019	2020 (p)
Luxembourg					
Hungary	170.8	184.5	175.7	180.8	198.1
Malta					
Netherlands					
Austria	523.3	567.8	775.8	601.6	453.0
Poland	208.9	237.1	247.0	268.4	296.3
Portugal	5.2	3.0	4.5	5.8	8.8
Romania	39.0	42.3	88.5	97.1	42.8
Slovenia	118.7	134.5	118.3	136.5	75.6
Slovakia	62.9	34.3	33.3	33.1	29.0
Finland	33.1	30.0	29.0	29.1	31.1
Sweden	33.2	32.6	28.3	31.3	41.3
Total EU-27	**7,025**	**7,002**	**8,500**	**8,253**	**6,556**
Total EU-27 (# of countries with data available)	20	21	21	21	22
Iceland	0.4	3.1	2.7		
Liechtenstein					
Norway	2.5	2.2		2.1	1.7
Switzerland		63.2			
Total EU-27 + EEA/EFTA	**7,028**	**7,070**	**8,503**	**8,255**	**6,558**
Total EU-27 + EEA/EFTA (# of countries with data available)	22	24	22	22	23

Source: Eurostat SBS.

***Table 5**: Production value in billion EUR*

	2016	2017	2018	2019	2020 (p)
European Union – 27 countries (from 2020)					
European Union – 28 countries (2013-2020)					
Belgium	127.5	112.6	133.4	130.8	130.5
Bulgaria	219.2	242.0	229.6	290.9	175.6
Czechia	873.6	811.7	886.1	890.1	919.6
Denmark					
Germany (until 1990 former territory of the FRG)	2,724.6	2,884.0	3,573.6	3,555.8	2,462.7
Estonia	1.4	1.1			0.9

	2016	2017	2018	2019	2020 (p)
Ireland					
Greece	10.6	8.9	9.3	10.1	9.2
Spain	522.6	525.6	536.8	550.6	491.3
France	388.5	316.7	374.4	377.2	368.6
Croatia		9.3	7.5	7.9	6.0
Italy	641.1	566.0	499.6	608.5	597.2
Cyprus			5.1	4.6	2.6
Latvia	5.6	6.3	5.7	5.9	7.5
Lithuania	3.0	3.5	4.0	6.0	6.3
Luxembourg					
Hungary	164.1	178.7	169.2	174.4	191.2
Malta					
Netherlands					
Austria	518.7	541.3	692.7	485.7	388.9
Poland	198.1	233.8	221.1	244.1	269.4
Portugal	4.3	3.2	4.2	5.3	7.8
Romania	40.1	41.9	58.4	73.5	43.5
Slovenia	118.3	142.6	123.3	138.1	58.1
Slovakia	42.2	23.1	25.7	30.8	24.7
Finland	30.1	25.1	30.9	23.6	26.9
Sweden	30.8	31.1	25.5	29.3	38.5
Total EU-27	**6,664**	**6,709**	**7,616**	**7,643**	**6,227**
Total EU-27 (# of countries with data available)	20	21	21	21	22
Iceland	0.4	2.8	2.9		
Liechtenstein					
Norway	2.5	2.2		2.1	1.7
Switzerland		62.9			
Total EU-27 + EEA/EFTA	**6,667**	**6,776**	**7,619**	**7,645**	**6,229**
Total EU-27 + EEA/EFTA (# of countries with data available)	22	24	22	22	23

Source: Eurostat SBS.

***Table 6**: Number of persons employed among toy producers*

	2016	2017	2018	2019	2020 (p)
European Union – 27 countries (from 2020)		**55,786**	**58,910**	**61,153**	
European Union – 28 countries (2013-2020)	**60,612**	**60,330**			

Belgium	602	743	679	732	574
Bulgaria	2,663	2,867	2,843	2,855	2,886
Czechia	7,278	7,327	7,180	7,206	7,308
Denmark					
Germany (until 1990 former territory of the FRG)	14,383	14,287	16,161	18,024	13,353
Estonia	36	38			33
Ireland					
Greece	211	238	304	287	284
Spain	3,363	3,337	3,389	3,490	3,397
France	2,366	2,057	2,394	2,857	
Croatia	122	170	135	163	165
Italy	2,662	2,643	2,599	2,378	2,358
Cyprus			64	58	41
Latvia	286	293	256	229	243
Lithuania	169	191	213	243	262
Luxembourg					
Hungary	4,093	4,074	3,961	3,955	4,088
Malta					
Netherlands	703	713	864	735	722
Austria	1,848	1,891	2,337	2,242	2,218
Poland	4,182	4,360	4,797	4,794	4,785
Portugal	229	185	214	216	278
Romania	1,836	2,018	2,550	2,364	1,642
Slovenia	465	525	568	596	558
Slovakia	634	611	684	749	750
Finland	192	203	220	212	191
Sweden	182	216	233	218	229
Total EU-27	**48,505**	**48,987**	**52,645**	**54,603**	**49,123**
Total EU-27 (# of countries with data available)	22	22	22	22	23

Iceland	7	27	25		
Liechtenstein					

	2016	2017	2018	2019	2020 (p)
Norway	31	29	32	21	21
Switzerland	403	297	504		
Total EU-27 + EEA/EFTA	**48,946**	**49,340**	**53,206**	**55,150**	**49,652**
Total EU-27 + EEA/EFTA (# of countries with data available)	25	25	25	25	26

Source: Eurostat SBS.

ANNEX 5. SME TEST SUMMARY

Step 1/4: Identification of affected businesses

According to the most recent Eurostat SBS data, SMEs account for 99% of the approximately 6,313 (2020) manufacturers of toys in Europe. In terms of turnover, SMEs account for a fourth of the overall EU market (EURbn 2,19) and they employ about half (approximately 29 thousand) of the workforce in the industry as shown in the charts below.
SMEs are in scope of the revision of the Toys Safety Directive, however the initiative does not specifically target SMEs. According to the estimates, it is likely that the SMEs will be highly impacted by the preferred policy options since these would affect the manufacturing process of certain toys. Due to the nature of the measures – increase of the safety of toys by reducing the limit values of chemical substances and additional restrictions on a wider range of substances – all companies will be affected in their production processes, however, larger companies, due to economies of scale, are likely to be able to better sustain the additional costs (i.e. substitution costs, adjustment costs). On the other hand, these measures increase the safety standards of toys on the European market and are likely to reduce the amount of non-compliant toys (which current estimates are around 20% of the overall EU toys market) and thus reduce the unfair competition of rogue manufacturers. Such measure would impact positively the EU competition and benefit especially the competitiveness of SMEs.

Key question: **To what extent is the initiative relevant for SMEs?** (not relevant, relevant, highly relevant)

This initiative is considered highly relevant for SMEs, as it would impact horizontally all EU businesses operating in the sector due to the nature of the initiatives under Option 1b (increase of the safety of toys) and Option 2b (introduction of the Digital Product Passport).

Step 2/4: Consultation of SME Stakeholders

The public consultation captured the specific input of SMEs by asking respondents to indicate the size of their organisation. The public consultation was signalled to SMEs organisations in general to ensure sufficient feedback in the public consultation. In addition, sectoral organisations (in particular TIE) which include a number of SMEs were also represented in the public consultation, not only at organisation level but also by their individual members. An SME targeted consultation was also carried out to assess the impacts of the different policy options. In terms of the interviews, the questionnaire was also distributed in writing allowing respondents to send their written contributions to this process, too, with a number of SMEs providing their contributions. This ensured that SME feedback was captured from different sources.
The compliance efforts are expected to be significant, in particular regarding the substitution costs and the adjustment costs. The impact assessment conducted a specific survey targeting SMEs which sought the participation of 201 businesses.
The input received in the survey by SMEs has informed significantly the analysis and provided precious information for the calculation of the administrative burden and other costs and potential benefits for SMEs.
In particular, respondents consider that the biggest sources of compliance costs linked to the application of the TSD are: (1) bureaucracy and extent of requirements, (2) need for specific knowledge or skills and extensive human resources for following the changing requirements and (3) testing requirements (especially done separately for similar products).
The input provided by SMEs has been carefully considered in the choice of the preferred option, and in particular the options to address the problem of the high number of non-compliant products. As such, options 2a and 2c increasing the number of products that should be subject to third-party conformity assessment were ultimately not chosen. In particular, while option 2c was considered to yield the most benefits in terms of reducing non-compliant products and streamlining market surveillance for toys, it was deemed to be particularly burdensome for SMEs.

Step 3/4: Assessment of the impact on SMEs

In the SME survey, companies were also asked to provide several quantitative information which allowed for the calculation of the compliance costs of the TSD for SMEs (baseline) and the estimates of the proposed policy options. More specifically, SMEs were asked:

1. Main causes of compliance costs, linked to the application of the Toy Safety Directive;
2. Measures that would help reducing costs for SMEs;
3. Type of costs of an EU type examination before introducing a new product (toy);
4. Cost of an EU type examination before introducing a new product (toy) (staff, outsourcing, equipment);
5. Cost of testing of a new toy-model (staff, outsourcing, equipment);
6. Costs of replacing / redesigning a new product if the product is found to be not compliant (or not compliant any more due to new regulations)? (staff, outsourcing, equipment)
7. Costs of adapting the labels indicating the chemical content of a product (staff, outsourcing, equipment);
8. Costs of making available the declaration of conformity online (per toy model) (staff, outsourcing, equipment)
9. Number of new Stock Keeping Unit (SKU), per year, to which the administrative costs would apply.

These estimates supported the quantification of the impacts on businesses of the proposed policy options individually and by business size. Nevertheless, the uncertainty of some aspects of the proposed measures (i.e. the actual means of implementation of the DPP, the expected increase of the share of toys subject to additional testing costs, etc.) allowed only for some approximation of the impacts.

Step 4/4: Minimising negative impacts on SMEs

SMEs are particularly concerned about the costs of banning additional chemicals in toys, as well as the possible impacts on their competitive position. In the SME survey, respondents were directly asked about potential measures able to minimize the negative impacts and maximise benefits. The respondents identified a number of different potential intervention points through which the most difficult compliance costs could be to a certain degree alleviated. In particular, SMEs requested that the procedures should be simplified and that an advisory support should be offered as many producers and sellers (especially among the SMEs) are struggling to understand the requirements as they pertain to their businesses. If hands-on and preferably free consultancy would be available on the different rules regarding production, labelling and packaging that would certainly alleviate some of the administrative burdens currently felt. Finally, testing of products should be alleviated as much as possible.

The final policy options were selected also taking into account the need to achieve the policy objectives in a manner which creates less burden to SMEs. First of all, while the introduction of the generic bans for chemicals certain hazard classes in toys will have costs for companies, and it may be more costly for SMEs, the possibility for derogations under this PO will mitigate the negative impacts to a certain extent. A sufficient transition period will be granted to allow for the costs to be accrued gradually rather than upfront. The actual implementation of this policy option in the future legal text will strive to make the provisions as straightforward for SMEs as possible, and in a manner that limits the need to carry out additional testing as much as possible. While PO2c was considered to be most effective in achieving the pursued policy objectives of reducing non-compliant products, it was ultimately not chosen as it could prove to be too burdensome for reputable industry, including SMEs. Indeed, it was considered only compliant manufacturers would face the additional costs of third-party certification, and that the policy objectives could be achieved with other policy options less burdensome. Finally, in order to help SMEs in complying with the toy safety rules, the Commission will continue relying on harmonised standards as well as producing and regularly updating a significant body of Guidance documents on all aspects related to toy safety.

ANNEX 6: LEGAL CONTEXT: MAIN PROVISIONS OF THE TOY SAFETY DIRECTIVE AND MARKET SURVEILLANCE

1. DEFINITION OF 'TOYS'

The scope of the Toy Safety Directive covers all 'products designed or intended, whether or not exclusively, for use in play by children under 14 years of age'.[194] Thus, a product does not have to be exclusively intended for playing purposes in order for it to be considered as a toy, but can have other functions as well. For example, a key-ring with a small plush teddy bear attached to it is considered as a toy, or a toy plastic figurine with a pencil sharpener in its foot.[195]

The main difficulty of this definition is the concept of 'use in play' or 'play value'. Children may play with virtually everything, but this does not make every object fall within the definition of 'toy'. To be considered as a toy for the purposes of the Directive, the play value has to be introduced in an intended way by the manufacturer since the intention for a (certain) use is included in the definition of 'toy' itself.

On the other hand, 'whether exclusively or not' requires to consider whether a product can have a play value in addition to its intended use, such as in the case of the above-mentioned key-ring with a small plush teddy bear attached to it. Since that product may as well be used by children in play, in addition to its primary function as key-ring, the product is considered to be a toy. The declaration by the manufacturer of the intended use is thus only one of the criteria to be considered, the reasonably foreseeable use in play is considered to prevail over the declaration of the intended use by the manufacturer.[196]

The Directive does however not apply to some products for public use fulfilling the definition of toys, such as playground equipment intended for public use, automatic playing machines, whether coin operated or not, when intended for public use.[197] Moreover, Annex I to the Toy Safety Directive enumerates examples of products that are not considered as toys but could be confused with toys. Since it would be impossible to enumerate all the products that are not considered as toys, the list is not exhaustive.

2. ESSENTIAL SAFETY REQUIREMENTS

The Toy Safety Directive lays down the safety criteria ('essential safety requirements') that toys must meet before they can be marketed in the EU. Toys must also comply with other EU legislation applicable to them, such as the following: 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

[194] Article 2.1 of the Toy Safety Directive.
[195] Paragraph 4 of section 2 of Guidance document No 4 'Grey zone problem: Is a specific product covered by the Toy Safety Directive 2009/48/EC or not?'
https://ec.europa.eu/growth/sectors/toys/safety/guidance/
[196] Paragraph 5 of section 2 of Guidance document No 4.
[197] Article 2.2 of the Toy Safety Directive.

(REACH),[198] 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,[199] and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).[200]

The essential safety requirements are designed to ensure a high level of product safety. They may cover identified hazards related to the characteristics of the product or to the product performance.[201] As a consequence there may be several safety requirements associated to the same product.

The essential safety requirements in the Toy Safety Directive cover:

- **general risks:** the health and safety of children, as well as other people such as parents or supervisors;
- **particular risks:** physical and mechanical, flammability, chemical, electrical, hygiene and radioactivity risks.

3. THE REQUIREMENTS FOR CHEMICAL SUBSTANCES IN DETAIL

- Chemicals that are susceptible to cause cancer, change genetic information, harm fertility or harm an unborn child ('CMR substances' [202]) are not allowed in toys beyond the concentration limits set in the CLP, or unless they are inaccessible to children, including by inhalation, or considered safe following a rigorous scientific evaluation and if they are not prohibited in consumer articles under REACH. In addition, for CMR substances of categories 1A and 1B which are of most concern, no suitable alternatives must exist. (For CMRs category 2, no analysis of alternatives is necessary.)
- Limit values are set out for nitrosamines (0,05 mg/kg) and for nitrosatable substances (1 mg/kg).
- 19 'elements' such as mercury or cadmium are not allowed in toy parts accessible to children beyond the limits laid down in Toy Safety Directive.[203] The Directive draws a distinction among three types of materials used in toys – dry, brittle, powder-like or pliable; liquid or sticky; scraped-off – each subject to a different migration limit.
- 58 allergenic fragrances are prohibited because the relevant Scientific Committee considered that they must not form part of cosmetic products due to their

[198] 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.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20180301
[199] 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 (Text with EEA relevance). OJ L 353, 31.12.2008, p. 1.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20180301
[200] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 22.12.2009, p. 59.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20171225
[201] The 'Blue Guide' on the implementation of EU product rules
[202] Substances that are carcinogenic, mutagenic or toxic for reproduction.
[203] Annex II, part III, point 13 of the Toy Safety Directive.

allergenicity in most cases (fragrances 1 to 31 and 36 to 40);[204] or they were (photo-) allergenic (fragrances 32 to 35);[205] or because they were most frequently reported as contact allergens (fragrances 41 to 53);[206] or because they contain allergenic species (fragrances 54 to 55).[207] The presence of traces of these 55 fragrances is however allowed if technically unavoidable under good manufacturing practice and if they do not exceed 100 mg/kg.

- A further 72 allergenic fragrances may be used in toys on condition that they are labelled when their concentration exceeds 100 mg/kg in the toy or any of its components. They were less frequently reported as contact allergens.[208]

- For 15 of the prohibited allergenic fragrances (namely numbers 41 to 55) and for the 11 allergenic fragrances that are to be labelled, specific conditions apply if such fragrances are used in olfactory board games, cosmetic kits and gustative games. Among others, the toys have to carry the warning that they are not suitable for children under 36 months.

- Specific limit values can be set for any chemical in toys but these limit values can only apply to toys for children under 36 months (who take 'everything' into their mouth) and to toys intended to be placed in the mouth, since those toys lead to a high exposure of children to chemicals. As a result, a new appendix C includes limit values in toys intended for children under 36 months or to be put in the mouth for the following chemical substances: TCEP, TCPP and TDCP, Bisphenol A, Formamide, Benzisothiazolinone, chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1, Phenol, formaldehyde and aniline.

4. HOW THE DIRECTIVE IS KEEPING UP WITH PROGRESS

In order to keep pace with latest technical and scientific developments, the Commission can amend certain parts of the Toy Safety Directive via the Regulatory Procedure with Scrutiny (RPS).[209] Such procedure may be used to amend specific provisions. It may adapt Annex I that lists examples of products that are not toys (but may be confused with them), the list of prohibited allergenic fragrances and the list of allergenic fragrances to

[204] Scientific Committee on Non-Food Products (SCCNFP) An initial list of perfumery materials which must not form part of cosmetic products. Opinion SCCNFP/0320/00 final, 3.5.2000.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out116_en.pdf
[205] Scientific Committee on Non-Food Products (SCCNFP) An update of the initial list of perfumery materials which must not form part of cosmetic products. Opinion SCCNFP/0771/03 final, 9.12.2003.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out251_en.pdf
[206] Scientific Committee on Non-Food Products (SCCNFP) Fragrance allergy in consumers. Opinion SCCNFP/0017/98 final, 8.12.1999. Table 6a, p. 22.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf
[207] Scientific Committee on Non-Food Products (SCCNFP) An initial list of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down. SCCNFP/392/00 final, 25.9.2001
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out150_en.pdf
and Scientific Committee on Consumer Products (SCCP) Opinion on Oak moss / Tree moss (sensitisation only). SCCP/1131/07, 15.4.2008.
https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_131.pdf
[208] Scientific Committee on Non-Food Products (SCCNFP). SCCNFP/0017/98 final, 8.12.1999, Table 6b, p. 23. See footnote above.
[209] Article 46 of the Toy Safety Directive.

be labelled in Annex II, it may adapt the limit values for heavy metals and other hazardous metals I Annex II, and the warnings for toys in Annex V.

In addition, the Commission may establish maximum limit values for any chemical in toys intended for children under 36 months of age and in all toys intended to be placed in the mouth, and it may also amend those limits (Appendix C to Annex II).

Finally, the Commission may allow the use of chemicals that are carcinogenic, mutagenic or toxic to reproduction (CMRs), albeit only following a strict scientific-technical assessment including an independent Scientific Committee.

In the period 2012 – 2020, the Directive was amended 17 times to address newly identified chemical risks and to revise limit values for chemicals such as chromium VI, lead, phenol, bisphenol A. The list of the amendments so far adopted is presented in section 8 below.

5. TOY SAFETY STANDARDS

As described above the Toy Safety Directive establishes the mandatory 'essential' health and safety requirements for toys. However it does not translate those requirements into detailed specifications for testing toys. These are provided by toy safety standards that are thus 'supporting' the Directive.

For example, '[t]oys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.'[210] In short, toys for children under 36 months (who take 'everything' in their mouth) and toys intended to be put in the mouth (such as a toy flute) must not be or release small parts on which a child can choke.

Standard EN 71-1 supports this requirement of the Directive by setting specifications how to test such toys: Any small part must not fit in the 'small parts cylinder',[211] which has the dimensions of a small child's throat. Even more, the standard also specifies that a toy for children under 36 months must not break off into small parts when it is dropped or compressed, or when someone is trying to pull off or twist off a part of the toy. [212] The standard thus sets the detailed specifications for testing a toy against the Directive's requirements.

European standards are developed by recognised European Standardisation Organisations (ESOs): CEN,[213] CENELEC,[214] and ETSI.[215] If developed following a request from the European Commission, the resulting standards are called European 'harmonised' standards.

[210] Annex II, Part I, point 4 (d) of the Toy Safety Directive 2009/48/EC.
[211] Standard EN 71-1:2014+A1:2018, clause 5.1 a).
[212] Standard EN 71-1:2014+A1:2018, clause 5.1 b).
[213] European Committee for Standardization. https://www.cen.eu/Pages/default.aspx
[214] European Committee for Electro-technical Standardization. https://www.cenelec.eu/
[215] European Telecommunications Standards Institute. https://www.etsi.org/

If a standard's specifications are considered sufficiently strict so that they indeed support the Directive, the Commission publishes a reference to the standard in the Official Journal. With such publication, a toy that complies with the specifications of the standard is presumed to be in conformity with the Directive, and thus to be safe. It will therefore be hardly possible for any market surveillance authority to restrict or ban the marketing of such a toy.

The use of European harmonised standards is voluntary, including for toys. Manufacturers can refer to harmonised standards to demonstrate that their products comply with the relevant EU legislation. Even more so, when toys are manufactured in conformity with European harmonised standards, the references of which have been published in the Official Journal of the EU (OJEU), they are presumed to comply with the essential safety requirements of the Toy Safety Directive that are covered by those standards. Due to those toys being presumed to comply, and thus presumed to be safe, hardly any market surveillance authority will restrict the marketing of such a toy.

Since 1 December 2018 the references of harmonised standards are published in, and withdrawn from, the Official Journal of the European Union by means of 'Commission implementing decisions'. The latest list of 11 European harmonised standards on toy safety referenced in the Official Journal[216] is below:

Toy safety standards, the references of which have been published in the Official Journal

No	Reference of standards published in the Official Journal
1.	EN 71-1:2014+A1:2018 Safety of toys – Part 1: Mechanical and physical properties
2.	EN 71-2:2020 Safety of toys – Part 2: Flammability
3.	EN 71-3:2019+ A1:2021 Safety of toys – Part 3: Migration of certain elements
4.	EN 71-4:2020 Safety of toys – Part 4: Experimental sets for chemistry and related activities
5.	EN 71-5:2015 Safety of toys – Part 5: Chemical toys (sets) other than experimental sets
6.	EN 71-7:2014+A3:2020 Safety of toys – Part 7: Finger paints – Requirements and test methods
7.	EN 71-8:2018 Safety of toys – Part 8: Activity toys for domestic use
8.	EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances *Informative note*: The limit values in point (a) of Table 2 of clause 4.2 of standard 'EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances' are lower than the limit values to be complied with set in point 8 of part III of Annex II to Directive 2009/48/EC. In particular those values are as follows:

[216] Commission Implementing Decision (EU) 2021/1992 of 15 November 2021 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council, OJ L 405, 16.11.2021, p. 14 http://data.europa.eu/eli/dec_impl/2021/1992/oj

	Substance	Standard EN 71-12:2016	Directive 2009/48/EC
	N-nitrosamines	0,01 mg/kg	0,05 mg/kg
	N-nitrosatable	0,1 mg/kg	1 mg/kg.
9.	EN 71-13:2021 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games		
10.	EN 71-14:2018 - Safety of toys — Part 14: Trampolines for domestic use		
11.	EN IEC 62115:2020 Electric toys — Safety EN IEC 62115:2020/A11:2020		

6. CONFORMITY ASSESSMENT

Before placing their toys on the Union market, manufacturers must carry out a safety assessment of the toy, to determine the risks that the toy may present as well as the essential requirements of the Toy Safety Directive that are applicable to it. This safety assessment also includes an assessment of the chemical substances in the toy and the risks they may present. This assessment must be documented in the technical documentation drawn up by the manufacturer; this document being of a commercially sensitive nature, is not provided to any economic operator in the distribution chain (for example, it is not to be provided to the importer or distributor) but only to market surveillance authorities upon a reasoned request, and only the parts of the documentation related to that request[217]. The conformity assessment of the toy is then mostly done by internal checks of the manufacturer.

Conformity assessment in the Toy Safety Directive is based on Decision No 768/2008/CE. The essential objective of a conformity assessment procedure is to demonstrate that products placed on the market conform to the requirements expressed in the provisions of the relevant legislation. This Decision contains a number of conformity assessment modules to be used EU product legislation, enabling the legislator to choose a procedure from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. The least onerous modules should be selected taking into account the type of products and hazards involved, the impact on the protection of public interests, the economic infrastructure of the given sector, the methods of production, etc. Conformity assessment must not be confused with market surveillance, which consists of checks by the national market surveillance authorities after the product has been placed on the market. However both techniques are complementary and equally necessary to ensure the protection of the public interests at stake and the smooth functioning of the internal market.

Conformity assessment under the Toy Safety Directive is to be carried out by the manufacturer or by a third party – a 'Notified Body' test laboratory that has been previously recognised for its quality both at national and EU level. In any case, manufacturers remain responsible for the safety of the product also after it has been placed on the market.

[217] See the Blue Guide on the implementation of EU product rules https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

There are two possible conformity assessments allowing toys to be sold in the EU. The manufacturer has to demonstrate the compliance of a toy:

- either via self-verification by exclusively using referenced harmonised European standards;
- or by third party verification through a Notified Body. This procedure applies when existing referenced harmonised standards do not cover all relevant safety requirements, or when the toy manufacturer has not applied or only partly applied referenced harmonised standards, or when a referenced harmonised standard has been published with a restriction,[218] or when the toy manufacturer considers that the characteristics of the toy require a third party verification.

It is the manufacturer, whether established in the EU or outside the EU, who decides which of these two procedures is appropriate for him to follow. Evidence from Notified Bodies suggests that around 97% of toys in the EU market are subject to the self-verification procedure.

By way of comparison with a non-EU regulatory framework, the USA requires a third party conformity assessment for any toy placed on the market in the USA. The only study identified in the desk research for this evaluation compares the US third party conformity assessment with the EU self-verification assessment.[219] The study concluded that third party conformity assessment leads to a much lower number of market restriction measures on toys than the EU self-verification assessment. However, this conclusion does not take account of the intensity of market surveillance in the EU which, according to the study, is higher in the EU than in the USA.

7. IMPLEMENTATION AND STATE OF PLAY

The 2009 Toy Safety Directive has been transposed by all Member States, although such transposition was not notified within the deadline by some of them. Following the failure by several Member States to timely notify the Commission about national transposition measures before the January 2011 deadline, the Commission opened 15 non-communication cases, but all of them were closed before the end of 2011, once transposition had been completed and notified.[220] The data in the European Commission database on infringements show that, except for a few delays in the transposition of the Directive in the member States' legislations, there have not been major problems in the transposition of the Directive and of its amendments into national legislation leading to the opening of infringement proceedings.

However, there have been cases of Member States going beyond the requirements of the Toy Safety Directive. For example, in 2011 Germany submitted an application to obtain the authorisation to maintain its (stricter) national provisions on, among others, nitrosamines and nitrosatable substances. Germany based its request on the need of protection of human health. In support of the request, the German authorities provided

[218] A restriction may change or invalidate certain specification(s) in the standard referenced.
[219] Larson DB, Jordan SR (2018) *Playing it safe: toy safety and conformity assessment in Europe and the United States*. Sage journals. https://journals.sagepub.com/doi/full/10.1177/0020852317747370
[220] Commission Staff Working Document – Situation per Member State Accompanying the document Report from the Commission 29th Annual report on monitoring the application of Community law [COM(2012)714 final] [SWD(2012)399 final], p.50.
https://ec.europa.eu/info/publications/2011-commission-report-monitoring-application-eu-law_en

detailed justifications including scientific studies on the health assessment of the concerned substances. The Commission acknowledged in a 2012 Decision[221] that the limit values for nitrosamines[222] requested by Germany were justified for a part of the toys covered by the Toy Safety Directive limits, due to a 'major need of protection of human health.' The Decision thus allowed Germany to keep its lower, stricter national limits.

Member States are required to appoint competent authorities responsible for the implementation of the Directive at national level and for ensuring that the Directive is effectively enforced within their territories. As such, they are also responsible for market surveillance, including penalties. In addition to that, they appoint and monitor Notified Bodies who assess and certify compliance with the Toy Safety Directive when requested to do so.

At EU level, the European Commission is organising meetings of Member States representatives and other stakeholders in order to support the effective implementation and application of the Directive through, amongst others, sharing of information and best practices, or addressing potential issues and barriers that could arise:

- The Toy Safety Committee is responsible for assisting the Commission in the implementation of the Directive, notably in the adoption of implementing measures. The possibility to adopt such measures is provided in the Toy Safety Directive for the update of certain provisions of the Directive to technical and scientific developments via the regulatory procedure with scrutiny.[223]

- The Expert Group on Toys Safety[224] is the setting for EU Member States, EEA-EFTA countries, Switzerland, Candidate Countries, stakeholders and the Commission. It assists in the consistent implementation of legislation on toy safety across the EU and provides advice on the preparation of new legislative proposals and policy initiatives. The Expert Group also develops guidance material. Its sub-group on Chemicals has been a forum for discussion between representatives of Member States on chemicals of concern and assists the Expert Group in the preparation of amending directives setting (stricter) limit values for chemicals.

- The Administrative Cooperation (AdCo)[225] group brings together the national market surveillance authorities responsible for enforcing the Toy Safety Directive. It enables the cooperation and exchange of information on market surveillance issues, including the discussion of 'grey zone' classification problems (toy or not, toy for children under 36 months of age or for older children, etc.).

- The co-ordination group of Notified Bodies under the Toy Safety Directive, known as NB-Toys, is a forum for the exchange of experience between Notified

[221] Commission Decision 2012/160/EU. OJ L 80, 20.3.2012, p. 19.
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1495625630954&uri=CELEX:32012D0160
[222] 'Nitrosamines' is here understood to mean 'nitrosamines and nitrosatable substances'.
[223] See Articles 46 and 47 of the Toy Safety Directive.
[224] Register of Commission Expert Groups and other similar entities.
http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1360
[225] The Toys-AdCo is the closed session of the Expert Group on Toys Safety (E01360) and comprises only market surveillance authorities.

Bodies. It meets twice a year in order to harmonise their practices through the adoption of guidance documents, also known as Recommendations and Protocols, to help them fulfil their tasks.[226] They are applied by the Notified Bodies on a voluntary basis.

Another important mechanism supporting the implementation of the Toy Safety Directive is European standardisation. Industry representatives active in the European standardisation organisations (CEN, CENELEC) together with Member States and consumer organisations have developed so far 11 harmonised European standards (hENs) which have been referenced in the Official Journal and thus give presumption of conformity and therefore facilitate the implementation of the Toy Safety Directive.[227] Harmonised standards translate the essential safety requirements of the Toy Safety Directive into detailed technical specifications for a large range of toys.

8. AMENDMENTS TO THE TOY SAFETY DIRECTIVE

To adapt the safety requirements on chemicals in toys to the latest technical and scientific developments, the Commission can amend certain parts of the Directive. The following amendments have so far been made:

1) June 2021: Adoption of specific limit values for aniline in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2021/903)
2) December 2020: Addition of 50 allergenic fragrances which are subject to labelling requirements in toys (Commission Directive (EU) 2020/2088)
3) December 2020: Prohibition of 3 additional allergenic fragrances in toys (Commission Directive (EU) 2020/2089)
4) November 2019: Adoption of specific limit values for the monomer and preservative formaldehyde in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2019/1929)
5) November 2019: Revision of the migration limits for aluminium (Commission Directive (EU) 2019/1922)
6) May 2018: Revision of the specific limit value for chromium VI (Commission Directive (EU) 2018/725)
7) May 2017: Revision of the specific limit value for the monomer bisphenol A in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2017/898)
8) May 2017: Adoption of specific limit values for the monomer and preservative phenol in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2017/774)
9) March 2017: Revision of the migration limits for lead (Council Directive (EU) 2017/738)
10) November 2015: Adoption of specific limit values for the preservatives chloromethylisothiazolinone (CMI), methylisothiazolinone (MI) and CMI and MI mixed together in a ratio of 3 to 1 (CMI/MI 3:1) in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2015/2117)

[226] Recommendations and Protocols under the Toy Safety Directive are available at https://ec.europa.eu/growth/sectors/toys/safety/guidance_en
[227] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/toys_en

11) November 2015: Adoption of a specific limit value for the preservative benzisothiazolinone (BIT) in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2015/2116)
12) November 2015: Adoption of a specific limit value for formamide in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive (EU) 2015/2115)
13) June 2014: Additional permitted use of the CMR substance nickel (Commission Directive 2014/84/EU)
14) June 2014: Adoption of a specific limit value for the monomer bisphenol A in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive 2014/81/EU)
15) June 2014: Adoption of specific limit values for the three flame retardants TCEP, TCPP and TDCP in toys intended for children under 36 months and in other toys intended to be placed in the mouth (Commission Directive 2014/79/EU)
16) July 2013: Revision of the migration limits for barium (Commission Regulation (EU) No 681/2013)
17) March 2012: Revision of the migration limits for cadmium (Commission Directive 2012/7/EU)

9. ENFORCEMENT OF THE TSD: MARKET SURVEILLANCE

The TSD imposes responsibilities on various economic operators along the toy supply chain and on competent national authorities. By way of overview, the relevant obligations of economic operators are as follows:

- Toy manufacturers are exclusively responsible for conducting a complete conformity assessment of their toys before placing them on the market (Articles 4 and 18 TSD). This is done either through a self-verification procedure if harmonised European standards are used, (Article 19 TSD) or through a third-party assessment by a notified body (Article 20 TSD).
- Toys' importers have the responsibility to ensure that the imported toys comply with the relevant EU rules and that the necessary conformity assessment has been conducted (Article 6 TSD).
- Toys' distributors have the responsibility to ensure that the toys have the necessary conformity marking and accompanying documentation (Article 7 TSD).

Market surveillance is carried out for the TSD in line with Regulation 2019/2020 on market surveillance. The competent national authority (market surveillance authority) must organise and perform the surveillance of the market within its jurisdiction (Chapter VI TSD). This includes testing toys, verifying toys' documentation, ordering withdrawals and recalls of toys from the market if they present a safety risk and other tasks.

Market surveillance authorities have to perform appropriate checks on an adequate scale of products made available online and offline (Article 11(1)(a) and 11(3) of Regulation (EU) 2019/1020). For market surveillance to be efficient, a risk-based approach has to be followed (Article 11(3) of Regulation (EU) 2019/1020). Resources should be concentrated where risks are likely to be higher or non-compliance more frequent. The risk-based approach should take into account aspects of products (level of potential hazards, non-compliance and associated risks; occurrence on the market), economic operators (activities and operations, past record of non-compliance) and information

about both received from other actors (such as border control authorities, consumer complaints, media) as well as other sources that might indicate non-compliance such as incidents and accidents.

Market surveillance authorities do not necessarily check all the possible requirements on, or all properties of, a product. Usually, only some of these requirements and properties are selected for inspection.

Checks by market surveillance authorities may include inter alia: — conducting online inspections; — visiting commercial, industrial and storage premises; — visiting, if appropriate, work places and other premises where products are put into service; requesting necessary information; and — taking samples of products, and to subject them to examination and testing.

The first level of control comprises documentary and visual checks, for example regarding the CE marking and its affixing, the availability of the EU declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. In the case of online checks, the first level of control is checking the information available on the website where the product is offered for sale, potentially followed by requesting compliance documentation or acquiring the product for further inspection. More in-depth checks may, however, be necessary to verify the conformity of the product, for example regarding the correct application of the conformity assessment procedure, the compliance with the applicable essential requirements, and the contents of the EU declaration of conformity. Especially when there are sufficient reasons to believe that a product presents a risk, market surveillance authorities carry out an evaluation in relation to the product concerned covering the requirements of the relevant Union harmonisation legislation.

Where, having performed an evaluation, a market surveillance authority finds that a product is non-compliant or that a product is compliant but presents a risk to the health or safety of persons or to other aspects of public interest protection, it has to follow a sequence of procedures aimed at ensuring that appropriate and proportionate action is undertaken across the EU. These procedures are laid down in Articles 16, 18, 19 and 20 of Regulation (EU) 2019/1020 and, for a large part, in more detail in the TSD, in line with the safeguard procedures laid down in Articles 42 and 43 of the TSD.

9.1. Enforcement in online sales

The adoption of the **Regulation 2019/1020 on market surveillance**[228] is expected to lead to stronger and more consistent checks on products by national market surveillance authorities across the EU. In particular, toys as products with a high risk of non-compliance can only be placed on the EU market if there is an economic operator (i.e. manufacturer, importer, authorised representative of these toys or the fulfilment service provider) established in the EU and responsible for a number of tasks in relation to the compliance of the toy (Article 4 of the Market Surveillance Regulation).

The inclusion of fulfilment service providers in the scope of Regulation 2019/1020 closes a significant gap that had emerged in market surveillance due to the development of business models supporting e-commerce, in particular the growing importance of online platforms. However, currently, the gaps in the coverage of the supply chain of toys

[228] 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 of 25.06.2019.

persist as various online intermediaries enabling sales of toys in the EU are not yet included in the surveillance mechanism. This would change once two legal acts recently adopted become applicable: the General Product Safety Regulation and the Digital Services Act.

The **General Product Safety Regulation** (GPSR) **2023/988** will replace the GPSD.[229] The GPSR is designed to be a safety net, just like the GPSD, and it will apply to the toys as long as there are relevant aspects not covered by the TSD (Article 2 GPSR). The GSPR will considerably enhance the safety of products, especially by introducing new rules applicable to the products (including toys) sold online; these provisions will apply to all consumer products, including toys.

Article 19 GPSR lists minimum information requirements for the products sold online or other means of distance sales, which includes any warning or safety information that must accompany those products in accordance with the applicable legislation. This will include all safety information on the toys sold. To enable such information provision, online marketplaces must design and organise their interface so that this mandatory information can be provided by the trader. To effectively and efficiently inform consumers about any safety issues with the products they purchased, the GPSR introduces an obligation for economic operators to notify all affected consumers that they can identify of the safety issues. To this end, economic operators can make use of the personal data they collect on consumers.

Chapter VI GPSR contains a new set of rules on the Safety Gate rapid alert system and how notifications should be exchanged via it. Importantly, Article 25 GPSR also states that the European Commission shall maintain a Safety Business Gateway – a web-based portal, through which economic operators can inform consumers (and competent authorities) about product safety issues. In this way, economic operators shall inform consumers about safety accidents.

Under Article 22 (4) GPSR, market surveillance authorities shall have the power to order online marketplaces to "*remove specific illegal content referring to a dangerous product from its online interface, to disable access to it or to display an explicit warning to end-users when they access it*". Furthermore, online marketplaces shall take into account regular information on dangerous products received via the Safety Gate and apply their voluntary content management measures to them.

The GPSR complements both the TSD and other relevant legislation by strengthening product safety rules in relation to online sales, which is the way of product acquisition that has grown considerably, especially due to the pandemic. Whilst online sales via marketplaces have grown exponentially in recent years (see analysis of market size and structure which includes estimates), a further major trend relates to the Direct to Consumer (D2C) element whereby producers in the EU and third countries sell products directly to consumers without the need for an importer, distributor or other intermediary, such as an online platform.

The new rules seem to be well designed to improve consumer information both before the purchases and after if a product safety issue comes to the fore. The new rules add

[229] 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.

more channels for communication between consumers and economic operators and economic operators and competent authorities.

These provisions of the GPSR are complementary to the provisions of the proposed **Digital Services Act** (DSA)[230] that will apply to online platforms of various kinds and to different types of online content. In particular, according to Recital 12 DSA, the term "illegal content" shall be understood as information – disregarding its form – relating *inter alia* to illegal products (for instance, textual descriptions and images of toys do not have the required CE marking). Concerning illegal products – namely such that do not comply with the relevant EU or national legislation – several additional obligations are imposed on online platforms.

9.2. Customs controls

The TSD requires enforcement as a prohibition and restriction at entry from the EU customs territory. Such enforcement of the current TSD is carried out within the framework of Regulation 2019/1010 on market surveillance.

All products made available on the Union market must comply with the applicable EU legislation, irrespective of their origin. The most effective approach to prevent non-compliant products or products presenting a risk from entering the EU is to carry out controls during the import process, before the products are released for free circulation and can subsequently circulate within the European Union. Thus, the authorities in charge of the control on products entering the Union market (mostly, though not always, customs and therefore hereafter referred to as 'border authorities') play a crucial role in carrying out first-line controls on the compliance and the absence of risks on products originating from third countries (hereafter referred to as 'border controls').

9.2.1. Role of border authorities

Border authorities may be the customs authorities of a Member State, market surveillance authorities or other entities depending on the national organisational structure (Article 25(1) of Regulation (EU) 2019/1020). In most countries, border controls are carried out by customs authorities. However, customs officials usually do not have the technical expertise to decide on compliance with the applicable EU product legislation: for this, they have to refer suspicious cases identified in their controls to the competent market surveillance authorities. Border controls therefore require close cooperation between customs and market surveillance authorities in order to be effective. When the border authority is a market surveillance authority, it can carry out its tasks autonomously in its fields of competence and does not have to interact with another authority in order to reach conclusions.

9.2.2. Principles of border controls

Border authorities perform controls on imported products regardless of their means of transport (sea, air, road, rail, inland waters) or shipment (containers, small packages and any other form). They perform such controls on the basis of risk analysis in accordance with the Union Customs Code. Where relevant, they should also consider the risk-based approach required from market surveillance authorities by Article 11(3) of Regulation (EU) 2019/1020 (Article 25(3) of Regulation (EU) 2019/1020). Border authorities and

[230] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act)

market surveillance authorities should regularly exchange risk information in order to increase the effectiveness of their risk analysis and the risk-based approach. In particular, market surveillance authorities are required to provide border authorities with information on the categories of products and economic operators that are more often found to be non-compliant (Article 25(5) of Regulation (EU) 2019/1020). This information should be regularly updated.

Border authorities may perform documentary or physical checks, and may also carry out laboratory checks. They may always contact the declarant or another relevant economic operator to request documents or additional information. The conditions for detailed controls, such as laboratory checks, can be agreed between customs authorities and market surveillance authorities, taking into account the working method they consider most efficient. Customs and market surveillance authorities should in any case work in close cooperation with each other.

The release for free circulation shall not be deemed to be proof of conformity with Union law (Article 27 of Regulation (EU) 2019/1020), since such a release does not necessarily include a complete check of compliance. Thus, even if released for free circulation, products may later be checked by market surveillance authorities and can be found non-compliant.

ANNEX 7: TOYS MARKET

Market research estimates place the size of the global toys industry in the range of **EUR 86-109 billion in sales in 2019**, growing from around EUR 81.7 billion in 2016.[231,232] As detailed further below, the European toys market achieved turnover of at least EUR 8.3 billion in 2019, increasing from EUR 7 billion in 2016. For 2019, this placed the European share of the global toys market at 7.6 - 9.7%, representing a significant decrease from the 28% market share calculated for 2011 in the context of the 2013 study on the competitiveness of the European toy industry. However, given missing data within Eurostat and a lack of clarity on the definitions and parameters used for the global toy industry market research, this key competitiveness figure should be viewed with caution.

This reduction in market share is supported by data on imports. In 2017, the EU was found to be the biggest global importer of toys with EUR 7.2 billion value of toy imports. The value of EU toy imports had grown by an estimated 70% during the preceding decade. The majority of toys imported to the EU come from Asia, with China the biggest supplier and the ASEAN countries, such as Thailand and Vietnam, increasing the volume of exported toy products.[233] The ASEAN countries are the third biggest toy exporters globally after China and Europe.[234]

Overview of the European toys industry

Overall, the data show that, since the *Study on the Competitiveness of the European Toys Industry* was published in 2013, **key industry indicators have experienced some turbulence, but have overall shown modest growth to 2019**:[235]

- There has been a favourable evolution in market size over the past decade. In the *Study on the Competitiveness of the European Toys Industry (2013),* based on 2010 data, there were around 5,300 enterprises. Although this figure was very similar in **2016 (5,332 enterprises)**, the European toys industry has experienced an increase in the years since to an **estimated 6,067 in 2019** and **6,313 in 2020.** This 18.4% increase has arisen despite Brexit (the UK also has a large toy manufacturing sector) and the COVID-19 pandemic.
- Regarding **turnover**, the picture is more static over the last decade. Whereas sectoral turnover for the European toys market was EUR 7.9 billion in 2008, it dropped to just under EUR 6 billion in 2012 and 2013. By 2016, it had risen to

[231] Khajeheian, D. (2018). *Market analysis, strategy diagnosis and opportunity recognition in toy industry* [in:] "International Journal of Entrepreneurship and Small Business", 33(2), DOI:10.1504/ijesb.2018.090138, p. 221.

[232] https://www.toyassociation.org/ta/research/data/population/toys/research-and-data/data/global-sales-data.aspx

[233] Ismail, R., et al. (2020). *Toy Safety in the ASEAN and European Union: A Comparative Approach* [in:] International Journal of Innovation, Creativity and Change, vol. 10/11, online, p. 118-119.

[234] Ismail, R., et al. (2021). *Towards a Framework for Establishing Children's Toys Safety Policy in ASEAN* [in:] "International Journal of Academic Research in Business and Social Sciences", vol. 11(3), DOI:10.6007/IJARBSS/v11-i3/8812, p. 894.

[235] As described further throughout, the 2020 Eurostat Structural Business Statistics (SBS) data is provisional and incomplete. For all indicators, this analysis presents overall figures based on available country-level data for the EU27 + EEA/EFTA, as well as data imputations where appropriate. As such, no figures consider data from the UK.

around EUR 7 billion before increasing further to EUR 8.5 billion in 2018 and EUR 8.3 billion in 2019. However, as for much of the global economy, 2020 also saw a downturn in turnover within the EU toys industry, to around EUR 6.6 billion (based on provisional Eurostat SBS data).

- Considering **employment,** around 53,000 persons were employed in the EU toys sector in 2010. This had decreased to just under 49,000 in 2016 before increasing to 55,150 by 2019 (a 4.1% increase). As for turnover, and due to COVID-19, provisional data for 2020 indicates a decrease in the number of employed persons in the EU toys market to an estimated 49,652 employees.
- **Turnover per enterprise**, **turnover per employee** and **employees per enterprise** generally follow similar trends, with a decrease from 2008/2010 to 2016, before growth to 2018-2019 and poor performance in 2020.

Table 7: Key indicators – European toy industry 2016-2020 (in million EUR)

Key indicators	2016	2017	2018	2019	2020 (p)
Turnover	€ 7,028	€ 7,070	€ 8,503	€ 8,255	€ 6,558
Enterprises	5,332	5,448	5,826	6,067	6,313
Employees	48,946	49,340	53,206	55,150	49,652
Turnover per enterprise	€ 1.32	€ 1.30	€ 1.46	€ 1.36	€ 1.04
Turnover per employee	€ 0.14	€ 0.14	€ 0.16	€ 0.15	€ 0.13
Employees per enterprise	9.18	9.06	9.13	9.09	7.87

Over this period, a **few notable market developments have emerged within the global toy industry**. Most prominently, in contrast to the decreasing EU share of the global market, the role of Chinese manufacturers has continued to grow. The influence of online sales and online marketplaces has significantly increased, with global online sales of toys estimated to have increased by an estimated 20% just in 2020-2021.[236] Considering the types of toys placed on the EU market, market research reports indicate increasing popularity of eco-friendly toys, as well as toys with digital components (e.g. internet-connected or AI-driven toys).[237] While the demand for innovative digital toys may be increasing, European manufacturers interviewed for this study have so far limited their development of internet-connected and AI-driven smart toys. This reticence is primarily due to instances of toy products being placed on the EU market without sufficient cybersecurity protections, thus leaving children vulnerable and impacting the reputation of manufacturers (e.g. My Friend Cayla doll[238]).

Beyond these market changes, some **structural characteristics of the European toy industry have remained similar** to those identified in the 2013 competitiveness study. For instance:

[236] https://www.npd.com/news/thought-leadership/2021/whats-driving-online-toy-sales/
[237] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/
[238] Holloway, D. & Green, L. (2016). *The Internet of Toys.* [in:] "Communication Research and Practice, Special Issue: ANZCA 2016 Creating Space in the Fifth Estate", Vol. 2, Issue 4, (eds. Fulton, J. & McIntyre, P.), DOI: 10.1080/22041451.2016.1266124, p. 513.

- There remains a strong geographical concentration of the European toy manufacturing industry both in terms of the number of enterprises, production and turnover.
- However, there are some differences based on which indicator is in question. For instance, whereas 8 countries (PL, FR, DE, NL, CZ, ES, SK and IT) cumulatively account for 73.2% of all enterprises, the share of turnover is much higher in some countries (e.g. DE, AT) relative to their share of the number of enterprises.
- A large proportion of European toy companies are reportedly SMEs. In 2020, the proportion was reportedly 99% of companies, employing around two thirds of employees in the sector.[239]
- Many toy manufacturing companies in Europe outsource a significant amount of their total production to East Asia, mainly China.

Shortcomings in official statistics and mitigation measures

It is important to highlight data gaps and shortcomings in the quality of data. The statistical analysis was partly hampered by data gaps in Eurostat SBS data in some Member States and EEA / EFTA countries, especially for some variables, such as turnover and the number of people employed. In some cases, there were insufficient data for Eurostat to estimate the total for the EU-27, while those estimates that are available are marked as low reliability by Eurostat. The most recent year for which data was available was 2020 for some variables, but there were provisional estimates only and remained gaps.

Regarding mitigation measures, we have focused on reporting the sum of the available data across the EU-27 and EEA/EFTA countries, rather than the overarching Eurostat EU-27 estimates. This allows increased traceability and analysis between the overarching figures and the country data. To ensure this is transparent, we have clearly stated in each case the number of countries whose data is included in the estimate. Furthermore, where appropriate, data imputations have been calculated for certain missing data points based on average market changes year on year.

1. Detailed analysis – EU statistics on the European toys industry

Descriptive statistics on the European toys industry are now provided, drawing mainly on Eurostat Structural Business Statistics (SBS), C32.4 – Manufacture of games and toys (NACE Rev 2). The analysis focuses on data covering the EU-27 and EFTA countries, while highlighting the respective shares of leading countries in the European toys industry. In section 9.2.7, detailed data tables presenting disaggregation for all Member States and EEA / EFTA countries where Eurostat SBS data is available are provided.

An overview of the **number of enterprises** in the European toys industry is provided below:

Table 8: No. of enterprises in the *European toys industry (aggregate-level):*

[239] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/

TIME	2016	2017	2018	2019	2020 (p)
EU-27 + EEA / EFTA	5,332	5,448	5,826	6,067	6,313

Source: Eurostat SBS. p – provisional data, with some data imputations developed by CSES for 2019/2020 data gaps.[240]

In the table above, the evolution in the number of enterprises in the European toy industry is shown. The number of enterprises has been progressively increasing from circa 5,332 in 2016, to an estimated 6,313 in 2020. This data excludes the UK, meaning that the number of firms in the toys industry has grown irrespective of Brexit, which is interesting as the UK market comprised accounted for around 600 firms in 2016, rising to around 675 in 2017 and 2018.

The data has also been analysed at a disaggregated data by Member State and EEA / EFTA country. Among the Member States that are the most significant producers of toys are:

Table 9: Number of enterprises among leading European countries in toy production

Member State	Number	%	Reference year (p)
Poland	904	14.3%	2020
France	848	13.4%	2020
Germany	683	10.8%	2020
Netherlands	536	8.5%	2020
Czechia	506	8.0%	2020
Spain	409	6.5%	2020
Slovakia	398	6.3%	2020
Italy	338	5.4%	2020 (e)
Others	1,691	26.8%	2020
EU27 + EEA / EFTA	6,313	100%	2020 (e)

Source: Eurostat SBS. e – data estimate; p – provisional data.

As shown in the previous table, a significant percentage (e.g. 73.2% or 4,622 enterprises) of toy manufacturers are located in eight Member States. It can be observed that toy production is concentrated in Member States either with a bigger population size (e.g. FR, DE, ES, IT), a significant tradition in the toys industry (e.g. NL) or major manufacturing countries of all types of products (e.g. PL, SK and CZ).

An overview of the **turnover of the European toys industry** at an aggregate level is now provided.

Table 10: Turnover in the European toys industry – 2016-2020 (million EUR)

Year	**2016**	**2017**	**2018**	**2019**	**2020 (p)**
EU-27 + EEA / EFTA	7,028	7,070	8,503	8,255	6,558

Source: Eurostat SBS. p – provisional data.[241]

[240] Approach to incomplete data - Data is missing in Eurostat for the following years and countries: IT (2020), CY (2016-2017), IE and MT (2016-2020), IS (2020), LI (2016-2020) and CH (2019-2020). Data imputations have been developed for IT (2020), IS (2020) and CH (2019-2020). Furthermore, all available 2020 data is marked as provisional by Eurostat.

Annual turnover was approximately EUR 7.03 billion in 2016, increasing to EUR 8.5 billion in 2018 and EUR 8.3 billion in 2019. However, 2020 data is provisional. A weakness in the data is that there are data gaps for 2016-2020 in eight Member States (DK, EE, IE, HR, CY, LU, MT, NL), and all four EEA/EFTA countries. Moreover, given that there is no data in the Netherlands, which has a significant number of enterprises in the toy production sector, turnover could be considerably under-estimated (e.g. by 10-15%). However, as illustrated by the above table, turnover for the European toys market is likely to be lower than in 2019 due to the pandemic, even if sales of toys shifted partially online (see later in this section for an analysis of online toy sales).

Table 11: Leading European countries by turnover in the production of toys

Member State	Million EUR	%	Reference year (p)
Germany	2,608.2	39.8%	2020
Czechia	898.2	13.7%	2020
Italy	560.1	8.5%	2020
Spain	546.4	8.3%	2020
Austria	453.0	6.9%	2020
France	421.5	6.4%	2020
Poland	296.3	4.5%	2020
Others	774.3	11.8%	2020
EU-27 + EEA / EFTA	6,558	100%	2020

Source: Eurostat SBS covering 23 countries. p – all available data from 2020 is provisional.

The highest turnover in 2020 has been reported by Germany, which contributed 39.8% of the European toy market's overall turnover. The second biggest turnover has been reported by Czechia, which contributed 13.7% of the total, despite being only the 10th most populous EU country (as of 1st January 2020). The next biggest turnovers were reported by Italy, Spain and Austria, followed by France and Poland.

Interestingly, the comparative analysis of the number of enterprises in the toys manufacturing industry operating in given countries and total turnover rates achieved by the local toys' manufacturing sectors indicates the significant diversification in the patterns observed across European industry. For example, in Germany, the Member State where around 11% of toy manufacturing enterprises operate, generates proportionally almost 12 times higher turnover per enterprise than Poland, more than twice as high as Czechia and Italy, and approximately three times more than Spain. Another country with high turnover per enterprise is Austria, hosting merely 92 toy manufacturing firms and achieving total turnover results similar to France, where over 9 times more toys' producing firms operate. This suggests that a disproportionate number of medium to large toy manufacturers operate in Germany and Austria.

In the following table, an overview of **production value** in billion EUR is provided. The data shows that production increased from circa EUR 6.7 billion to EUR 7.6 billion EUR by 2019, an increase of 13.4%. However, production value declined to approximately EUR 6,229 billion in 2020. While the fact that the Eurostat data for 2020 is provisional

[241] Data is missing in Eurostat for the following countries and years: DK, IE, LU, MT, NL, LI (2016-2020); EE (2018-2019); HR (2016); CY (2016-2017); IS (2019-2020); NO (2018); and CH (2016, 2018-2020). As such, the number of countries covered by the data per year are as follows: 2016 (22); 2017 (24); 2018-2019 (22); 2020 (23). Furthermore, all available 2020 data is marked as provisional by Eurostat.

may have an impact, it is anticipated that this decline is primarily due to the impact of the national and EU responses to the COVID-19 pandemic on production capacities across the internal market.

Table 12: ***Production value of the European toys industry – 2016-2020 (in million EUR)***

Year	2016	2017	2018	2019	2020 (p)
EU-27 + EEA / EFTA	6,667	6,776	7,619	7,645	6,229

Source: Eurostat SBS. p – provisional data.[242]

According to Eurostat data, the Member States in the EU-27 that had the highest production value were as follows:

Table 13: Production value in billion EUR *in leading European countries*

Member State	Number	%	Reference year(p)
Germany	2,462.7	39.5%	2020
Czechia	919.6	14.8%	2020
Italy	597.2	9.6%	2020
Spain	491.3	7.9%	2020
Austria	388.9	6.2%	2020
France	368.6	5.9%	2020
Poland	269.4	4.3%	2020
Hungary	191.2	3.1%	2020
Bulgaria	175.6	2.8%	2020
Belgium	130.5	2.1%	2020
Others	234	3.8%	2020
EU-27 + EEA / EFTA	6,229	100%	2020

Source: Eurostat SBS covering 23 countries. p – all available data from 2020 is provisional.

The biggest toys' producer in Europe is Germany, which generates approximately 40% of total EU production value. The value generated by Germany is close to three times as large as that reached by the second largest manufacturing Member State in the EU – Czechia – and four times as big as the production value generated by Italy in third place. The next best performers in terms of production value are Spain, Austria, and France.

The data for the 2016-2020 period for the ten highest performing countries indicates that only four countries have experienced overall increases in the production value of the toy manufacturing industry over that period. The biggest increase was witnessed in Poland, where the production value of the industry rose by 36% from 2016 to 2020, followed by Hungary (17% increase), Czechia (5%) and Belgium (2%). These four Member States are also the only countries from this group that did not experience a reduction of production value in 2020.

In the remaining six countries, an overall decrease in production value was experienced from 2016-2020. The biggest proportional decrease was witnessed in Austria, where

[242] Data is missing in Eurostat for the following countries and years: DK, IE, LU, MT, NL, LI (2016-2020); EE (2018-2019); HR (2016); CY (2016-2017); IS (2019-2020); NO (2018); and CH (2016, 2018-2020). As such, the number of countries covered by the data per year are as follows: 2016 (22); 2017 (24); 2018-2019 (22); 2020 (23). Furthermore, all available 2020 data is marked as provisional by Eurostat.

production value dropped by around 25% (EUR 129.8 million). In absolute terms, Germany experienced the largest decrease, by EUR 261.9 million (around 10% of 2016 production value).

However, there is more nuance within these overarching figures, primarily driven by national responses to the COVID-19 pandemic. This is illustrated by the following findings:

- In each year from 2016-2019, at least six of the ten highest performing countries reported increased production value compared to the previous year.
- Seven of the ten highest performing countries reported higher production value in 2019 than 2016, with increases of 33% (BG), 31% (DE) and 23% (PL).

Contrastingly, from 2019 to 2020, six of these countries reported decreases in production value. These decreases vary significantly from limited reductions of around 2% in France and Italy to more extensive contractions of around 40% in Bulgaria, 31% in Germany, and 20% in Austria. In total, across all 23 countries where data is available, only eight experienced an increase in production value from 2019 to 2020, while total production value across these countries declined by around 19%.

Regarding the **number of workers employed in toy manufacturing**, the sector employed approximately 55,150 persons in 2019, rising from around 48,946 in 2016; however, this figure is anticipated to have dropped under 50,000 for 2020. As for the data on number of enterprises, the data shows positive progression in the number of employees in the sector from 2016-2019, with a decrease in 2020. This is illustrated in the following table:

Table 14: Number of persons employed in the European toys industry

Year	2016	2017	2018	2019	2020 (p)
EU-27 + EEA / EFTA (e)	48,946	49,340	53,206	55,150	49,652

Source: Eurostat SBS. e – data estimate; p – provisional data[243]

As was the case for data on other variables presented earlier, the data on workers employed is not complete across the EU-27 and EEA / EFTA countries.244 The available data indicates approximately 13% increase in the number of employees working in the EU toys' manufacturing sector between 2016 and 2019. This was followed by an estimated 10% decrease from 2019 to 2020.

The EU countries where the biggest shares of those persons employed in toy manufacturing have been presented in the table below:

Table 15: Leading European countries by number of employees

[243] Data is missing in Eurostat for the following countries and years: DK, IE, LU, MT, LI (2016-2020); EE (2018-2019); FR (2020); CY (2016-2017); IS (2019-2020); and CH (2019-2020). However, data imputations have been developed for FR in 2020, and IS / CH in 2019 and 2020. As such, the number of countries covered by the data per year are as follows: 2016-2019 (25); and 2020 (26). All available 2020 data is marked as provisional by Eurostat. Furthermore, Eurostat provides overall figures for the EU-27 in the years 2017-2019; however, to provide comparability with data for 2016 and 2020, we have presented our estimated

[244] There are no national datasets on no. of workers employed for DK, IE, LU, MT, LI. Data is missing for 2 years / 5 years for CY and CH. However, unlike for the turnover data, data exists for major producer countries, such as NL.

Member State	Number	%	Reference year (p)
Germany	13,353	26.9%	2020
Czechia	7,308	14.7%	2020
Poland	4,785	9.6%	2020
Hungary	4,088	8.2%	2020
Spain	3,397	6.8%	2020
Bulgaria	2,886	5.8%	2020
France	2,758	5.6%	2020 (e)
Italy	2,358	4.7%	2020
Austria	2,218	4.5%	2020
Romania	1,642	3.3%	2020
Others	4,859	9.8%	2020
EU-27 + EEA / EFTA	49,652	100%	2020 (e)

Source: Eurostat SBS. e – data estimate; p – provisional data

The largest number of employees in the European toy manufacturing industry is found in Germany, covering just over one quarter of all workers. The next biggest EU employment markets in the context of toys manufacturing are Czechia (around 15% of employees), Poland (~10%), Hungary (~8%), Spain (~7%), Bulgaria, and France (~6%). Together, these 10 Member States account for 90.2% of total persons employed in the toy manufacturing industry in the EU-27 plus EEA / EFTA countries.

A comparison of the number of toy manufacturing enterprises with the number of people employed in the industry indicates that the average number of employees per enterprise varies significantly across the EU. In Bulgaria, where this rate is the highest, there are, on average, around 56 people employed per enterprise. Austria averages 24 people, while Germany (~20), Hungary (~17) and Switzerland (~16) all employ more than 15 people per enterprise. Czechia (~14), Slovenia (~13) and Cyprus (~10) all report an average of 10 or more employees per enterprise, while the remaining 18 countries for which comparable data is available employ between 0.8 and 8.3 people per enterprise.

Interestingly, Poland and France, two of the highest performing countries in terms of the number of toy manufacturing firms, turnover and production value, as well as the Netherlands, which has the fourth highest number of toy manufacturing enterprises, have low enterprise to employee ratios. Poland has around 5 employees per firm, while France and the Netherlands have an average of 3.3 and 1.3 employees per enterprise, respectively. This suggests that, in these countries, small and micro-enterprises may play a more important role in the toy sector.

In common with the comparison of the number of enterprises operating in a given Member State and the overall turnover, this analysis points to the fact that the characteristics of the local toy manufacturing sector vary significantly across the European market, with some hosting significant numbers of micro and small enterprises, compared with others where there are more medium and large-sized businesses (e.g. CZ, BG).

2. Key trends in the European toys industry

Whilst Eurostat data is more reliable regarding the overall size of the European toys industry, it is worth complementing the analysis by reviewing available market research

reports and other literature on the industry. These provide additional estimates as to the industry's size, including the speed of growth of particular national markets, and share of the market accounted for by online sales. The remainder of this section presents the findings on these issues.

The European toy market size was estimated to be worth around **EUR 20 billion in 2020**[245], making it the third-biggest global market after North America and Asia. This figure suggests the European market is significantly larger than the Eurostat data indicates. However, the definitions used by the market research reports identified for both the toys and the countries covered by the analysis are either unclear or differ significantly from the Eurostat SBS data.

Within the market research report identified, the four most significant EU-27 national markets with highest revenue from toys in 2020 were as follows:

- **Germany:** ~EUR 3.6 billion worth of revenue.
- **France:** ~EUR 3.3 billion worth of revenue.
- **Italy:** ~EUR 1.2 billion worth of revenue.
- **Spain**: ~EUR 0.9 billion worth of revenue.

As for the overall sales figure, these estimates are significantly higher than the data provided within Eurostat SBS, suggesting differences in the types of toys covered by the datasets.

Key trends in the toys market include:

- Toy production is highly concentrated, with 96.2% of production value generated across ten countries and 88% of turnover concentrated in seven EU Member States (see earlier table).
- Around 99% of European toy companies are SMEs, employing around two thirds of employees in the sector.[246]
- Online sales have grown significantly, accelerated by the global pandemic, with one market research commentator noting that "the European toy market aggressively moved online in all countries"[247] (see sub-section below for further information).
- Eco-friendly toys, as well as toys with digital components, are becoming increasingly popular.
- Volume of sales reportedly decreased slightly in 2020; however, this was accompanied by an increase in average prices.

3. Estimates of online sales of toys in Europe

Consumers are increasingly buying toys online instead of in retail stores. For instance, according to a study by a market research firm, all national markets in the EU recorded

[245] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/
[246] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/
[247] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/

growth in **online toy sales** in **2020-2021**. At the global level, online sales of toys were estimated to have increased markedly, by an estimated 20%, in 2020-2021.[248]

The main drivers of increased sales of online toys are now considered:

- **Digitalisation trends, including the increase in e-commerce and role of online marketplaces.** In common with other types of products, there is a general trend towards e-commerce and click and collect away from physical stores. In the EU's Market Monitoring Reports, there is an increased tendency towards e-commerce across a range of industry sectors, even in Member States where online transactions were historically less prevalent (e.g. in some Southern European and Central and Eastern European Member States).
- **COVID-19 pandemic.** As a response to the pandemic, consumers sought alternative retail channels through which to purchase toys and the trend towards buying toys online accelerated. For instance, in the US between January and September 2020, online sales reportedly gained 10% share points, growing from a 23% share in 2019. This ultimately brought a 75% increase in online toy sales overall, year-on-year. Over a similar time-period, the average 2020 traffic growth in online shops for the EU-27 rose by 13% in the area of 'sporting goods, toys & hobbies' in comparison to the pre-pandemic year of 2019. Based on Eurostat data, the authors of the European E-Commerce Report for 2021 estimated that, for the analysed period of 3 months, online purchases comprised 17% of EU-27 purchasing of children toys and childcare items.[249]

There is an apparent correlation between different geographies within the EU-27 and online sales, with a bigger e-commerce market for toys in northern European countries (e.g. Germany, Netherlands, and the Nordic countries). During the pandemic, the same countries also experienced the strongest increase in online revenues of around 50%.[250] In southern Europe (**France, Spain, Italy,** and **Portugal**), the online toys market is still growing (by a reported 30-35% in 2020[251]), but it is smaller overall.

This mirrors the findings in EU-funded market monitoring reports on a range of product markets, as well as consumer attitudes, where online sales are catching up in southern Europe, but from a much lower baseline than in northern European countries.

At a general level, there has been a major shift in purchasing trends in recent years, with consumers moving towards e-commerce in search of time-savings and lower prices. Overall, in the several years prior to 2020, the number of European online shoppers had risen by 85%, and it is now expected to reach around 36% of overall world trade in less than a decade.[252] According to the 2021 European E-commerce Report, between 2017 and 2021, the share of EU-27 internet users involved in e-commerce as customers rose from 65% to 75%.[253] This growth pattern has been additionally reinforced by the impact of the COVID-19 pandemic, which is expected to shift EUR 650 billion of non-food

[248] https://www.npd.com/news/thought-leadership/2021/whats-driving-online-toy-sales/

[249] https://ecommerce-europe.eu/wp-content/uploads/2021/09/2021-European-E-commerce-Report-LIGHT-VERSION.pdf

[250] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/

[251] https://globaltoynews.com/2021/02/05/the-european-toy-market-2020-and-digital-trends-2021/

[252] Bjerkan, K. Y., Bjørgen, A., Hjelkrem, O. A. (2020). *E-commerce and prevalence of last mile practices,* [in:] "Transportation Research Procedia", vol. 46, DOI: 10.1016/j.trpro.2020.03.193, p. 293.

[253] Lone, S., Harboul, N., & Weltevreden, J. W. J. (2021). *2021 European E-commerce Report*, online: https://www.cmihva.nl/wp-content/uploads/2021/09/EuropeanEcommerce-Report-2021.pdf, p. 13.

spending towards online sales by 2025, with 20% of consumers (and 42.2% of home-working consumers) permanently increasing the volume of online purchases in their daily habits.[254]

The negative impact of the increasing trend in online sales in the context of the European toy market is that online shopping enables customers not only to purchase products directly from the websites of economic operators, but also from secondary sources, such as *Amazon*, *AliExpress* or *Alibaba*. This makes it much more difficult to ensure the correct application of the product safety requirements stipulated through EU legislation. That is, because many of those online purchases are made internationally from markets where the relevant, precautionary regulations are not (yet) introduced.[255] However, even though online customers are able to purchase considerably cheaper products via online shopping platforms, it needs to be acknowledged, based on the recent study on *Amazon*'s practices connected to toy sales, that online shopping platforms might increase the prices of the products they sell once they gain enough market power to do so, hence reducing the price difference between toys sold online and in the physical world.[256]

In addition, through the current IA study, toy manufacturers, including both SMEs and leading global firms were asked to estimate the percentage of their sales that were online. Although one large toy manufacturer noted that almost all products are available for sale online, manufacturers in general were unable to provide further information on the percentage of their sales that were conducted online.

[254] Metapack (2022). *Ecommerce Delivery Benchmark Report 2022. Welcome to the age of ecommerce*, online:https://info.metapack.com/rs/700-ZMT-762/images/Ecommerce%20Delivery%20Benchmark%20Report%202022%20%282%29.pdf, p. 6.
[255] Negev, M. et al. (2018). *Regulation of Chemicals in Children's Products: How U.S. and EU Regulation Impacts Small Markets* [in:] "Science of the Total Environment", vol. 616-617, DOI: https://doi.org/10.1016/j.scitotenv.2017.10.198, p. 469.
[256] He, L., Reimers, I., & Shiller, B. (2021) *Does Amazon Exercise its Market Power? Evidence from Toys R Us*. Online: http://dx.doi.org/10.2139/ssrn.3910636, p. 16.

ANNEX 8: CONCLUSIONS OF THE EVALUATION OF THE TSD[257]

Toys have to be safe when children play with them. The **Toy Safety Directive** (Directive 2009/48/EC) therefore lays down rules to make toys safe, including when they are exposed to children's sometimes 'unforeseeable' behaviour.

At the same time, the Directive ensures the successful functioning of the internal market for toys, worth almost EUR 20 billion a year. The toy industry is dynamic and innovative: around one third of the toys on the market each year have new features or are newly developed.

The Toy Safety Directive had been adapted 12 times since its adoption at the time of the Evaluation, resulting most often in strict(er) limit values for hazardous chemicals that might be present in toys, such as for chromium VI, lead, phenol and bisphenol A. There is a focus on chemicals because knowledge about their toxicity evolves more often than knowledge about other hazards in toys; chemicals are more often recognised to be more hazardous than previously known.

The evaluation of the Toy Safety Directive assessed the functioning of the Directive since its entry into force. It is based on the following sources:

- a 2015 external study evaluating the Directive;
- online questionnaires addressed to Member States and stakeholders (a public consultation and a specific consultation of economic operators on the costs caused by the Directive);
- the Member States' reports on the application of the Directive in their national territory; these are due every 5 years, covering 2009–2013 and 2014–2018;
- a study on the Directive's costs and benefits, supplied by the Commission's Joint Research Centre (JRC); and
- several Commission fitness checks and related studies on chemicals legislation, insofar as they refer to toys;
- a 2013 external report on the toy industry prepared on behalf of the Commission;
- knowledge and experience acquired in the Directive's day-to-day management, including from discussions with Member States and stakeholders.

1. Effectiveness

The scope of the Toy Safety Directive is effectively defined: a toy is defined as a product that has a play value for children under 14 years of age, even if it may have other uses. Products that fall into a 'grey zone' of 'toy or not a toy?' are classified through guidance documents, which are continuously being updated, and email exchanges between Member State authorities. These documents and exchanges also make it possible to distinguish between toys for children under 3 years of age, who are particularly vulnerable to harm since they regularly put objects in their mouth, and toys for older children.

[257] Commission Staff Working Document (2020) 287 final – Evaluation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys

The Directive is more effective than its predecessor regarding protecting children from chemicals in toys. This is due to a higher number of restrictions on specific (groups of) dangerous chemicals. However, the Directive's effectiveness as regards the protection of children is limited in the following aspects that require urgent attention:

- Under the Directive, specific limit values for chemicals can only be set for toys for children under 36 months of age and toys that are intended to be placed in the mouth, instead of for all toys.
- The Directive makes it possible to derogate from the prohibition on using chemicals that are carcinogenic, mutagenic or toxic for reproduction (CMR). In particular, CMR chemicals may be present in toys if they do not exceed certain concentrations, which are set in a separate piece of legislation and which are useful to classify chemical mixtures as dangerous. The concentrations allowed however appear to be too high and can still pose a risk to children.
- The Directive sets limit values for carcinogenic nitrosamines and nitrosatable substances (that may convert into nitrosamines). However, a Commission Decision of 2012 has recognised that these limit values are too high and can still pose a risk to children.
- The Directive provides labelling requirements for specific allergenic substances in certain 'experimental' toy sets. However, these requirements cannot be easily updated when the related lists of allergenic substances are being updated.

For risks other than those related to chemicals, the Directive appears to be sufficiently effective. There is no reason to doubt any of the non-chemical safety requirements, there have been no discussions about their application. The 'small parts requirement' is an exception and is discussed almost permanently. It requires that toys must not be or release small parts that children under 36 months of age could easily swallow and choke on. Since the requirement is demanding in the eyes of manufacturers, some rogue manufacturers try to circumvent it by claiming that their toys are intended for children of 36 months and over. However, guidance documents and exchanges of views between market surveillance authorities have so far ensured a consistent (and protective) approach in such cases.

Standards appear to effectively support the requirements of the Directive through their detailed technical specifications. There have been no major incidents with toys, formal objections highlighting insufficiencies of standards have been rare, and standards newly adopted by the standardisation organisations can be promptly referenced in the Official Journal in virtually all cases.

The Directive's effectiveness as regards the enforcement of its rules appears to be only partially satisfactory. The Directive only provides for a general obligation for Member States to carry out market surveillance, however detailed (and binding) EU-wide market surveillance rules have recently been set in the Regulation on market surveillance and compliance of products. It can be expected that these detailed rules will make the enforcement of the Directive's provisions more effective. [258]

[258] See 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, Article 2.1 ("Scope"): "This Regulation shall apply to products that are subject to the Union harmonisation legislation listed in Annex I ('Union harmonisation legislation'), in so far as there are no specific provisions with the same objective in the Union

The Directive's effectiveness as regards the free movement of toys was analysed by looking at the intra-EU trade of toys and its evolution over the years, as well as stakeholder feedback. The figures on intra-EU export of toys covered by the Toy Safety Directive, and in particular on the remarkable increase since 2012/2013, suggest that applying the Directive and all its requirements since mid-2013 did not hamper growth in this area.

The Directive is a maximum harmonisation directive: toys that comply with all of its applicable requirements can move freely and be made available throughout the EU. There is therefore no need for other provisions on free movement: the current provisions have proven to be effective in ensuring the smooth functioning of the internal market for toys.

The Directive could possibly be more effective if it were converted into a Regulation, as this would free up staff in Member States working on transposing the repeated amendments of the Directive into national legislation, and free up staff in the Commission from the required transposition and conformity checks necessary to detect possible infringements. Moreover, since the Directive provides for maximum harmonisation of the provisions on toys, it leaves no room for Member States to deviate and could thus appear to be a '*de facto* regulation'.

2. Efficiency

Complying with the Toy Safety Directive when it became applicable in mid-2009 (and when new chemical requirements were introduced in mid-2013) has reportedly caused one-off costs to economic operators, in particular manufacturers, due to the many new requirements. These one-off costs were reported to be between 1% and 3% of turnover. The ongoing costs for producing toys are considered to be higher than under the previous Directive, since there are now more requirements to be met.

On the other hand, costs did not prevent several hundred companies from entering the market, increasing the total number of companies by some 10% between 2013 and 2017. – To note that 99% of the companies in the toy sector are SMEs.

Furthermore, the Toy Safety Directive does not appear to have hindered the cost competitiveness of the toy industry. Profits dropped in 2009, probably due to the financial crisis of 2008 and perhaps also due to companies internalising some of the one-off costs. However the EU toy industry recovered during the following years, its turnover growing steadily since 2009 by a total of 16% and its profits being almost 15% higher in 2017 than in 2008.

Furthermore, manufacturers are only exceptionally required to request the intervention of a third party (a 'notified body'), namely when producing novel toys that have hazardous features not covered by the existing toy safety standards, the references of which have been published in the Official Journal.

Whereas the costs related to the Toy Safety Directive have been quantified to a certain extent, it does not appear possible to quantify the benefits due to missing data. The 2008

harmonisation legislation, which regulate in a more specific manner particular aspects of market surveillance and enforcement.

impact assessment on the then-proposal for the current Toy Safety Directive already noted that '[t]hese benefits cannot be quantified based on the available data.' Nevertheless, stakeholders see benefits in the Directive's detailed provisions, whether regarding the definition of 'toy' or the roles of economic operators, because they ensure legal certainty and a level playing field.

In addition, although it is not possible to provide a quantitative balance of benefits and costs, some 50% of the companies and business associations that took part in the 2018 public consultation considered the benefits of the Toy Safety Directive to outweigh the costs, sometimes even by far; a further 20% of participating companies considered the costs proportionate to the benefits. Public authorities, consumer organisations and notified bodies responded that the benefits outweigh the costs even by 60% to 80% (or outweigh them by far).

The efficiency of the Toy Safety Directive is limited because chemical limit values for toys are currently also provided in other pieces of legislation, such as REACH. This means that economic operators, Member States' market surveillance authorities and other stakeholders cannot find all applicable limit values in the Directive.

3. Relevance

The requirement that all toys be safe in order to protect children – which is one of the two key objectives of the Toy Safety Directive – is undoubtedly still relevant, in particular in light of the weekly notifications on dangerous toys in the EU's safety gate RAPEX. Member States and stakeholders also confirmed this requirement as relevant. The Toy Safety Directive is, therefore, still a relevant policy measure for ensuring the safety of toys, in that it requires that all toys placed on the EU market comply with its safety provisions.

However, there have been doubts about the speed with which the Toy Safety Directive is being adapted to technical and scientific developments; this is in contrast to the 2015 external study, where authorities had generally confirmed the relevance of the adaptation mechanisms. In the 2018 public consultation, public authorities complained mostly about the slow adaptation process in general, compared to the rapidly evolving market. However, the allegedly slow adaptation progress was due to the need to collect sufficient data to ensure the quality of the adaptation directives, so that they could be resistant to any potential legal challenge, including before the WTO.

The recent issue of the security of internet-connected toys and the related protection of privacy (cybersecurity) emerged as a concern: the security threats that new technologies (including toys) pose cannot be addressed by the Directive in force, because of its limited scope, which focuses on health and safety, but not on privacy and security issues. In order to increase the security of internet-connected toys whilst ensuring a level-playing field for businesses, these issues could be (and are being) addressed under the Radio Equipment Directive, as they are not only relevant for toys but also for other Internet of Things (IoT) devices for many daily-use products. Covering toy-related aspects of security and privacy risks separately could lead to a fragmentation of privacy and cyber security rules and thus undermine the internal market.

The requirement that toys move freely in the EU market – the second key objective of the Toy Safety Directive – is equally relevant, as confirmed by a very large majority of

Member States and stakeholders. Harmonising national requirements is crucial in order to eliminate any possible barriers that would stem from different regulatory systems in the Member States, and to ensure a level playing field for all toys placed in the EU market.

The current data monitoring system does not seem to make it possible to clearly relate the Toy Safety Directive to effects on health protection or the internal market. The available data are often incomplete or not representative, or there are too many confounding factors. As a consequence the data available did not make it possible to draw firm conclusions on the effects of the Toy Safety Directive, whether with regard to safety or the free movement of toys. Only information on implementation costs for the toy industry could be considered as data on the effects of the Directive, but this was collected as part of a non-representative consultation.

The Toy Safety Directive provides for only a general reporting obligation for Member States. It does not identify the indicators and related data needs for future monitoring and evaluation that could help draw a detailed picture of the Directive's effects or identify impediments to its functioning. The data reported are not always comparable, for example those on the number of non-compliant toys vis-à-vis the total number of inspections carried out or the total number of toys traded in each Member State. Furthermore, Member States are not obliged to report on their measures relating to specific (categories of) toys, novel toys 'flooding' the market, blockages of toys at the EU border, or similar matters.

4. Coherence

In their daily management of the Directive, the Commission has not identified any areas in which the Toy Safety Directive is incoherent with other EU or national legislation, with the exception of the limit values for nitrosamines and nitrosatable substances (see section on 'effectiveness'). Where Member States and stakeholders claimed that 'different limit values for chemicals' exist, they may have been referring to the existence of migration and content limit values for the same chemical, which can be confusing but does not signal incoherence, and other similar situations.

5. EU added value

In terms of toy safety and the creation of a large internal market for safe toys, the current evaluation has confirmed the EU added value of the Toy Safety Directive. In particular, without the Directive, Member States could set diverging limit values for chemicals, which would be to the detriment of the internal market.

All categories of stakeholders highly appreciated the existence of the same safety requirements across the EU, and companies valued the creation of a large market for toys and the simplification of trade as major achievements. Possibly diverging national rules were not considered as being more beneficial. Notified bodies in particular agreed that the Directive contributes to streamlining testing and standards, and public authorities welcomed the harmonisation of testing and standards and the opportunity to work together with authorities from other Member States.

Therefore, the Directive clearly provides EU added value by harmonising the rules on toy safety and facilitating the free movement of safe toys in the internal market.

ANNEX 9: EU CHEMICALS LEGISLATION

1. THE CLP REGULATION

CLP requires manufacturers, importers and downstream users to classify hazardous substances and mixtures. CLP contains rules on how to classify chemicals. A classification can be harmonised and applied across the EU to all duty holders. Such classification is adopted at EU level according to a regulatory procedure. Where such harmonised classification does not exist, duty holders have to assess and classify according to available data ('self-classification').

The hazard classification determines, amongst others, the appropriate labelling and packaging of the chemicals in the supply chain, in particular to protect workers, consumers and the environment. Hazard communication also relies on notifications of substances which are self-classified by industry and included in the CLP classification and labelling inventory, a public database managed by ECHA. CLP also covers the notifications self-classifications of mixtures of chemicals to poison centres, to provide adequate emergency health response.

CLP focuses on the identification and classification of the intrinsic hazards of chemicals, i.e. the hazardous effects of chemicals on human health or the environment, and on communicating them to users of chemicals and decision makers (consumers, industry and authorities). Identifying the intrinsic hazardous properties of substances to derive a hazard classification is the first step in assessing chemical risks. The second step aims at quantifying at which dose the adverse effects happen, whose outcome is a reference value, and is currently performed outside CLP. Risk management measures are adopted under REACH and relevant sectorial pieces of legislation (e.g. cosmetics, toys, waste, detergents etc.), see Figure 7 and Figure 8 below.

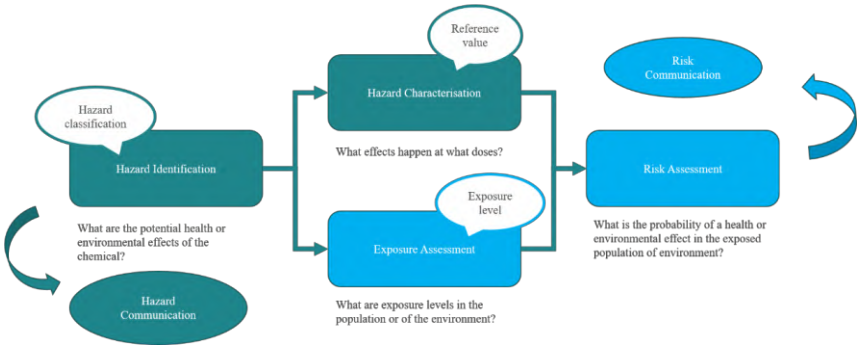


Figure 7: Steps in risk assessment and related EU regulations. Steps in dark green are based on the intrinsic properties of a chemical (hence covered by CLP), whereas the blue ones relate to the context of use (relevant for REACH and other sectorial regulations). Deliverables are displayed in bubbles.[259]

[259] Source: Commission Staff Working Document - Impact Assessment Report - Accompanying the document Proposal for a 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} - {SEC(2022) 452 final} - {SWD(2022) 434 final} -

CLP follows the United Nations' Globally Harmonized System (GHS) of classification and labelling of chemicals setting up criteria for classification and communication of physicochemical, health, and environmental hazards. GHS is partly established on a "building blocks" approach, whereby each jurisdiction has the option to implement a GHS block into its own legislation[260]. So far, 83 countries worldwide implement the GHS[261]. CLP implements the GHS criteria into EU legislation, but complements them with certain elements from former EU legislation (Dangerous Substances Directive[262] and Dangerous Preparations Directive[263]).

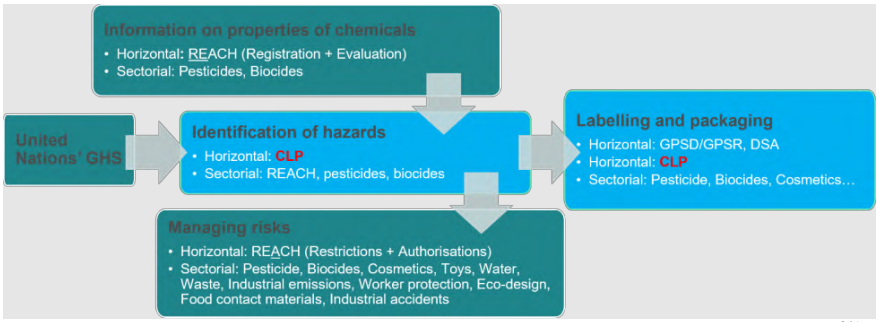


Figure 8: Mapping of the pieces of legislation according to the different steps of hazard and risk assessments[264]

2. MAIN STEPS IN LEGISLATING CHEMICALS: FROM HAZARD IDENTIFICATION TO RISK MANAGEMENT MEASURE

Chemical risk assessment involves the analysis of the inherent hazardous properties of a substance or a mixture and the extent of exposure to that substance or mixture. The human health and environmental risks related to exposure to hazardous chemicals are addressed via the hazard and risk assessment procedures and requirements set out in the different key pieces of the EU chemicals legislation such as the CLP, the Plant Protection Products and Biocidal Products Regulations, etc.

The main steps of these procedures involve (see figure 7 above):

- hazard identification (based on toxicity tests and other relevant information);
- dose (concentration) – response (effect) assessment;
- exposure assessment – exposure scenarios (based on models and measurements of the occurrence of the chemical);
- risk characterisation; and
- risk estimation.

{SWD(2022) 436 final}

[260] Global implementation map of GHS, September 2021.

[261] GHS Implementation, last updated 19 October 2021.

[262] Directive 67/548/EEC.

[263] Directive 1999/45/EC.

[264] Commission SWD- Impact assessment report on the revision of the CLP Regulation, see footnote 259 above.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

3. RISK MANAGEMENT APPROACHES

There are two basic approaches to risk management often used in combination, in the EU chemicals acquis: one based on specific risk assessment (SRA) and the other one based on generic risk management approach (GRA). The main difference between these two approaches is the point in time when the exposure assessment is considered and the specificity of the exposure assessment. For risk management based on GRA, the potential exposures and risks are considered generically, prior to the adoption of legislation. The GRA is built into the legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of the chemical, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. One could also note that even when the GRC approach is applied, a specific risk assessment in some cases will still be carried out including when considering a possible derogation from an automatically triggered measure. For example, this is the approach the TSD currently follows as regards any substance classified as CMR 11 categories 1A/B and 2 which is banned from use in toys (subject to strict derogations). Similar approaches have been taken for active ingredients in plant protection products and biocides, in cosmetics, etc.

The decision to link particular hazard properties (e.g. CMR, persistent bioaccumulative and toxic substances (PBTs), endocrine disruptors (EDs)) to automatic risk management measures without the intervening step of a specific risk assessment is done on the basis of generic risk consideration without prejudice to performing also a full risk assessment for the other properties of the substances which are not linked to the related hazard properties.

In the legislation evaluated in the Fitness Check on chemicals legislation excluding REACH[265], the generic risk consideration approach was found to be typically applied for the following use applications and the following substances:

Use applications:

- when there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management (e.g. labelling obligations under the CLP, labelling requirements and use instructions under the Plant Protection Products and the Biocidal Products Regulations).
- for use in widely dispersive or open applications which result in a significant exposure of humans or the environment (e.g. plant protection products).

[265] SWD(2019) 199. See section 2.1.5

• for use in applications where the exposure is considered to be more difficult to control and monitor (e.g. plant protection products).
• for use in applications resulting in exposure of vulnerable groups (e.g. children).
• for use to prioritise the risk assessment of certain chemicals and under certain conditions (e.g. food contact materials)

Substances:

• for substances with hazard properties that result in severe adverse effects on human health or the environment should exposures occur (e.g. CMRs, PBTs, EDs, chemicals with Single Target Organ Toxicity (STOT) properties); and
• for substances where it is difficult/impossible to identify a safe threshold and, therefore, where most specific risk assessments are likely to identify risks that lead to a need for risk management measures (e.g. PBTs, vPvBs, respiratory sensitizers).

On the other hand, in the case of the specific risk assessment approach, the exposure assessment is performed on a case-by-case basis when each substance is risk assessed under a specific legal framework. The risk management measures are triggered based on the outcomes of the specific risk assessment which considers the use of the substances and in which both the hazards and the potential specific exposure scenarios for humans and the environment to the hazardous substance or mixture in question are assessed at the same time. The specific risk assessment approach is used more widely for uses which are not necessarily or obviously going to lead to widespread and difficult to control exposures and/or where the hazard properties of a substance are of less concern. In many instances, individual pieces of chemicals legislation use a combination of both of these approaches. For example, the current TSD applies the specific risk management approach to establish limit values for certain substances in toys intended for children under 36 months or to be put in the mouth. In addition, for substances identified and classified as a CMRs categories 1A/B and 2, the generic risk management approach is applied (such substances shall be banned and cannot, therefore, be used in toys subject to strict derogations).

Overall, findings of the Fitness Check in section 5.2.7 show that both the GRC and SRA have their role to play in the EU chemicals legislative framework and that the current balance between the use of generic and specific risk management approaches works well, each under particular circumstances:

	Advantages	**Drawbacks**
Generic Risk Approach (GRA)	Provide a clear signal to all the actors involved (enforcement authorities, industry and downstream users) on the types of hazardous substances which should be avoided	Automatically triggered risk management measures may lead to disproportionate outcomes and unintended (legal and/or socio-economic) consequences if a mechanism for derogation is absent or not appropriate
	The outcome of the risk management decision making process is more predictable	Potential consequences of automatically triggered measures in downstream

	(compared to SRA)	legislation might influence the upstream scientific debate leading to the classification
	Might be more appropriate for substances of higher concern and where vulnerable populations are at risk and/or cannot be protected through e.g. training or protection equipment (e.g. children under the Toy Safety Directive)	Less appropriate where exposures are minimal or would not occur through the route of exposure of concern and therefore can lead to over-regulation for non-relevant routes of exposure
Specific Risk Assessments (SRA)	Allow more targeted and differentiated consideration of exposures and thus risks and therefore more appropriate identification of actual risks and of risk management measures	The process might be slower compared to GRA and often more costly
	Allow more targeted consideration of costs and benefits of various risk management options	Predictability of risk management decisions can be more difficult

***Table 16**: Main comments received from stakeholders regarding the GRA and SRA application in the context of the Fitness check*

Where a derogation mechanism is connected to the GRA approach (i.e. a derogation from e.g. an automatic restriction or ban if certain conditions are fulfilled, such as demonstration of negligible exposure), industry stakeholders stated that it helps to ensure that the risk management measure stipulated will not lead to disproportionate costs or unintended effects e.g. regrettable substitution.

CLP, together with other pieces of EU legislation, was evaluated in 2019[266]. An additional and more targeted Fitness Check was also published on endocrine disruptors[267]. Those evaluations, identified important issues and weaknesses holding CLP back from delivering its full potential. These evaluations pinpointed nine potential areas of intervention:

- Introducing criteria for five outstanding **new hazard classes**
- Providing **harmonised reference values** in addition to harmonised classification
- Improving **harmonised classification**
- Improving and streamlining industry's **self-classifications**
- Clarifying rules for **hazard (physical) labelling**
- Introducing **digital labelling**
- Reviewing the **exemption of a number of chemical products** from CLP
- Addressing low compliance rate for **online sales of chemicals**

[266] SWD(2019) 199.
[267] SWD(2020) 251.

- Closing **notification gaps for poison centres**

Accordingly, the CLP Regulation is currently under revision. In particular, new hazard classes will be added in the CLP Regulation for endocrine disruptors.

4. LINK BETWEEN THE TSD AND REACH

REACH aims at improving the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, REACH has an impact on most companies across the EU.

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used, and they must communicate the risk management measures to the users.

If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

REACH applies to a great variety of products supplied and used in the form of chemical substances, mixtures and articles. REACH and CLP define a substance, mixture and article as follows: **Substance** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition: *examples*: metals (aluminium, zinc, iron, chromium, etc.), acetone, phthalates, ethanol. Substances are very exceptionally classified as toys; only if they are supplied for example as part of a chemistry set.

Mixture means a mixture or solution composed of two or more substances: *examples*: paint, glue, ink, metal alloys, household cleaners. Certain toys are considered to be mixtures, for example finger paints, modelling clay or bubble solutions.

Article means an object given a special shape, surface or design that determines its function to a greater degree than its chemical composition does: *examples*: clothing, furniture, electronics and practically all objects of modern life. Most toys are considered to be articles under REACH.

Some substances or mixtures which pose unacceptable risks can be totally banned on the EU market (e.g. asbestos), have restrictions on specific uses (e.g. phthalates in toys and childcare articles), or have limits on the concentration of the substance (e.g. in consumer products such as tyres, clothing or jewellery). When certain uses are restricted or the substance is banned on the EU market, substitution is a must. Restrictions are not linked to the procedure of registration.

Restrictions are designed to manage unacceptable risks that are not addressed by the other REACH processes or by other EU legislation. These restrictions therefore co-exist with those set out in the product safety and sector specific legislation, for example, on detergents, cosmetics, toys, electronics. In order to ensure a high level of protection of children against risks caused by chemical substances in toys, the TSD specifies that toys should comply with general chemicals legislation, in particular 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). By means of the TSD, these provisions are adapted to the particular needs of children, who are a vulnerable group of consumers.

Accordingly, toys are covered by REACH and restrictions can be applied to them as articles, for the purposes of protection of human health or the environment. In addition, the TSD provides for a more complete and targeted approach for toys to protect the safety and health of children. Coherence between the two has been assured in the past for example by exempting toys from a REACH restriction if the limits in the TSD were more protective. Around 40% of businesses or business associations and 45% of SMEs considered that the limit values in other pieces of legislation beyond the TSD were not problematic at all or to a small extent.

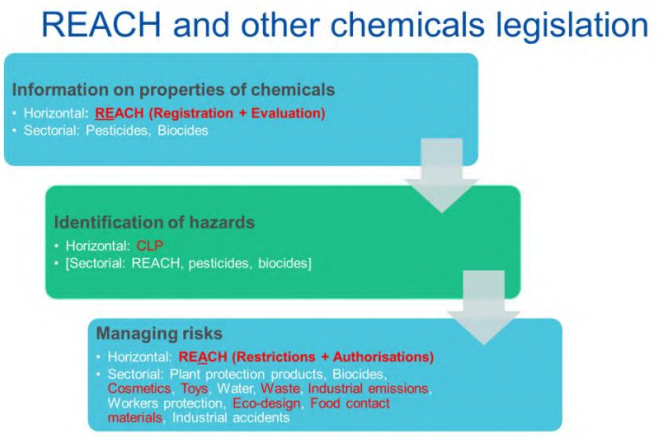


Figure 9: Hazard identification and risk management in EU legislation

A central aspect of the revision of REACH is reforming the processes of risk management for both REACH authorisations and restrictions. One option envisaged especially for REACH restrictions is the extension of the generic approach to risk management for which REACH will rely on the hazard classes in the CLP Regulation. Currently, the faster, more preventive REACH restriction procedure is available for consumer uses to substances classified as carcinogenic, mutagenic or reprotoxic under CLP. The REACH revision envisages extending this procedure to some of the newly introduced or existing hazard classes such as endocrine disruptors or PBT/vPvB substances.

ANNEX 10: THE MOST HARMFUL CHEMICALS CURRENTLY NOT ADDRESSED BY THE TSD

1. THE MOST HARMFUL CHEMICALS AND THEIR CONSEQUENCES ON HUMAN HEALTH

Endocrine disruption[268]

The World Health Organisation defines an endocrine disruptor (ED) as '*an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations*'.[269]

Over the last 30 years, the endocrine disrupting properties of chemicals have been the focus of increasing scientific research, and the accumulated knowledge identifies EDs as a concern to public and wildlife health[270]. The high and increasing incidence of many endocrine-related disorders in humans – such as asthma, birth defects, neurodevelopmental disorders, cancer, diabetes and obesity in children and cardiovascular diseases, cancer, diabetes and obesity, allergic and autoimmune diseases in adults – have important parallels in some wildlife populations. Evidence on the roles played in the disease outcomes by environmental and other non-genetic factors, including chemical exposure, is growing. Some links have become apparent (e.g. polychlorinated biphenyls' exposure as a risk factor in breast and prostate cancers; relationships between perfluoroalkyl substances and child and adult obesity, impaired glucose tolerance, gestational diabetes, reduced birthweight, reduced semen quality, polycystic ovarian syndrome, endometriosis, and breast cancer) while more research is necessary on the associations between EDs and other endocrine-related diseases[271].

Importantly, only a small proportion of the chemicals on the market have been tested for endocrine effects and the disease risk due to EDs' exposure may be significantly underestimated[272].

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[268] See the Commission Staff Working Document – Impact Assessment report accompanying the Proposal for a Regulation of the European Parliament and of the Council amending 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.

[269] International Programme on Chemical Safety. (2002). Global assessment on the state of the science of endocrine disruptors. World Health Organization. https://apps.who.int/iris/handle/10665/67357

[270] UNEP State of the Science of Endocrine Disputing Chemicals - IPCP-2012, available at: https://www.unep.org/resources/publication/state-science-endocrine-disputing-chemicals-ipcp-2012?_ga=2.148289463.183897156.1643356524-1526509983.1643356524

[271] UNEP State of the Science of Endocrine Disputing Chemicals - IPCP-2012, available at: https://www.unep.org/resources/publication/state-science-endocrine-disputing-chemicals-ipcp-2012?_ga=2.148289463.183897156.1643356524-1526509983.1643356524

[272] UNEP State of the Science of Endocrine Disputing Chemicals - IPCP-2012, available at: https://www.unep.org/resources/publication/state-science-endocrine-disputing-chemicals-ipcp-2012?_ga=2.148289463.183897156.1643356524-1526509983.1643356524

Since 1999, the European Commission has been working on prioritising suspected EDs for evaluation, monitoring exposures and effects, develop and validate new testing methods and increase public awareness on EDs[273].

- Identification of known or presumed EDs is required for actives substances by the Plant Protection Products Regulation (PPPR)[274] and for actives substances and products by the Biocidal Products Regulation (BPR)[275] according to criteria established, respectively, in 2017 and 2018. REACH does not contain identification criteria for EDs, but these are identified as substances of very high concern (SVHCs) on a case-by-case basis following the IPCS/WHO definition and the assessment of the "equivalent level of concern" carried out by the REACH Member State Committee. It should be noted that the same definition and guidelines are used by REACH, BPR and PPPR.

- Sector-specific legislation on toys but also cosmetic products, medical devices, food contact materials or detergents does not require the identification of EDs. However, the use of potential endocrine disrupting substances may be subject to the scientific opinion of expert advisory bodies. For example, while the TSD does not have specific provision for endocrine disruptors, it does ban the use of substances that are toxic to reproduction (which may for some substances also be toxic via an endocrine disrupting mode of action).

- Because the lack of CLP on EDs is not filled by systematic identification in other regulations, there is incomplete information on the human health and environmental hazards of these substances. It should also be noted that EDs are not included at UN GHS. As substances and mixtures with ED properties are not systematically identified and classified, this has been identified as resulting in the failure to define risk management provisions in downstream sector-specific regulations and directives referring to CLP hazard classification. Moreover, substances suspected of having ED properties may be assessed multiple times according to different regulations, contributing to the inefficient use of limited resources.

The inclusion of horizontal criteria for the identification and classification of EDs was identified as an area for action in the EU's 7th EAP and their absence has been criticized by many stakeholders[276][277].

Table 17 *The number of substances expected to be identified as ED in the CLP Regulation differentiated by ED category and impact area among all substances is set out below. The last column shows the total number of substances identified as ED already reported above. As noted earlier, the impact areas used here are not mutually exclusive: in other words, any given substance may be counted in HH and ENV.*

[273] COM(2018) 734 final.
[274] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009.
[275] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167 27.6.2012.
[276] SWD(2020) 251.
[277] SWD(2019) 199.

Table 17: Estimated number of substances expected to be identified as ED with categorisation and differentiation by impact area							
Type of estimate	**ED Cat. 1**		**ED Cat. 2**		**ED Total**		
	HH	**ENV**	**HH**	**ENV**	**HH**	**ENV**	**All**
Lower end (AA-1)	334	502	374	562	708	1,064	1,772
Central estimate (ECHA approach)*	405	607	453	680	858	1,287	2,145
Upper end (AA-2)	510	766	572	857	1,082	1,623	2,705
*Notes: * Note again that ECHA only derives the ED Cat. 1 estimate and does not differentiate by impact area. The sum of 1012 ED Cat. 1 substance is included in ECHA (2021a), but the assignment to HH (N=405) and ENV (N=607) is performed in this study.*							

Based on the total number of 23,751 unique substances in ECHA's combined inventory, the central estimate of 1,012 substances identified as ED Cat. 1 represents 4.3%. Using the derived factor of 1.12, an additional 1,133 substances are estimated to be identified as ED Cat. 2 (4.8% of the combined inventory). In total, 2,145 substances (9.0%) are identified as ED in the central estimate.

Overall, the high uncertainty of the estimated figures reflects the fact that the data required for the classification as ED (including categorisation and differentiation by impact area) are not yet available. It must also be stressed that – even if the estimated numbers prove to be close to the real numbers – they would only materialise if all necessary studies have been conducted for all substances.

Human and environmental exposure to EDs — through multiple routes — is the result of their presence in a wide variety of products, including food packaging, pharmaceuticals, cosmetics and personal care products, pesticides, fabrics and upholstery, electronics, plastic bottles, metal food cans, detergents and toys. EDs can mimic or interfere with the body's endocrine system, and associated effects include impacts on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology.[278] Vulnerable groups, such as young children, are particularly affected by exposure to EDs, which can have life-long impacts and exhibit in adulthood. The table below reproduces health outcomes attributable to exposure to specific EDs — with strength of human evidence and probability of causation — as reported by Kahn et al. (2020).

Table 18: Strength of evidence and probability of causation for outcome-exposure associations		
Outcome	**Strength of human evidence**	**Probability of causation**
Perinatal outcomes		
Low birthweight	Not assessed	Not assessed
Preterm birth	Not assessed	Not assessed
Reduced anogenital distance	Not assessed	Not assessed
Neurodevelopmental		
IQ loss and intellectual disability	Moderate to high	70-100%
Attention-deficit disorder	Low to moderate	20-69%
Autism spectrum disorder	Low	20-39%
Metabolic		
Childhood obesity	Moderate	40-69%
Adult obesity	Low	40-69%

[278] National Institute of Environmental Health Sciences. (n.d.) Endocrine Disruptors. https://www.niehs.nih.gov/health/topics/agents/endocrine/index.cfm

Adult diabetes	Low	40-69%
Reproductive outcomes		
Cryptorchidism	Low	40-69%
Low testosterone, resulting in increased early mortality	Low	40-69%
Male infertility, resulting in increased use of assisted reproductive technology	Low	40-69%
Endometriosis	Low	20-39%
Fibroids	Low	20-39%
Testicular cancer	Very low to low	0-19%
Semen quality	Not assessed	Not assessed
Polycystic ovarian syndrome	Not assessed	Not assessed
Breast cancer	Not assessed	Not assessed
Notes: Kahn et al. (2020) report strength of evidence and probability of causation per specific EDs and time of exposure (prenatal, pregnancy, adult, lifetime). This table reproduces only the highest strength of human evidence and probability of causation among specific EDs and time of exposure.		

Kahn et al. (2020) is part of a series of papers published by Trasande and colleagues starting in 2015[279] estimating the socioeconomic impacts of health outcomes attributable to EDs' exposure. These papers use the population attributable fraction methodology and calculate the attributable costs as the product of disease rate, attributable fraction, population size and cost per case. The cost per case includes health care direct costs, rehabilitation costs and lost productivity. To establish the probability of causation, the authors adapted the Intergovernmental Panel on Climate Change (IPCC) approach, combining the assessment of the strength of the epidemiological and toxicological evidence. Bond and Dietrich (2017) have criticised the methodology used in this series of papers, pointing to a number of criticalities: skewed and non-transparent selection of experts for the panels establishing probability causation for each outcome-exposure association; limited evidence for certain outcome-exposure association; non-transparent selection of the literature evaluated; monetisation of health outcomes with low to moderate probability of causation; insufficient number of experts in the panels.

For the purpose of this assessment, one outcome for each outcome category has been selected:

- Low birth weight (perinatal outcomes);
- IQ loss and intellectual disability (neurodevelopmental);
- Childhood obesity (metabolic);
- Male infertility (reproductive outcomes).

A very low weight at birth can have consequences on development, including an increased prevalence of neurosensory problems, behavioural and social competence problems, and intellectual and learning disabilities. As noted in ECHA (2016c), the actual outcomes associated to very low birth weight cannot be known in advance. Alberini and Ščasný (2014) value that the prevention of one case of very low birth weight at €$_{2012}$405,000 (equal to €$_{2021}$450,000)[280] from a public perspective.

[279] Trasande et al. (2015); Bellanger et al. (2015); Hauser et al. (2015); Legler et al. (2015); Hunt et al. (2016); Trasande et al. (2016)
[280] Rounded to the nearest ten thousand.

Neurodevelopmental disabilities have been associated with IQ productivity losses and other associated health and societal costs. A number of authors[281] [282] [283] have estimated the cost of an IQ point lost as USD_{2010}19,269 (equal to EUR_{2021}30,500) in discounted lifetime costs. Honeycutt et al. (2004) report average lifetime costs per case of intellectual disability of USD_{2003}1,014,000 (equal to €$_{2021}$1,690,000).[284]

Obesity presents significant healthcare costs to society and can result in various related conditions and subsequent reductions in life expectancy. Direct costs considered include drugs, hospitalisations, monitoring and obesity-associated pathologies. Indirect costs are productivity losses, in terms of both presenteeism and absenteeism.[285] Hamilton and Dee (2017) value the total lifetime excess cost per obese child as €$_{2021}$160,000.[286]

There are significant individual and societal costs associated with male reproductive health problems, with costs including medical and fertility treatment. Alberini and Ščasný (2014) estimated the value of a statistical pregnancy among the general population in €$_{2012}$37,900 (equal to €$_{2021}$42,000).

Single Target Organ Toxicity (STOT)

A substance will be classified as a Specific Target Organ Toxicant (STOT) under the CLP Regulation if it produces target organ toxicity/systemic effects that are not specifically addressed in any of the other hazard classes of the CLP Regulation. STOT substances cause specific but non-lethal effects, reversible or irreversible, on organs or organ systems in the body following exposure to a substance. All significant health effects that can impair function, both reversible and irreversible, following single exposure or repeated exposure, are included. Other specific toxic effects, such as acute lethality/toxicity, eye and skin corrosivity/irritation, skin and respiratory sensitisation, carcinogenicity, mutagenicity and reproductive toxicity are not considered since they are assessed by other hazard classes under the CLP Regulation.

There are two main classifications as STOT: Single Exposure and Repeated Exposure. STOT Single Exposure is differentiated into:

—Specific target organ toxicity — single exposure, Category 1 and 2;

—Specific target organ toxicity — single exposure, Category 3.

Categories	Criteria
Category 1	Substances that have produced significant toxicity in humans or that, on the basis of evidence from studies in experimental animals, can be presumed to

[281] Attina TM, Trasande L (2013): *Economic costs of childhood lead exposure in low and middle-income countries*. Environ Health Perspect 121:1097-1102

[282] Trasande L, Liu Y (2011): *Reducing the Staggering Costs of Environmental Disease in Children*, Estimated at $76.6 Billion In 2008. Health Affairs 30:863-870

[283] Bellanger et al. (2013): *Economic benefits of methylmercury exposure control in Europe: monetary value of neurotoxicity prevention* Environmental Health 12

[284] Converted using the purchasing power parities and inflation rates reported by the OECD (https://data.oecd.org/conversion/purchasing-power-parities-ppp.htm) and (https://stats.oecd.org/index.aspx?queryid=82174)

[285] Presenteeism refers to the lost productivity that occurs when employees are not fully functioning in the workplace because of an illness, injury, or other condition. Absenteeism occurs when people are sick, injured, unwell or are unable to come to work due to circumstances.

[286] Rounded to the nearest ten thousand.

	have the potential to produce significant toxicity in humans following single exposure Substances are classified in Category 1 for specific target organ toxicity (single exposure) on the basis of: (a) reliable and good quality evidence from human cases or epidemiological studies; or (b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations.
Category 2	Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following single exposure Substances are classified in Category 2 for specific target organ toxicity (single exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations.
Category 3	Transient target organ effects This category only includes narcotic effects and respiratory tract irritation. These are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function.

From the unofficial information made available by ECHA, there appear to be currently around 291 substances classified as STOT SE, in all three categories combined.

Chemicals under STOT repeated exposure are differentiated into:

—Specific target organ toxicity — repeated exposure, Category 1;

—Specific target organ toxicity — repeated exposure, Category 2.

Categories	Criteria
Category 1	Substances that have produced significant toxicity in humans or that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following repeated exposure. Substances are classified in Category 1 for target organ toxicity (repeat exposure) on the basis of: reliable and good quality evidence from human cases or epidemiological studies; or

	observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations.
Category 2	Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated exposure. Substances are classified in category 2 for target organ toxicity (repeat exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations.

From the unofficial information made available by ECHA, there appear to be currently around 542 substances classified as STOT repeated exposure, in both categories combined.

Under the Biocidal Products Regulation, substances classified as STOTs under the CLP Regulation are subject to risk management measures based on generic risk considerations (i.e. automatically prohibited from use by the general public). There are no equivalent provisions under other product specific legislation within the scope of the Fitness Check for Chemicals Legislation (excluding REACH).

In the Fitness Check, NGOs and some Member State authorities pointed out a potential gap for some "new emerging endpoints" e.g. neurotoxicity, immunotoxicity. These hazard aspects present health and environmental risks of a similar level of concern to those associated with CMRs, PBTs/vPvBs and EDs but are not always explicitly addressed by the EU framework of chemicals legislation e.g. these do not constitute a hazard class under the CLP Regulation. In principle, neurotoxicity can be addressed via the STOT hazard class under CLP. However, in practice, expert stakeholders indicated that testing for neurotoxicity is rarely undertaken despite the availability of internationally recognised test methods. With respect to immunotoxicity, there are currently no internationally recognised test methods to identify substances with this hazard characteristic. It requires further research and development for legislation to be able to address the potential adverse effects on human health.

Respiratory sensitizers

Respiratory sensitizer means a substance that will lead to hypersensitivity of the airways following inhalation of the substance.

Sensitisation includes two phases: the first phase is induction of specialised immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e. production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitised individual to an allergen.

For respiratory sensitisation, the pattern of induction followed by elicitation phases is shared in common with skin sensitisation. For skin sensitisation, an induction phase is

required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardised elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitisation in humans normally is assessed by a diagnostic patch test.

Usually, for both skin and respiratory sensitisation, lower levels are necessary for elicitation than are required for induction.

Hazard categories

Respiratory sensitisers are classified in Category 1 where data are not sufficient for sub-categorisation.

Where data are sufficient a refined evaluation shall allow the allocation of respiratory sensitisers into sub-category 1A, strong sensitisers, or sub-category 1B for other respiratory sensitisers.

Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitisers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table 3.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

Substances shall be classified as respiratory sensitisers in accordance with the criteria in Table 3.4.1 in the CLP Regulation:

Category	Criteria
Category 1	Substances shall be classified as respiratory sensitisers (Category 1) where data are not sufficient for sub-categorisation in accordance with the following criteria: (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity; and/or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitisation rate in humans based on animal or other tests. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitisation rate in humans based on animal or other tests. Severity of reaction may also be considered.

Human evidence

Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

When considering the human evidence, it is necessary for a decision on classification to take into account, in addition to the evidence from the cases:

(a) the size of the population exposed;

(b) the extent of exposure.

The evidence referred to above could be:

(a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) in vivo immunological test (e.g. skin prick test);

(ii) in vitro immunological test (e.g. serological analysis);

(iii) studies that indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g. repeated low-level irritation, pharmacologically mediated effects;

(iv) a chemical structure related to substances known to cause respiratory hypersensitivity;

(b) data from one or more positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

Clinical history shall include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history shall also include a note of other allergic or airway disorders from childhood, and smoking history.

The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is however recognised that in practice many of the examinations listed above will already have been carried out.

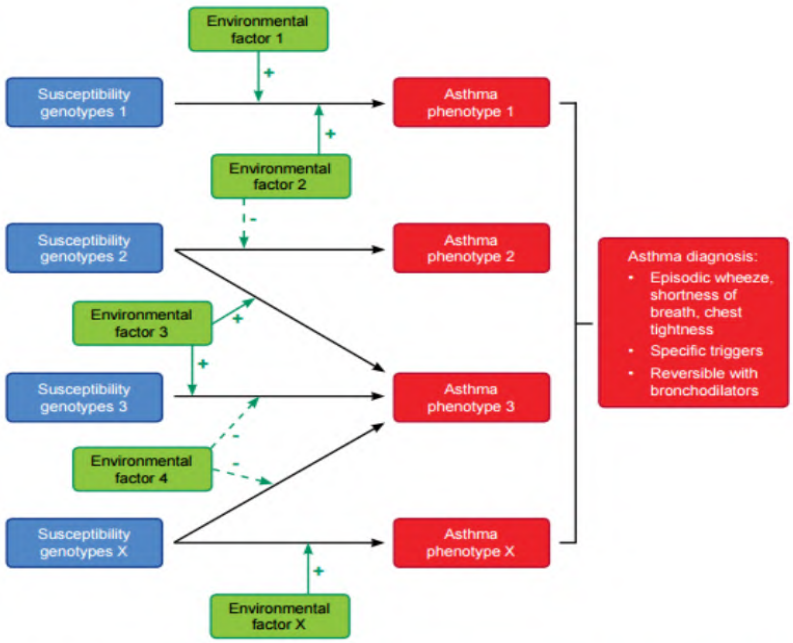
From the unofficial information made available by ECHA, there appear to be currently around 116 substances classified as respiratory sensitisers, in both categories combined..

Asthma[287]

Despite considerable research over the last few decades, there is still an incomplete understanding of why and how asthma develops. This in part reflects the various causal factors and the complexity of their interaction. Figure 10 illustrates the impact of different environmental factors on individuals who in turn have different genetic susceptibility. Exposure to specific environmental factors (green boxes) will give rise to specific asthma phenotypes (red boxes) in individuals with specific genotypic susceptibility profiles (blue boxes). One environmental factor (i.e. chemicals exposure) may have very different impacts on individuals with different genotypic susceptibilities.

Occupational asthma may develop in persons with no previous history of chest disease and can sometimes persist after exposure to the causal agent is removed. The EAAC noted additional research was required on the causes of asthma as well as on the effects of workplace practices – such as personal protective equipment and of regulation[288].

Figure 10: complex interactions in asthma incidence

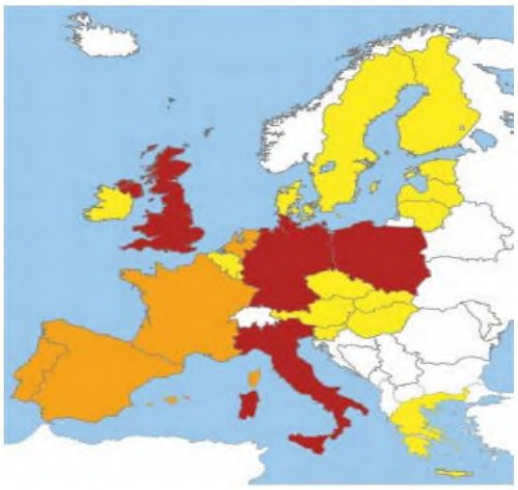


Source: EAACI Global Atlas of asthma 2014 http://www.eaaci.org/GlobalAtlas/Global_Atlas_of_Asthma.pdf

[287] Study on the cumulative health and environmental benefits of chemical legislation, Amec Foster Wheler Environment & Infrastructure UK Limited June – 2017

[288] EAACI Global Atlas of asthma 2014 http://www.eaaci.org/GlobalAtlas/Global_Atlas_of_Asthma.pdf Page 41.

Figure 11 Average annual costs of childhood asthma per country (2005)



Source: EAACI, Global Atals of Asthma (2014) Yellow denotes annual costs of less than €100 million; orange between €100 and €300 million and red more than €300 million.
[1] Average annual costs in the figure are based on published EU-level estimates and include direct medical costs, direct non-medical costs and indirect costs. Detailed methodology can be found at: http://onlinelibrary.wiley.com/doi/10.1111/j.1398-9995.2005.00692.x/full

What is clear from the available evidence is that childhood, adult and occupational asthma is a major issue across Europe.

- The ERS White book, published in 2003 estimated the total costs of asthma in Europe at approximately €17.7 billion per annum. The UK has the highest number of asthma related consultations followed by Greece and Germany, whilst Poland had amongst the least. Costs per patient in Europe were identified in 2012 study at €1,583[289].

- An estimate of the costs of asthma in children in 25 EU countries was published in 2005, which estimated the costs at €3 billion (note this is all cause, not just environmentally attributable asthma). The estimate is based on average annual costs shown in Figure 11. If "wheeze" is included within the definition, this leads to higher costs of €5.2 billion. In terms of childhood asthma, data presented in the EAACI Global atlas of asthma 2014 contains estimated annual costs per country (Figure 11). Yellow denotes a cost of less than €100 million; orange between €100 and €300 million and red more than €300 million[290]. A paper from Bartlett and Trasande study estimates the

[289] Source: EAACI, Global Atals of Asthma (2014)
[290] (Based on data from van den Akker-van Marle ME, Bruil J, Detmar SB. *Evaluation of cost of disease: assessing the burden to society of asthma in children in the European Union.* Allergy 2005; 60:140-149.) presented in EAACI, Global Atals of Asthma (2014).

environmental attributable costs of childhood asthma to the EU in 2013 amounted to €1.6 billion per year[291].

2. REGULATING CHEMICALS IN THE TOY SAFETY DIRECTIVE

The Toy Safety Directive emphasizes the protection from chemical risks in its general safety requirement: 'Toys, including the chemicals they contain, shall not jeopardise the safety and health of users …'. [292]

The Directive further lists a range of 'particular' safety requirements on chemicals in its Annex II, Part III. In addition, cosmetic toys have to comply with the compositional and labelling requirements of the Cosmetics Regulation.[293] Finally, toys that are themselves substances or mixtures have to comply with the CLP Regulation.[294]

In addition, the Toy Safety Directive was given the possibility to include 'Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth …'. The specific limit values in the related Appendix C should 'ensure adequate protection [of children] in the case of toys involving a high degree of exposure … intended for use by children under 36 months and in other toys intended to be put in the mouth …'.[295]

Indeed, eight amendments to the Toy Safety Directive have inserted specific limit values for a number of CMR substances and highly sensitising substances in Appendix C (see annex 5). However, experts in the subgroup Chemicals, but also in the Expert Group on Toys Safety,[296] repeatedly raised the need that children of 36 months and over be equally well protected as those under 36 months. Over 80% of respondents to the public consutlation believed that the toy safety rules sohuld allow for setting limit values for any toy when new scientific knowledge emerges.

In the 2018 public consultation in the context of the Evaluation, two Member States submitted position papers calling to expand Appendix C in order that the limit values also be applicable to toys for children of 36 months and over. In their 2009 – 2013 national reports on the application of the Toy Safety Directive,[297] four Member States proposed that Appendix C limit values also apply to toys for children of 36 months and over. These views have been confirmed in the 2014 – 2018 national reports, submitted in 2019, where Member States indicated that the limitation to toys for children under 36 months and to toys intended to be taken in the mouth is clearly inadequate, in particular for sensitising substances and preservatives, and that such limits should apply to all toys.

[291] Bartlett, E, Trasande, L (2013) *Economic impacts of environmentally attributable childhood health outcomes in the European Union*.
[292] Article 10(2) of the Toy Safety Directive.
[293] See footnote on Regulation (EC) No 1223/2009 further above.
[294] 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.
[295] Recital 24 of the Toy Safety Directive.
[296] See footnote on the Register of Commission Expert Groups further above.
[297] See footnote on the Commission Summary of Member States' Reports further above.

In the 'Fitness check on chemicals legislation (excluding REACH)',[298] the supporting case study on toys[299] reports that, in light of specific limit values for allergenic isothiazolinones in Appendix C, a Member State expressed the view that 'Limiting these restrictions to toys used by children under 36 months or toys intended to be placed in the mouth does not reduce the health risk in the case of relevant dermal exposure of hazardous substances, which might increase the health risk for children over 36 months of age.' The Notified Bodies under the Toy Safety Directive (NB-Toys group) noted at their meeting on 17 September 2019 that allergies in children are independent of the age, a 36 months divide for sensitising substances is therefore not justifiable. Finally, 11 Member States underlined, in a letter of April 2019 to the Commission,[300] their strong belief that limit values in Appendix C should also apply to children of 36 months and older, in light of the chemicals emitted from squishy toys and preservatives in toy slimes and in toy modelling clays. An adaptation of the Toy Safety Directive in this regard was urgently requested.

The above shows that the Toy Safety Directive is not considered effective enough in the eyes of Member States and Notified Bodies. They suggest the specific limit values for chemicals apply to the toys for children of all ages.

Older children may also be exposed to chemicals via the skin or via inhalation. Examples are the sensitising preservatives benzisothiazolinone,[301] chloromethylisothiazolinone and methylisothiazolinone[302] for which specific limit values have been inserted in Appendix C to the Directive. Taking account of all exposure paths for chemicals thus would require the specific limit values in Appendix C to apply to all toys for children of all ages.

In addition, the risk from chemicals is not much different when comparing children under 36 months and older children. The bodyweight of children under 36 months was estimated to be 7.5 kg[303] when calculating the migration limits for toxic 'elements' such as arsenic, cadmium or lead; for children of 36 months and over the bodyweight was assumed to be 15 kg. This 2-fold difference is only minor from the toxicological point of view, a notable difference would be 10-fold.

Finally, only the limit values in Appendix C have an age limit and the limitation to mouthing toys, all other chemical limit values in the Toy Safety Directive apply to all toys for children of all ages. This puts a general question mark on the Appendix C limit values.

a. CMR SUBSTANCES IN GENERAL – GENERAL BAN AND DEROGATIONS

The Toy Safety Directive prohibits the use of substances that are classified, under the CLP Regulation, as carcinogenic, mutagenic or toxic for reproduction (CMR). CMR substances may be identified as substances of very high concern under REACH.[304] The hazardous effects of such substances are of particular severity, they can only be seen in

[298] http://ec.europa.eu/growth/sectors/chemicals/ec-support_en. Click 'Supporting studies and consultations', click 'Annex VI'.
[299] http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/
[300] Letter of 25.4.2019.
[301] See the related amendment in annex 6.
[302] See the related amendment in annex 6.
[303] National Institute for Public Health and the Environment (RIVM)
[304] See footnote on Regulation (EC) No 1907/2006 further above, Articles 55 and 57.

the long term and can almost never be traced back to the chemical of origin, and are often irreversible.

However, the Toy Safety Directive tolerates the presence of CMRs in toys or its components up to the 'relevant concentrations' of the CLP Regulation. 'Relevant' are either the specific concentration limits assigned to specific substances in Annex VI, table 3.1 of the CLP Regulation; if no specific concentration limits are indicated in that table, the generic concentration limits in Annex I of the CLP Regulation apply: 0.1% and 1% for carcinogens[305] and mutagens[306] of categories 1 and 2, respectively, and 0.3% and 3% for reproductive toxins[307] of categories 1 and 2, respectively.

These 'relevant concentrations' of the CLP Regulation are hazard-based and have been set for the purpose of classification and labelling of mixtures containing hazardous substances, with the primary aim to ensure that the hazards of such mixtures are properly identified and communicated. They do not take account of possible exposures, do not entail an assessment of risk related to the uses of a substance, and thus are inadequate to manage the risk when a substance is present in an article such as a toy.

To take account of the exposure of children to chemicals in toys the subgroup Chemicals was established to recommend limit values for chemicals in toys when those chemicals could pose a risk. On the basis of the work of the subgroup the Toy Safety Directive was amended six times to include (in its Appendix C) risk-based limit values for several CMRs: TCPP and two similar flame retardants, bisphenol A, formamide, phenol, bisphenol A and formaldehyde.[308]

Those risk-based limit values are often migration limits. They cannot be compared with the 'relevant concentrations' taken from the CLP Regulation, which are content limits. There is no relationship between the concentration of a substance inside a material, i. e., its content, and the migration of the substance out of that material though the highest possible migration of the substance would be its content. Both therefore cannot be converted into one another. Nevertheless, for a few substances the Directive sets risk-based content limits and comparisons are therefore possible:

Chemical substance	**'Relevant concentration' in the CLP Regulation, mg/kg**	**Content limit in Appendix C, mg/kg**	**Difference factor**
TCEP	3,000	5	600
Phenol	10,000	10	1,000
Formamide	3,000	200	15
Formaldehyde	1,000	30 and 10	33 and 100

The limit values in Appendix C are thus 15 to 1,000 times lower than the 'relevant concentrations' in the CLP Regulation. The Toy Safety Directive's derogation from the CMR prohibition therefore does not appear to be well justifiable with regard to the protection of children's health.

[305] Table 3.6.2 of the CLP Regulation.
[306] Table 3.5.2 of the CLP Regulation.
[307] Table 3.7.2 of the CLP Regulation.
[308] See the related amendments in annex 6.

This likely inadequacy of the CMR derogation based on the concentration limits for classification of mixtures from the CLP Regulation was referred to by public authorities (70% of public authorities responding disagreed or strongly disagreed with it) and by consumer organisations (75%) in the open public consultation.

The fitness check on chemicals legislation (excluding REACH)[309] reported in its case study on toys[310] about a consumer association indicating that the thresholds outlined in the CLP Regulation for CMR substances were not originally intended to be used as a limit for consumer products and were therefore not appropriate for application to consumer products (and in particular toys, as children are vulnerable). Also, a Member State authority noted that the CLP Regulation follows a hazard-based approach and the generic classification limits of 0.1% for human carcinogens were too high meaning that health risks to children could not be excluded. Also the 2015 external study reported consumer organisations deeming the limits for CMR substances to be too high.

The SCHEER also identified a number of problems that can arise from the approach to address CMRs in relation to content limits, due to the fact that classification limits set for substances or mixtures are applied to articles (as the toys should be considered). First of all, the percentage composition refers to the toy as a whole, to components of the toy and to distinct, microstructural parts of the toy. However, a CMR substance present in a specific part of the toy may not be homogeneously distributed, so that the local % concentration could be higher in that specific part and possibly above the limit. Secondly, limits are cut- off values, defined for a practical approach to be used for regulatory purposes. Finally, the classification of mixtures as CMRs is based on the presence of at least one of the CMR substances above the classification limits, without taking into account possible interactive effects of the CMR substances in the mixture, hence in the toys. These considerations make the suitability of the classification approach applied to toys quite limited, according to SCHEER[311].

In addition to the above the Toy Safety Directive provides for two further derogations for the use of CMRs in general:

- The second derogation in the Toy Safety Directive allows CMRs in toys that exceed the 'relevant concentration' in the CLP Regulation. Such higher concentrations are allowed if the CMRs are inaccessible in any form, including through inhalation, when children are playing with the toys.
- The third derogation that allows CMRs in toys is conditioned by an evaluation by the relevant Scientific Committee that a CMR is safe in toys, and that REACH does not prohibit the CMR in consumer articles. For the 'stronger' CMRs (categories 1A and 1B under the CLP Regulation), the third condition is the non-availability of alternatives, which is not needed for CMRs category 2. – So far only a single derogation of this kind was allowed, namely for nickel in toys and toy components made of stainless steel and in toy components which are intended to conduct an electric current.[312]

[309] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0264&from=EN
[310] http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/ , p. 33.
[311] SCHER Opinion on risk from organic CMR substances in toys, 18 May 2010.
[312] Annex II, Appendix A of the Toy Safety Directive.

From the above it appears that a generic approach to the risks of a whole class of chemicals could be missing effectiveness if derogations are set that ignore one of the two constituents of risk, namely in this case the exposure of a vulnerable group of consumers.

b. SPECIFIC CMRS: NITROSAMINES AND NITROSATABLE SUBSTANCES

The Toy Safety Directive sets migration limits for nitrosamines and nitrosatable substances in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth: 0.05 mg/kg for nitrosamines, 1 mg/kg for nitrosatable substances.[313] Relevant nitrosamines may be genotoxic and very strong carcinogens. Nitrosatable substances can be converted into nitrosamines in the human body.

Germany however insisted on its lower national limits of 0.01 mg/kg for nitrosamines and of 0.1 mg/kg for nitrosatable substances in toys made of natural or synthetic rubber designed for children under 36 months and intended or likely to be placed in the mouth. The Commission allowed Germany in a Decision of March 2012 to keep its lower limits, acknowledging that 'the German request is based on a real concern with regard to children's health …'.[314] The German limits were consistent with the limits for (parts of) teats and soothers made of elastomer or rubber, of 0.01 mg/kg for nitrosamines and of 0.1 mg/kg for nitrosatable substances.[315] – And the Commission declared in its 2012 Decision to '… *require CEN to consider … to lower the limit values within the standardisation process*.'

As a consequence, the Commission mandated CEN in March 2012 to revise the limits for nitrosamines and nitrosatable substances in Standard EN 71-12 on N-nitrosamines and N-nitrosatable substances.[316] Standardisation should take account of the latest data on the mouthing behaviour of children (which is related to all toys), not only of the mouthing of balloons. With this, CEN's work resulted in the adoption of standard EN 71-12:2017, made available in January 2017, and including lower limits for nitrosamines and nitrosatable substances in accordance with the Commission's mandate.

Thus, the Evaluation concluded that the Directive was not effective with regard to the protection from nitrosamines and nitrosatable substances. Also, referencing EN 71-12:2017 with its strengthened limits for nitrosamines and nitrosatable substances in the Official Journal is not possible since that would lead to a conflict with the limits in the Directive. EN 71-12:2017 therefore cannot provide the presumption of conformity until the Directive has been revised.

In their letter of April 2019 to the Commission,[317] 11 Member States considered that there was an urgent need to lower the limits for nitrosamines and nitrosatable substances. In the 2018 public consultation, public authorities commented that the limits for nitrosamines and nitrosatable substances should be aligned, according to position papers submitted by Denmark, Germany and Sweden, with the limits that the Commission had

[313] Annex II, Part III, point 8 of the Toy Safety Directive.
[314] Recital 88 of Commission Decision 2012/160/EU. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012D0160&qid=1571656440439&from=EN
[315] Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer of rubber teats and soothers. OJ L 93, 17.4.1993, p. 37. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0011&qid=1571656528598&from=EN
[316] Letter of 29.3.2012.
[317] See letter of 25.4.2019.

requested from CEN and available in standard EN 71-12:2017. Industry and Notified Bodies considered the existence of lower limits in national legislation as an incoherence with the Toy Safety Directive. Consumer organisations considered the limits for nitrosamines and nitrosatable substances to be inadequate already in the 2015 external study on the Directive.

c. AN ILLUSTRATION OF THE PROBLEM - BISPHENOL A

The substance Bisphenol A is a high volume chemical that is widely used in the production of a large variety of consumer products. Bisphenol A is used in the manufacture of polycarbonate plastics. Since 2002 Bisphenol A was classified under the CLP Regulation as toxic for reproduction category 2. In the absence of any specific requirements, the Toy Safety Directive allowed the presence of Bisphenol A in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it as CMRs, namely 5 % as from 20 July 2013 and 3 % as from 1 June 2015 respectively.

European standards[318] provided a migration limit of 0,1 mg/l for Bisphenol A in toys, as well as the relevant test methods. These were used by the toy industry but did not constitute harmonised standards as they did not correspond to requirements in the Directive.

The risk assessment report, entitled 'Updated European Union Risk Assessment Report 4,4'-isopropylidenediphenol (Bisphenol-A)'[319], found, among other things, that Bisphenol A has endocrine modulating activity and concluded that further research was needed to resolve the uncertainties surrounding the potential for Bisphenol A to produce adverse effects on development at low doses. Nevertheless, a high level of protection of children against risks caused by chemical substances in toys, in the light of the particular needs of children, who are a vulnerable group of consumers, warranted incorporating the migration limit of 0,1 mg/l for Bisphenol A into Directive 2009/48/EC. This was done by Commission Directive 2014/81/EU amending appendix C of the Directive[320].

This limit value was subsequently revised by Commission Directive 2017/897 amending appendix C in view of new data on Bisphenol A and refined methodologies by the European Food Safety Authority (EFSA)[321]. According to the EFSA[322], high doses of Bisphenol A are likely to harm kidney and liver.

[318] EN 71-9:2005+A1:2007 and EN 71-10:2005 and EN 71-11:2005

[319] Joint Research Centre, Institute for Health and Consumer Protection, *Updated European Union risk assessment report 4,4'-isopropylidenediphenol (bisphenol-A) : human health addendum of February 2008*, Pakalin, S.(editor), Aschberger, K.(editor), Munn, S.(editor), Publications Office, 2010, https://data.europa.eu/doi/10.2788/40301

[320] COMMISSION DIRECTIVE 2014/81/EU of 23 June 2014 amending Appendix C of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards bisphenol A, OJ L 183, 24.6.2014, p. 49.

[321] COMMISSION DIRECTIVE (EU) 2017/898 of 24 May 2017 amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards bisphenol A, OJ L 138, 25.5.2017, p. 128.

[322] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/factsheetbpa150121.pdf

Since then, in January and June 2017, the ECHA Member States Committee identified Bisphenol A as a substance of very high concern (SVHC) because of its repro-toxic properties, and endocrine disrupting properties on human health, respectively. Bisphenol A may damage fertility and has been identified as a substance affecting the hormonal systems of humans and animals. In addition, it damages eyes and may cause allergic skin reactions and respiratory irritation. This is why as of 1 March 2018, Bisphenol A is classified in the EU under the CLP regulation as a substance that: causes toxic effects on our ability to reproduce (Repr. 1B); may cause respiratory irritation (STOT SE 3); causes serious eye damage (eye dam. 1); and may cause skin allergies (skin sens. 1)[323].

EFSA has re-evaluated the risks of Bisphenol A and in its April 2023 opinion considers that scientific literature since 2013 until 2018 indicate adverse effects of Bisphenol A on the immune system and suggests a significantly lower tolerable daily intake[324]*. The TDI is around 20,000 times lower than before.*

In light of the scientific evidence, the derogation in the Toy Safety Directive allowing for the presence of CMRs up to the relevant concentrations of the CLP Regulation allows for too much presence of Bisphenol A in toys. While the Toy Safety Directive has allowed for the introduction of specific limit values for Bisphenol A, this can only be done in appendix C of the Directive, which applies to toys intended for children under 36 months or to be put in the mouth. Older children than 36 months are not protected under the current Directive from exposure to Bisphenol A in toys.

d. USES OF CHEMICALS IN TOYS

In the framework of the Study being conducted to support the revision of REACH and the extension of the Generic Risk Management approach (GRA)[325], a use mapping has been conducted on the basis of the ECHA registration dossiers. For the most relevant product categories an assessment on the number of substances that would fall under specific hazard classes was developed. Below, as an illustration, are the results for 3 product categories particularly relevant for toys: PC 32: Polymers, PC9a: Finger paints and PC9c: Plasters and modeling clay. It is quite clear that many substances counted under this will not be used in toys but seeing the variety of toys and the polymer compounds used in them it is nonetheless a good approximation to understand the scale of the challenge.

The list consisted of 3 baskets with the following characteristics, according to an accompanying ECHA document:

- **Basket 1- Substances with confirmed hazard(s)**: For endpoints included in CLP these are based on either their harmonised classification (inclusion in Annex VI to CLP) or the reported self-classification in the registration

[323] COMMISSION REGULATION (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, OJ L 195, 20.7.2016, p. 11.

[324] Re- evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs - - 2023 - EFSA Journal - Wiley Online Library https://doi.org/10.2903/j.efsa.2023.6857

[325] Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction, Annex 1: report on task 2 – use. To be published.

dossier. For other endpoints, these are based on identification as SVHC (inclusion in the Candidate List), identification under the Biocidal Products Regulation (BPR) or agreed in the ED/PBT Expert Groups. Hazard(s) are based on available information; lists as well as numbers of substances provided.

- **Basket 2 – Substances where the hazard(s) are under consideration** : These are substances with on-going data generation or assessments; lists as well as numbers of substances are provided; it also includes an estimate on the number of substances for which the hazards are likely to be confirmed (based on past experience).
- **A third basket** is represented by estimates of the number of substances in the chemical universe that may be classified according to the new hazard classes based on the assumption that the same proportion of hazardous substances exists regardless of their manufactured and/or imported quantities (and therefore registered providing different information requirements according to REACH Annex VII, VIII, IX and X). It is important to note that Basket 3 is not a list of identified substances and therefore cannot be used for the purpose of use mapping.

The initial list in Basket 1 contains both cat. 1 and cat. 2 substances in the area of STOT SE and RE substances. Cat. 2 substances, analogous to CMR substances, would possibly not be the subject of a future GRA. It was therefore not considered further in the use mapping. STOT RE and SE is only represented by cat 1. This distinction was not made in Basket 2, as there was no information on this. it is possible that the same substance is assigned several times to the individual PCs due to several hazardous properties. It should be noted that substances can not only appear in an additional hazard class but can also be named in three or four categories (especially in the comparison of Baskets 1 and 2 due to the high number of suspected substances in PBT/vPvB, ED and PMT). In addition, environmental hazards (ED ENV, PBT/vPvB and PMT) are not within the scope of the revision of the TSD.

Table 19: Number of substances Basket 1 according to PC with consumer Life cycle stage[326]

PC	ED ENV	ED HH	PBT/ vPvB	Resp. Sens.	STOT RE (Cat. 1)	STOT SE (Cat. 1)	PMT	CMR
PC 32: Polymer preparations and compounds	6	5	11	16	15	3	0	30
PC 9c: Finger paint	0	1	2	1	20	0		50
PC 9b: Fillers, putties, plasters, modelling clay	1	2	4	7	25	1		62
≤10 green, >10 - ≤ 50 light green, >50 - ≤ 100 yellow, > 100 red								

Table 20: Number of substances Basket 2 according to PC with consumer Life cycle stage

PC	ED	PBT/ vPvB	Resp Sens	STOT RE	STOT SE	PMT

[326] When data are shown for a hazard class, duplicates are always included to make a description of the respective hazard class.

PC	ED	PBT/ vPvB	Resp Sens	STOT RE	STOT SE	PMT
PC 32: Polymer preparations and compounds	83	55	8	7	7	54
PC 9c: Finger paint	48	31	8	6	7	31
PC 9b: Fillers, putties, plasters, modelling clay	82	41	8	9	9	43
≤10 green, >10 - ≤ 50 light green, >50 - ≤ 100 yellow, > 100 red						

In that Study, a number of caveats were highlighted in respect of this information. In particular, it was argued that the use of CMR substances in PC 32 polymers seems to rather reflect the further application of polymers and plastics. Substances are found that are incorporated as monomers into more complex compounds and subsequently no longer exist. Therefore, a CMR property would no longer exist in the service life.

Nevertheless, the above could give a broad illustration of the implications of the generic risk management approach (options 1b and 1c) in toys.

ANNEX 11: NON-COMPLIANT TOYS ON THE UNION MARKET

1. NON-COMPLIANT PRODUCTS: RAPEX DATA

The Safety Gate system, formerly known as the Rapid Exchange of Information System (RAPEX), is the EU's rapid alert system for sharing information between national authorities on measures taken against dangerous non-food products, including toys. The system operates as follows:

- When a national authority in an EU Member State or EEA / EFTA country identifies and adopts measures against dangerous products placed on the market, it submits an alert to Safety Gate. Each alert follows a template and provides a wide range of information, including the type of product, a description of the risk, the country of origin and the measures ordered by the authority or taken by the economic operator.

- All other authorities are required to follow up on each alert and share any information on the presence of the dangerous product on their own market.

Data on SafetyGate (/RAPEX) alerts are available for the period 2005-2021. This section first presents an overview of the key methodological considerations related to the SafetyGate alert data, before presenting an analysis of the toy-related alerts across the period 2016-2021, in line with the time period examined through the market analysis.

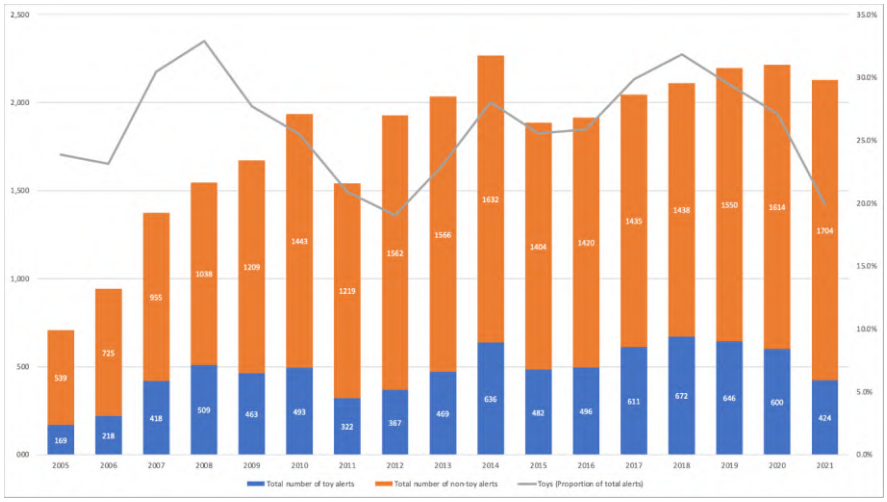
Within this context, the SafetyGate alert data for the period 2016-2021 is now analysed, focusing first on headline data points, before examining a range of relevant variables, including the risk categories for alerted toy products, the types of alerts, the countries of origin and the countries submitting alerts.

Over the period 2016-2021, the 'Toy' category comprised 27.4% of total SafetyGate alerts (3,449 of 12,610 alerts); the highest proportion of any specific product category. This proportion has varied significantly over the years, with a peak of 31.8% of total alerts in 2018 and a low of 19.9% in 2021. The below figure 12 illustrates this percentage per year since 2005, alongside the total number of toy and non-toy alerts.

As can be seen, the number of alerts increased year on year between 2005-2010, as market surveillance authorities became more familiar with SafetyGate following its introduction. However, a clear drop in both toy and non-toy alerts was experienced in 2011 followed by an increase to 2014 – the highest year to date in terms of total alerts and the third highest for toy-related alerts. Given the entry into force of Regulation (EC) No 765/2008 – part of the New Legislative Framework (NLF) – in 2010 and the subsequent application of national transpositions of the updated Toy Safety Directive 2009/48/EC by July 2011 (as well as the alignment of many other pieces of industrial product legislation to the NLF), one prominent explanation for this trend is the need for market surveillance authorities to familiarise and integrate these new rules into their processes and procedures.

In the years since 2014, the level of both non-toy and toy related SafetyGate alerts has remained relatively stable. In line with the abovementioned challenges, this result could indicate a plateau in terms of market surveillance authorities capacity (in terms of resources) to identify and report dangerous products.

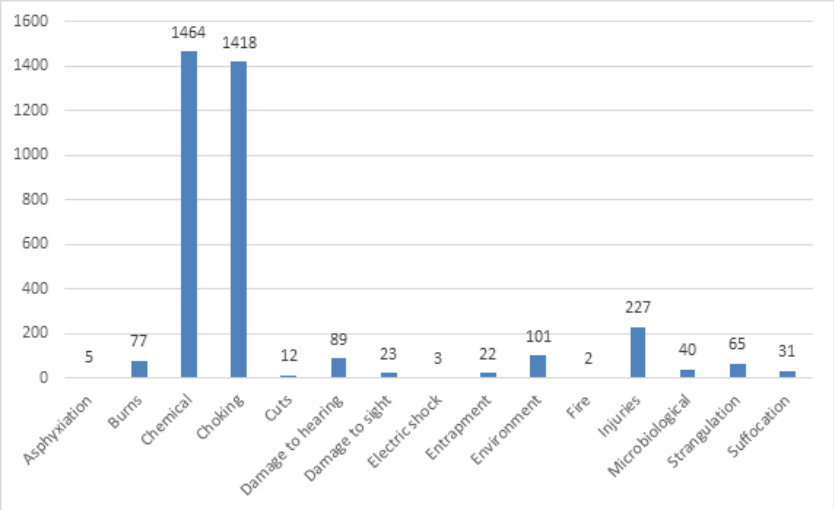
Figure 12: **SafetyGate alerts 2005-2021: Toy and non-toy product categories**

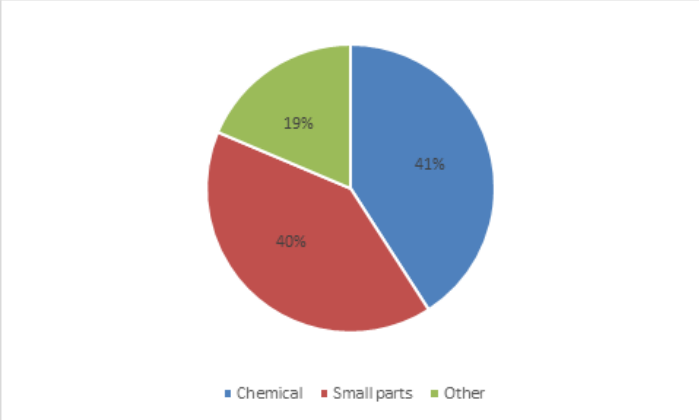


From the above, it is also clear that the toys comprise a sizeable proportion of total SafetyGate alerts. In fact, the 'Toys' category has been the product category subject to the highest number of alerts in five of the last six years. The next highest categories across this period were 'Motor vehicles' (22.5%, 2,840 alerts), 'Clothing, textiles and fashion items' (9.4%, 1,182 alerts) and 'Electrical appliances and equipment' (8.6%, 1,088 alerts). The remaining 57 categories comprised around 32.1% of alerts.

Within the 'Toys' category, the two **most common risk categories** over the period 2016-2021 by more than 1,000 alerts are choking risks (1,507, 37.7%) and chemical risks (1,404, 35.1%). In fact, with general injury risks added (398, 10%), these three risk types comprise 82.8% of toy related SafetyGate alerts in this period. No other risk type makes up more than 4% of toy-related alerts.

Figures 13 and 14: **SafetyGate alerts 2005-2021: Types of risks in dangerous toys**



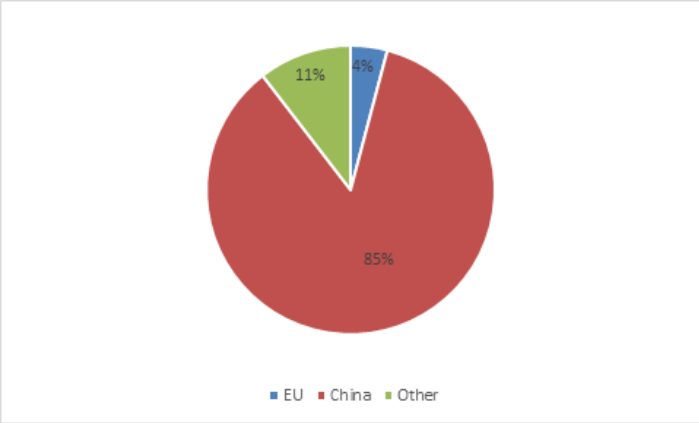


Concerning the **types of alerts** possible within SafetyGate, the vast majority (91.4%) concern serious risks. The other options ('Other risk levels' and 'Other types of alerts') are used in a relatively limited manner.

Another important variable to analyse is the **country of origin of alerted products**; particularly given the challenges raised by all stakeholder types of non-compliant products being placed on the market by third country economic operators, often via online marketplaces. In this respect, the analysis of the SafetyGate data supports the views of stakeholders, with a significant proportion of 85.6% of toy-related alerts (2,951) in the period 2016-2021 concerning products originating in China. This proportion has remained relatively stable over the entire history of RAPEX / SafetyGate, starting at 75.1% in 2005, rising to 90.7% in 2016 and 2017, before decreasing in 2020 (78.5%) and 2021 (81.1%).

A further 5.5% of the products subject to alerts are of 'Unknown' national origin; however, experts in the field believe many of these are likely to also originate in China. The next most common country of origin is Germany (1.3% of toy-related alerts), while each of the remaining countries comprises less than 1% of alerts.

Figure 15: Country of origin of dangerous toys in RAPEX (2016-2021)



Beyond the product's country of origin, it is also interesting to examine which **European countries are submitting the most toy-related alerts**. Poland has submitted the most toy-related alerts in the period 2016-2021, with 435 (12.6% of toy-related alerts). In addition, Hungary (327, 9.5%), Spain (323, 9.4%), France (283, 8.2%) and Cyprus (277, 8.0%) are particularly active.

Building on these data, the proportion of total alerts per country that are focused on toy products could be used as a proxy for the level of priority different market surveillance authorities place on toys. In this respect, the data suggest that while some countries place significant focus on toy-related product safety issues, others do not. More specifically, the proportion of total alerts that relate to toy products is higher than the overall EU-wide average (27.4%) in 17 countries. In fact, this figure is above 50% in Czechia (60.2%), Poland (59.2%), Slovakia (56.3%) and Spain (53.9%) and above 40% in a further seven countries (LV, LT, IS, AT, CY, NL, LU).

This finding suggests not only that these countries place a particular focus on identifying and submitting alerts related to toy products, but that the EU-wide average is strongly influenced by the data from Germany. Only 3.8% (93) of the 2,465 SafetyGate alerts submitted by Germany in the period 2016-2021 related to toys. Indeed, when removing the German data, the proportion of total alerts that are related to toys increases from 27.4 to 33.1%.

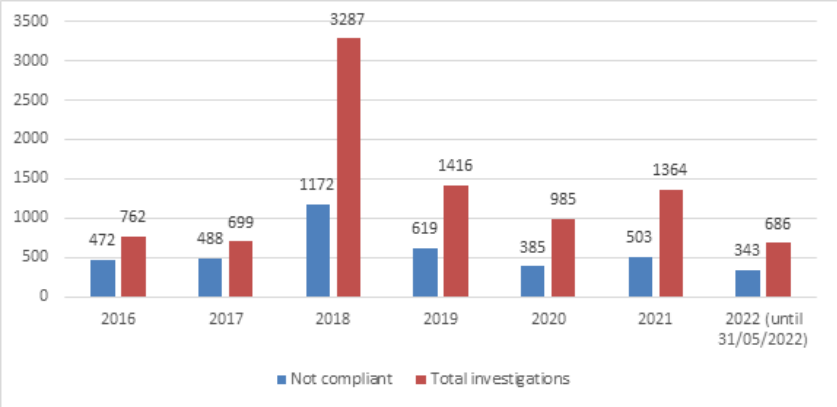
According to this assumption, other European countries that appear to place less of a focus on toy-related products included Ireland (1.5% of total alerts), Bulgaria (2.4%), Portugal (6.8%) and Romania (6.8%).

2. NON-COMPLIANT PRODUCTS: ICSMS DATA

Market surveillance authorities are also required to enter into the information and communication system for market surveillance (**ICSMS**) **information** in relation to products made available on the

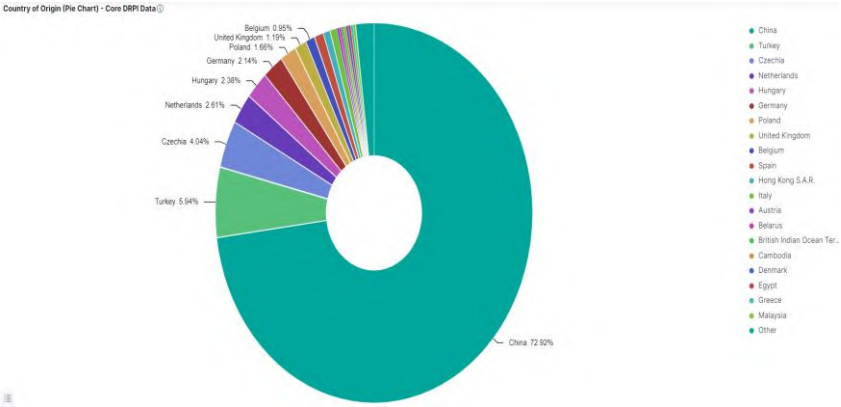
Union market for which an **in-depth check of compliance** has been carried out, in addition to their obligation to alert of dangerous products under RAPEX. This obligation has become more explicit with the new Regulation 2019/1020 on market surveillance[327], which is fully applicable since July 2021. Data from the period 2016-May 2022 shows that out of the 9199 toys subject to in-depth investigations, 3982 were found to be non-compliant, which corresponds to 43.2% of inspected toys.

Figure 16 : non-compliant toys and total number of in-depth toy investigations per year in ICSMS



The data on the country of origin of products subject to in-depth investigations also corroborates the fact that most risks in toys of non-compliance come from third countries.

Figure 17: country of origin of inspected toys in ICSMS (2016-2022)



[327] See article 34 of this Regulation.

3. DATA FROM THE EVALUATION BASED ON THE NATIONAL REPORTS

Under their obligation to report on the application of the Directive,[328] Member States have to present their market surveillance activities. For 2014 – 2018, 21 Member States (mostly small Member States corresponding to a little more than 50% of the EU-28 population[329]) provided for the first time data on marketing restrictions of toys that could be consistently evaluated.

The evaluation showed that market surveillance authorities in all 21 Member States together (visually) inspected a little more than 14,000 toys on average each year during 2014 – 2018. As an average during each of these year five years, tests were carried out on 2,100 toys; 2,800 toys were assessed as non-compliant (due to the fact that some defects were so obvious that they did not need laboratory tests) and restrictive measures were taken on 690 toys found to be dangerous.

Looking at each individual Member State (of the 21), almost 30% of the inspected toys were tested, more than 30% of the inspected toys were assessed as non-compliant, and on a little more than 15% of the inspected toys national measures to restrict the marketing were taken.

Thus, almost every third toy inspected was non-compliant. This reflects the capacities of market surveillance authorities to find non-compliant toys through targeting economic operators likely to break the rules (such as those that have a history of non-compliance) and toys marketed in large numbers or having severe health impacts when non-compliant. [330]

By comparison, four joint market surveillance actions on toys,[331] supported by the Consumer Programme of the European Commission,[332] showed non-compliance rates for the tested toys between 10% and 96%, with an average of 43%.

It thus appears that market surveillance is able to detect non-compliant toys at an average rate of 30% – 40%, although with a sometimes considerable variability around this average. Rates around 10% or less in some small Member States may however be caused by too little testing compared to those Member States that were nearer to the average. This became evident from the Member States' 5-yearly reports 2014 – 2018. Any reasons for the low rates were not reported but can be assumed, based on informal contacts with market surveillance authorities, to be linked to too little financial

[328] Article 48 of the Toy Safety Directive.
[329] Population data taken from Council Decision (EU, Euratom) 2018/2076 amending the Council's Rules of Procedure. OJ L 331, 28.12.208, p. 218.
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D2076&qid=1571646130303&from=EN
[330] Good practice for market surveillance. Guidance document developed by market surveillance experts who are members or Chairpersons of various Administrative Cooperation (AdCo) groups. P. 7. https://ec.europa.eu/docsroom/documents/23041/attachments/1/translations/en/renditions/pdf
[331] Chemical risks in plasticised toys
http://prosafe.org/images/Documents/JA2015/Reports/PROSAFE_Final_Technical_Report%20_TOYS-JA2015_09.04.2018.pdf
Acoustic toys
http://prosafe.org/images/Documents/JA2014/2017_Deliverable%20D7.6-final_technical_report%20-%2012.04.2017%20rev%20CHAFEAnt.pdf
Toys intended for childrens under 3 years
http://prosafe.org/images/Documents/JA2013/JA2013_Toys_Final_Technical_Report_24-02-2016.pdf
Children's kick scooters
http://prosafe.org/images/Documents/JA2013/JA2013-Kick_scooters-Deliverable_D11.2-Final_Technical_Report.v6_24.03.2016.pdf
[332] Consumer Programme 2014-2020. http://ec.europa.eu/chafea/consumers/programme/index_en.htm

means or the non-existence of a national test laboratory. A 'best practice' conclusion may thus be that market surveillance has to be sufficiently well equipped, whether with financial resources or other, in order to perform well.

Due to the fact that the only available data for measuring the effectiveness of market surveillance is data on non-compliant toys, a more detailed differentiation according to Member States, type of toys, company size, EU toys vs. Third Country toys could not be made in the context of the evaluation.

4. RESULTS FROM 2020 AND 2021 COORDINATED ACTIONS ON THE SAFETY OF PRODUCTS (CASP)

The *2020 CASP joint action on nitrosamines in toys* focused on the level of nitrosamines and nitrosatable substances in balloons, squeeze toys and finger paints. 16% of the 220 products tested exceeded the limit values set in standard EN 71-12:2013 for nitrosamines and/or nitrosatable substances. Eight samples of balloons exceeded the limit values for both substances. Only 24% of the samples met the labelling and warnings requirements. The percentage of balloons that did not meet the chemical requirements (33%) was significantly higher than that of finger paints (9%) and squeeze toys (3%). The majority of samples (179) were purchased in physical stores. The percentage of samples that exceeded the limit values for chemical testing did not vary considerably between samples purchased online and those from physical stores. However, a higher percentage of the samples purchased online (88%) did not meet the labelling and warnings requirements compared to the samples purchased in physical stores (73%).

The *2021 CASP joint action on toys from non-EU workshops* focused on plastic toys and toys with plastic parts for children under and above 36 months collected online and originated from third countries: 84% of toys tested did not meet the applicable safety requirements. The detailed results of the project were as follows: Number of toys tested: 92 (50 toys intended for children above 36 months and 42 toys intended for children under 36 months). A total of 15 toys (16%) met the testing requirements while 77 toys (84%) did not meet the testing requirements. Toys intended for children under 36 months presented a slightly larger number of samples that did not meet the requirements (88%) than toys for children above 36 months (80%). The market surveillance authorities' checks on warnings, labelling and instructions showed that all the samples (except one) did not meet the requirements. Full report expected to be published in June 2022.

The *2021 CASP joint action on electrical toys* focused on electric toys with button cells/other cells; electric ride-on toys; electric toys with lasers/ other lights; and remote-control toys. Compliance with the Toy Safety Directive but also other legislation like Directive 2011/65 on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) was assessed: 25% of the samples did not meet all the applicable requirements. The detailed results of the project were as follows: The number of toys tested was 130 (58 electric toys with button cells/other cells; 34 electric ride-on toys; 24 electric toys with lasers/ other lights; and 14 remote-control toys). A total of 75%of the samples (97) met the requirements while 25% of the samples (33) did not meet all the applicable requirements. The product categories where the most samples did not meet all requirements were remote-control toys (36%) and electric toys with button cells/other cells (33%). The majority of samples (72%) came from physical shops. A considerably higher percentage of electric toys purchased online did not meet at least one of the relevant requirements (47%) compared to the percentage of those purchased in physical shops (17%). Full report expected to be published in June 2022.

ANNEX 12: DIGITAL ASPECTS AND INTERNET-CONNECTED TOYS

The Evaluation concluded on the Directive not being able to quickly adapt to technical and scientific progress, compared to the rapidly evolving market. The scope of the Directive is focused on health and safety (see the particular safety requirements in Annex II: physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene, radioactivity[333]) and does not cover other issues such as privacy or information security. As a result, there were cases in the past where risks posed by cybersecurity or privacy concerns on toys could not be addressed.

Currently, advanced children's toys on the market include varieties of dolls and toy creatures that can change their behaviour in order to entertain (such as by remembering answers given by a child, knowing what time it is or giving a weather forecast, and otherwise adapting to the child's responses); construction games permitting children to build programmable gadgets; and specially-designed tablets that have various features permitting children to interact with their environment in different ways (including by uploading photos and documents to personalise) [334].

Regarding internet-connected toys, the new connecting functionalities can create new vulnerabilities for children and require that internet-connected toys are protected against cyberattacks. Children are particularly at risk because they may not become aware that a toy speaking to them, such as an internet-connected doll or robot, can actually be a misleading intruder who has hacked the toy in order to get access to the home of a child. This is also the case with regards to toys which rely on artificial intelligence[335]. In 2017, My Friend Cayla[336], a smart doll that used facial and voice recognition, was declared an illegal surveillance tool in a number of countries, including Germany. With the abundance of personal information collected, processed and shared through advanced technologies such as artificial intelligence and predictive analytics, children's data may also be used for the purpose of profiling, potentially affecting their fundamental legal rights and freedoms. The age and maturity of the child may affect their ability to understand the motivation behind this type of data collection and uses or the longer term privacy consequences[337].

The TSD does not contain any rules on cybersecurity, and in common with other Union harmonisation legislation does not explicitly mention the word "security", although this could be argued to be implicitly covered, as in other sectoral legislation as it is part of the broader concept of product safety.

However, cybersecurity risks relating to personal data protection and privacy and protection from fraud for toys are now addressed through the adoption of a delegated act pertaining to Articles 3(3)(e) and 3(3)(f) of the **Radio Equipment Directive** (RED) in October 2021[338] (as of 01/08/2024, radio toys have to comply with minimum baseline security requirements pertaining to personal data protection and privacy and as of 01/08/2024, internet-connected toys have to comply

[333] See section 2.1.2 above.
[334] See also Consumer Product Safety in the Internet of Things (oecd-ilibrary.org)
[335] See for example https://www.datanami.com/2022/03/29/are-we-ready-for-the-dangers-of-smart-toys/
[336] Generation AI: What happens when your child's friend is an AI toy that talks back? | World Economic Forum (weforum.org)
[337] https://www.oecd-ilibrary.org/docserver/9b8f222e-en.pdf?expires=1649682232&id=id&accname=guest&checksum=75B41EC6A1648ACD89848BB4F8FB1FF5
[338] Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that directive, OJ L 7/6 of 12.01.2022.

with minimum baseline security requirements pertaining to protection from fraud). This delegated act has strengthened cybersecurity by requiring manufacturers of radio equipment, including of radio toys, as defined in the delegated act, to ensure that minimum security requirements are complied with from the outset. This has further embedded the specific provisions in the GDPR pertaining to ensuring privacy by design and default but emphasising broader security by default principles.

This ought to ensure that connected toys area designed in a way that ensures they remain cybersecure, with software updates to ensure product security post-market placement. Although there are concerns expressed by stakeholders regarding the need to strengthen cybersecurity in connected toys through the TSD, this has already been addressed through parallel legislation, which all radio toys would have to adhere to. This has closed the regulatory gap.

The Delegated Regulation, applicable from 1 August 2024, will apply to the radio equipment covered by the TSD processing personal data, traffic and location data and require the manufacturers to take data protection and privacy measures before putting toys on the internal market. The manufacturers will have to perform a conformity assessment to meet such requirements as regulated by Article 17 RED. This would mean that they need to demonstrate full compliance of their toys with the GDPR requirements,[339] thus, operationalising the GDPR's focus on data protection by design and default in relation to toys.

Safety issues specific to AI-based toys will be subject to the EU **Artificial Intelligence Act** (AIA)[340] when it is adopted. According to Article 6 in conjunction with Annex II AIA, toys with AI components may be classified as high-risk systems "if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation". Toys are expected to be included as high risk AI in the final Regulation once adopted, they will be subject to ex-ante and ex-post compliance and enforcement mechanisms both under the TSD and under the AIA. The risk management for such high-risk AI systems will be an iterative process that runs throughout the entire life cycle of the system, with regular updates, following the steps described in Article 9 (2) AIA. Article 10 AIA prescribes special data governance requirements for training, validation and testing data for high-risk systems. In this context, the AIA is well placed to complement the TSD by closing one of the gaps in the scope of product safety, namely the safety of AI-based toys. In addition, the AIA also prohibits a number of AI practices, and in particular deploying subliminal techniques beyond a person's consciousness in order to distort a person's behaviour in a manner that can cause physical or psychological harm (Article 5.1 (a)) and exploiting the vulnerabilities of a specific group of persons due to their age that could distort the behaviour of that person in a manner that can cause harm (Article 5.1(b)).

Smart connected toys often involve the collection and processing of data, including the data generated by children playing with such toys, in order to ensure the toy functionality and optimal playing experience. Such sensitive personal data is subject to strict rules of the **General Data**

[339] 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) 287 final of 19.11.2020, p 80.
[340] European Commission (2021). Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, COM(2021) 206 final of 21.04.2021.

Protection Regulation (GDPR).[341] The TSD does not contain any relevant rules; the GDPR is a horizontal legal act complementing sectoral legislation such as the TSD.

Recital 38 GDPR recognises that children merit special protection because they may be less aware of risks, consequences and safeguards concerned and their rights in relation to their data. Special protection should apply when children are using services offered to them directly (e.g., when playing with smart connected toys). Recital 71 GDPR recommends that such practices as profiling should not concern children (though there is no explicit prohibition of this practice in their regard).[342]

The GDPR introduces data protection by design and by default (Article 25), lawfulness, transparency and fairness of data collection and processing, data minimisation, purpose limitation of data collection and processing, accuracy, integrity and confidentiality of data storage and processing (Article 5). The GDPR imposes certain obligations on data controllers and processors. Data controllers are any natural or legal person that determines the purposes and means of the processing of personal data (Article 4(7) GDPR), which means that a producer would fall under this category and have to comply with special obligations. Recital 78 GDPR encourages producers of products who are not themselves controllers to take due account of data protection requirements and to design their products in such a way that controllers and processors can fulfil data protection requirements. Article 32 GDPR mandates the controllers and processors to ensure a level of data security appropriate to the risk of the processing and lists security mechanisms that need to be implemented. This is of particular importance for smart connected toys, as children are characterised as "vulnerable" data subjects in Recital 75 GDPR that explains risks to rights and freedoms of natural persons.

Sales of connected toys in the EU

The study underpinning the IA has also sought estimates of sales of connected toys. In this section, we first provide an overview of available market research data on connected toys, before presenting the results of our consultations with manufacturers and industry representatives.

The connected toys' market, worth approximately EUR 2.66 billion in 2015, was expected to reach a high of EUR 10.75 billion by 2020.[343] Other more conservative market research estimates suggest an increase to a 2020 market value of EUR 7.23 billion[344], or EUR 5.32 billion[345]. For the period 2021-2026, the estimated CAGR amounts to 24.3%, or, in line with some alternative estimations, 19% for a period of 2020-2027, with the global industry reaching the value of EUR 17.94 billion by

[341] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119 of 4.5.2016.
[342] Article 29 Data Protection Working Party (2018). Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679, WP251rev.01: https://ec.europa.eu/newsroom/article29/items/612053 .
[343] Chaudron, S., et al. (2017) Kaleidoscope on the Internet of Toys Safety, security, privacy and societal insights, JRC Technical Reports, online: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC105061/jrc105061_final_online.pdf, DOI:10.2788/05383.
[344] Mordor Intelligence (2021). *Connected Toys Market – Growth, Trends, COVID-19 Impact, and Forecasts (2022-2027),* online: https://www.mordorintelligence.com/industry-reports/connected-toys-market
[345] BusinessWire (2021). *Global Connected Toys Market Report 2021: Market to Reach $18.9 Billion by 2027 - Console-Connected Toys is Projected to Account for $7.7 Billion - ResearchAndMarkets.com,* online: https://www.businesswire.com/news/home/20210318005627/en/Global-Connected-Toys-Market-Report-2021-Market-to-Reach-18.9-Billion-by-2027---Console-Connected-Toys-is-Projected-to-Account-for-7.7-Billion---ResearchAndMarkets.com

2027.[346] One of the explanations for this extensive development of the market for connected toy products might be the possibility of selling them at prices significantly higher than those of the 'traditional' toys. For example, a study carried out in Korea proved that installation of 'smart' elements in toys might increase their market prices to levels not seen in non-smart toy products.[347]

Although these market research data report rapid market expansion in this area, interviews with toy industry representatives have noted that this is being significantly limited by concerns relating to cybersecurity and the protection of personal data and privacy in connected toys. There have been extensive discussions in the public discourse about the cybersecurity challenges and resulting children's safety implications of internet-connected toys.[348] This has been sparked by instances of toy products without sufficient protective minimum baseline security requirements or privacy by design measures built into their IT-systems, such as the My Friend Cayla doll[349], VTech Tablets, or Fisher Price Smart Toy Bear[350].

More specifically, a 2016 report by the Norwegian Consumer Council[351] investigated issues relating to toy safety in the Toy Fail report.[352] This found that Internet of things (IoT) technologies raise serious issues regarding their suitability for use in toys without due consideration of cybersecurity and child safety risks and without adequate cybersecurity measures.

As regards the manufacturing industry, it needs to be acknowledged that the overall toys' EU manufacturing sector consists mostly of the SMEs, as 99% of the EU firms in this sector can be categorised as such. The small and medium-sized companies provide also 61% of employment within the overall industry[353]. In comparison, according to a 2018 study, 80% of the 1,800 toy manufacturing firms in China were considered to be small, medium or micro-sized enterprises.[354] In light of these statistics, it should be emphasised that the challenges faced by the small stakeholders in industry might be proportionally bigger, in comparison with the situation of the biggest industry players. This pertains particularly to the lack of IT capabilities and regulatory compliance[355] – both substantially significant as regards manufacturing of connected toys.

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[346] BusinessWire (2021). *Global Connected Toys Market Report 2021: Market to Reach $18.9 Billion by 2027 - Console-Connected Toys is Projected to Account for $7.7 Billion - ResearchAndMarkets.com*.

[347] Jung, S. (2017). *Research on synchronization between smart toys and smart phones for classifying smart toys*, [in:] "International Journal of Internet, Broadcasting and Communication", Vol.9, No.4, pp. 25-30, DOI: 10.7236/IJIBC.2017.9.4.25, p. 29.

[348] Holloway, D. & Green, L. (2016). *The Internet of Toys*. [in:] "Communication Research and Practice, Special Issue: ANZCA 2016 Creating Space in the Fifth Estate", Vol. 2, Issue 4, (eds. Fulton, J. & McIntyre, P.), DOI: 10.1080/22041451.2016.1266124, p. 516.

[349] Holloway, D. & Green, L. (2016). *The Internet of Toys*. [in:] "Communication Research and Practice, Special Issue: ANZCA 2016 Creating Space in the Fifth Estate", Vol. 2, Issue 4, (eds. Fulton, J. & McIntyre, P.), DOI: 10.1080/22041451.2016.1266124, p. 513.

[350] Nelson, B. (2016). *Children's Connected Toys: Data Security and Privacy Concerns. Office of Oversight and Investigations, Minority Staff Report,* Committee On Commerce, Science, and Transportation, United States Senate, online: https://www.hsdl.org/?view&did=797394, pp. 10-12.

[351] https://www.forbrukerradet.no/siste-nytt/connected-toys-violate-consumer-laws/

[352] Toyfail report by Norwegian Consumer Association - https://fil.forbrukerradet.no/wp-content/uploads/2016/12/toyfail-report-desember2016.pdf

[353] Michalitsi-Psarrou, et al. (2019). *Empowering Product Co-creation Approaches Through Business Interoperability Concepts: The Toy Industry Case,* [in:] (K. Popplewell et al., eds.) "Enterprise Interoperability VIII, Proceedings of the I-ESA Conferences 9", DOI: 10.1007/978-3-030-13693-2_33, pp. 397-398.

[354] Kwong, C. W., Mak, S. L. & Li, C. H. (2020). *The Exploration of a Technical Model for Toy Factories in China to Deal with European and US Toy Safety Requirements,* [in:] "International Journal of Business, Humanities and Technology", Vol. 10, No. 2, DOI:10.30845/ijbht.v10n2p4, p. 26.

[355] Michalitsi-Psarrou, et al. (2019). *Empowering Product Co-creation Approaches Through Business Interoperability Concepts: The Toy Industry Case,* [in:] (K. Popplewell et al., eds.) "Enterprise Interoperability VIII, Proceedings of the I-ESA Conferences 9", DOI: 10.1007/978-3-030-13693-2_33, pp. 397-398.

During the interview programme, it was confirmed that the size of the connected toys' market is smaller than the adverse publicity surrounding children's safety when using connected toys would suggest. All respondents addressed with the question concerning the market for connected toys (i.e. manufacturers and industry representative organisations) assessed the share of the toys' market constituted by the connected products as very low, or insignificant. For instance:

- Overall, from this small sample of manufacturers and industry representative organisations, most of those consulted either do not work with internet-connected toys or reported percentages of below 1%. One organisation stated an internet-connect toy portfolio that comprised around 5% of their total toy product portfolio.
- A major top 3 toys manufacturer interviewed stated that they had steered away from designing or producing connected toys since the My Friend Cayla Doll scandal for reputational reasons. As a result, they currently have no active internet-connected toy products on the market.
- One of the business organisations pointed out that its member-firms are mostly SMEs, and that only a tiny part of their products portfolios are the connected toy products, as SMEs tend not to have technological capabilities to manufacture this type of products. Another interviewee assessed that the discussion on connected toys' safety as being disproportionate in its scope compared to the actual share of this type of products in the market.

However, as noted above, this is a small sample that primarily comprises EU-based manufacturers and industry associations. As such, the extent to which internet-connected toys are being produced in other regions and imported into the EU is largely unknown.

ANNEX 13: DIGITAL PRODUCT PASSPORT UNDER THE PROPOSAL FOR AN ECODESIGN FOR SUSTAINABLE PRODUCTS REGULATION

The proposal for the ESPR foresees the possibility for the Commission to require that for products covered under the delegated acts, a Digital Product Passport (DPP) containing specific information is available (see chapter III). The precise information to be included in the DPP is expected to be determined when preparing product-specific rules. It may include information 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 others. The proposal for the EPSR contains detailed provisions as to the technical design and operation of the DPP, as well as the requirements. It already foresees that other Union legislation requires information to be added to the DPP. Work will now be carried out with standardisation organisations to prepare the necessary technical features for the implementation of the DPP with the adoption of the ESPR and the first delegated acts on specific products. Furthermore, Annex III specifies the type of information that may be required as part of the DPP. The DPP may contain compliance documentation and information required under this Regulation or other Union law applicable to the product, such as the declaration of conformity, technical documentation or conformity certificates.

As to the interaction with customs, the proposal for the ESPR foresees that the DPP are registered in a Product Passport Registry to be set up and maintained by the Commission (see article 12). In order to ensure the customs controls, the registry will be interconnected with the EU Customs Single Window Certificates Exchange (EU CSW-CERTEX). If discrepancies between the information contained in the registry and the customs declaration occur, the release for free circulation of that product will be refused.

For more information:

- 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, COM (2022) 142 in particular Chapter III.
- Annex III of the Proposal, on the requirements for the DPP.
- Staff Working Document – Impact Assessment accompanying the proposal and annex 18 to the Impact Assessment.

ANNEX 14: IMPACTS OF THE OPTIONS[356]

1. ECONOMIC IMPACTS

1.1. Public authorities

Reliable data on the costs for market surveillance authorities (MSAs) of implementing the Directive and the impact of the policy options on these costs is difficult to obtain in a detailed way. No information was available on the 'cost of an inspection' by a market surveillance authorities. As such, a number of proxies have been used in developing these cost calculations.

A) Baseline

The Summary of EU Member States and EEA EFTA States' assessment and review of the functioning of market surveillance activities according to article 18(6) of Regulation (EC) No 765/2008 for the period 2014-2016 is the latest period for which information on the costs of market surveillance is available disaggregated by sector. Out of the 18 reporting Member States and Norway (BE, BG, HR, CY, DK, EE, FI, FR, ES, HU, IE, IT, LU, NL, NO, PL, RO, SI, SE), a total budget of EUR 8.5 million was available to market surveillance for toys, almost equally divided between laboratory testing and in-house testing on average per annum between 2014 and 2016. Furthermore, internal staff resources represented a total of 373.4 FTE for these 19 countries.

Over the same period, an average of 11,533.6 inspections on toy products were undertaken per annum by the reporting countries. On the basis of this information, the **average price per inspection** can be calculated as being the total cost of inspection (EUR 8,517,890.09) divided by the number of inspections (11,533.6) = **EUR 738.52.** In terms on staff resources, it is estimated that that one staff member can undertake 30.89 inspections per annum. This is of course a gross oversimplification given the different roles of staff in market surveillance authorities, but it provides a rough estimate to help assess the impact of the different policy options on market surveillance authorities.

The REFIT evaluation accompanying the proposal for a Regulation laying down rules and procedures for compliance with and enforcement of Union harmonisation on products provides more comprehensive data on toy inspections. The table below provides the number of inspections undertaken in 22 Member States. By using proxies for the number of inspections for those Member States for which no data is available (DE, ES, LT, NL, SK), we have extrapolated the **number of inspections undertaken annually at a total of 25,259[357].**

Table 21: Annual number of inspections

Country	Inspections	Inspections per million inhabitants	Proxy used	Total inspections for all Member States
AT	584	65.38		584.00
BE	1,270	109.90		1,270.00

[356] See the accompanying Impact Assessment Study on the revision of the Toy Safety Directive 2009/48/EC, 2022, VVA, CSES and Asterisk

[357] By using these proxies and the average price per inspection calculated above, the overall budget for toy inspections across the EU would be EUR 18,654,257.

Country	Inspections	Inspections per million inhabitants	Proxy used	Total inspections for all Member States
BG	1,739	251.43		1,739.00
CY	960	1,123.07		960.00
CZ	1,631	152.40		1,631.00
DE		-	42.02[358]	3,490.20
DK	113	19.35		113.00
EE	402	302.24		402.00
EL	28	2.62		28.00
ES		-	40.78[359]	423.31
FI	1,351	244.14		1,351.00
FR	2,834	42.02		2,834.00
HR	384	95.14		384.00
HU	1,180	121.26		1,180.00
IE	4	0.80		4.00
IT	1,115	18.82		1,115.00
LT		-	61.27[360]	171.29
LU	51	80.35		51.00
LV	116	61.27		116.00
MT	149	288.70		149.00
NL		-	109.9[361]	1,920.53
PO	754	19.93		754.00
PT	420	40.78		420.00
RO	1,496	77.97		1,496.00
SE	84	8.09		84.00
SI	1,757	833.11		1,757.00
SK		-	152.4[362]	832.10
	18,422	**179.94**		**25,259.43**

If no change to the TSD would occur, the costs for public authorities in conducting market surveillance are expected to remain equal. The share of online sales is expected to grow, following the path of the previous years (increasing by 20% between 2010 and 2020). Member States authorities would have to increase their market surveillance activity in order to identify the same share of non-compliant toys. However, given their budget is unlikely to be increased, it is likely that the impact would not be on Market Surveillance authorities (MSAs), but would merely result in a greater number of non-compliant toys on the market.

In the baseline scenario, changes to the TSD could still be made as is the case today, by introducing limit values in Appendix C of the TSD for toys intended for children under 36 months. In order to estimate the cost of the human resources, data about the amount of person days needed for transposition is taken from previous Impact Assessments, which assesses the number of person days needed for transposition of a Directive to be between 20 and 60. Using the Member State daily

[358] inspections per million inhabitants in France.
[359] inspections per million inhabitants in Portugal.
[360] inspections per million inhabitants in Latvia.
[361] inspections per million inhabitants in Belgium.
[362] inspections per million inhabitants in Czechia.

labour cost (i.e. EUR 309[363]), the overall cost of transposition is estimated to be in the range of EUR 6,174 to EUR 18,522 per Member State. [364].

Impacts on customs

In case of physical controls of toys, customs authorities will notably check:

1) CE marking and any labelling requirements, and the declaration of conformity (DoC).
2) User instructions
3) Technical file (upon request if evidence is requested by market surveillance authorities liaising with customs authority)

The customs will also control compliance with other EU environmental legislation applicable to toys, such as the Packaging Directive.

Under the baseline situation in the TSD, the controls by customs occur at the import stage, in cooperation with the relevant market surveillance authorities, as appropriate on a risk based approach. The enforcement applies on the entire EU customs territory.

As concerns Information Technology (IT) aspects and customs, currently, a number of IT systems are coexisting at EU level to allow for improved coordination of customs controls amongst Member States with the support of the European Commission, such as the Single Window Environment for Customs and the TARIC Information System. Specific resources are allocated for these tools.

If toys are found to be non-compliant at EU borders, a restriction on their release for free circulation may be imposed until such time as the compliance issues have been addressed.

If not detected by customs, the introduction in the EU customs territory of a toy infringing the TSD could present a serious risk for health, safety and the environment. For example, products with higher limit values than permitted under the TSD (and/ or in EN standards supporting the essential requirement) may indeed pose health risks to children. The nature and magnitude will depend on 1) the type of substance and its harmful effects) and 2) the level of potential exposure. If no change to the Directive was to take place, and with the increasing use of the internet to sell toys, the number of non-conforming toys on the EU market would only increase.

B) Policy options to strengthen the protection of children from harmful chemicals - PO1a, PO1b and PO1c

These options are not expected to lead to significant costs for public authorities, as compared to the baseline scenario.

One-off costs relating to the transposition of the new limit values into national legislation will be similar to the baseline. These costs would disappear if the legal instrument chosen was a Regulation;

For market surveillance authorities, the number of inspections would not be expected to rise. In any case, it is likely that their budgets would not be increased.

Impacts on customs

Under policy options 1a, 1b and 1c, the role of customs would be the same as under the baseline. In case of identification of a product with high risk, competent market surveillance authorities are

[363] Data about labour costs comes from Eurostat's Labour Cost Survey, (2016), category 'public administration and defence, compulsory social security' per employee FTE and adjusted for inflation.
[364] IA study on the revision of the Toy Safety Directive by VVA, CSES and Asterisk.

notified following the already existing cooperation procedures in place between national customs and market surveillance authorities.

However, it is likely that, in case of changes in limit values of substances in toys, manufacturers located in third-countries might adapt to new rules only after a transition period. This might lead to a higher number of imported toys to be identified by competent market surveillance authorities as being non-compliant and subsequently increase the number of alerts to customs to block imports of those specific products. This would thus indirectly lead to an initial increase of the burden on customs (for example an increase in number of alerts received from market surveillance authorities, or increase of physical checks of imported products or of shipments that are placed on hold at the border subject to a refusal for free circulation). These cases are expected to progressively decrease in proportion to the adaptation of third-country manufacturers to EU standards, but it is likely that in an initial period customs might incur in additional burden.

C) Policy options to reduce the number of non-compliant toys

PO2a

Under Option 2a, no significant costs are expected for market surveillance authorities. Market surveillance authorities consulted explained that the time necessary to inspect EU-type examined toys was the same as for those that were self-tested by manufacturers. While some suggested that extending third-party conformity assessment would not significantly change the amount of time necessary for inspections (under 3% of efficiency gain), other disagreed. They argued that the time necessary to collect information from a notified body is significantly lower than economic operators. They assumed that the time saving would be over 5%. This only relates to time saving on requesting documents and not on any tests market surveillance authorities may undertake. As an average, the introduction of option 2a would result in a 5% time saving for the average inspection by market surveillance authorities, which would translate into a **5% increase in the number of inspections**. Given the average number of inspections was 25,259[365], the number of inspections in the EU is expected to rise to 26,522 per year. Dividing the total budget available by the increased number of inspections, the cost per inspection could be reduced to **EUR 738.52 to EUR 703.35.** This is based on the assumption that the budget will remain equal at national level and that the resources freed up by the efficiency will continue to be dedicated to inspections on toys. In addition, the precise number of inspections also depends on other practical factors including the specific toys subject to inspection and or tests. Therefore, the precise impact of this option on the number of inspections could be lower.

With the extension of third-party conformity assessment to i) toys intended for children under 36 months and ii) toys which are chemical mixtures, **Notified bodies** may incur costs relating to the increase in the testing capacity required to undertake these tests. In certain MS (in particular Germany) NBs argue that the necessary capacity exists already.

As for the role of **customs** under this policy option, for toys for children under 36 months, and toys designed to be put in the mouth, market surveillance authorities would need to indicate to customs (e.g. an alert on TARIC) a specific notice on identified product categories that would require an additional EC type approval certificate (i.e., mandatory 3rd party conformity assessment check by notified body). Customs systems would then be required to ensure that such certificate is present for the identified product categories.

[365] See Table 21: Annual number of inspections

PO2b

The introduction of a digital passport would simplify the work of market surveillance authorities and would therefore significantly reduce the time spent chasing information from manufacturers. As such, the number of inspections undertaken by market surveillance authorities for the same resources would be expected to increase. While it is difficult to assess the exact scale of the reduction in the times needed to undertake inspections, interviews undertaken during the study, suggest that this could be in the range of **10% to 20%,** which would translate into an equivalent percentage **increase in the number of inspections** which could be undertaken with the resources available. Given the average number of inspections was 25,259[366], **the number of inspections in the EU is expected to rise to between 27,785 and 30,311**. Dividing the total budget available by the increased number of inspections, the cost per inspection is expected to lower from EUR 738.52 to between EUR 671.37 and EUR 615.42. This is based on the assumption that the budget will remain equal at national level and that the resources freed up by the efficiency will continue to be dedicated to inspections on toys. In addition, the precise number of inspections also depends on other practical factors including the specific toys subject to inspection and or tests. Therefore, the precise impact of this option on the number of inspections would probably be lower.

There would be one-off costs relating to market surveillance authorities adapting their information systems and procedures to allow them to verify these. However, these would be required by the ESPR regardless of whether toys are included in a delegated act by the ESPR.

Under Option 2b, there would be no significant impact for **notified bodies**.

Customs authorities

This option would require that the existence of a DPP with the Declaration of Conformity is verified at customs. The reference to the DPP will be included in a central registry; when the release for free circulation is requested, customs authorities will verify that this DPP is included in the registry. DPPs will have to include the DoC for toys to be generated and included in the registry.

Currently, customs controls are done on a risk-based manner. This option will rely on the interconnection of the DPP central registry with the customs IT infrastructure (as proposed in the ESPR) leading to automatic controls at customs of the presence of the DPP. The costs associated with the interconnection of the relevant IT infrastructures are required under the ESPR, this option for revision of the TSD would not impose additional costs in this respect. The automation of controls would allow customs to decrease their costs and it would allow them also to do more checks, and to be able to prevent more non-compliant toys being released for free circulation and thus placed on the Union market.

The technical aspects of the DPP under this option are not set but it is expected that there would be some costs associated with defining the data needs and information exchange protocols and permissions between any DPP system and the EU SWE-C to allow customs authorities to check for the existence of the DPP on imported toys. Interconnection between the central registry of DPP and the EU SWE-C is already foreseen under the ESPR.

On the other hand, the introduction of the DPP would likely entail the submission of the required documentation by the importer at a stage before the actual shipping of the product. This would lead to potential savings for customs with less shipments on hold at the border. In case of actual harmonisation and standardisation of the DoC within the DPP, this would also lead to a reduction of the physical controls. Customs, however, would exclusively check through automated systems of

[366] See Table 21: Annual number of inspections

the provision with the imported shipment of the DPP, not its actual content which would be still subject to checks of the relevant national market surveillance authority.

PO2c

Under Option 2c the effect of option 2a and option 2b would be cumulated. For market surveillance authorities, the **time savings for inspections** would be **in the range of** (5% for option 2a + 10% for option 2b =) **15% and** (5% for option 2a + 20% for option 2b =) **25%**. The cumulative effect is due to the fact that under 2a saving are linked to the reduced time in collecting documents, while under 2b they relate to the reduced testing, as well as the time needed to chase and find the manufacturer. Given the average number of inspections was 25,259[367], the number of inspections in the EU is expected to rise to between 29,048 and 31,573. Dividing the total budget available by the increased number of inspections, the cost per inspection could lower from EUR 738.52 to between EUR 642.18 and EUR 590.83. This is based on the assumption that the budget will remain equal at national level and that the resources freed up by the efficiency will continue to be dedicated to inspections on toys. In addition, the precise number of inspections also depends on other practical factors including the specific toys subject to inspection and or tests. Therefore, the precise impact of this option on the number of inspections would probably be lower.

Notified bodies would incur costs relating to the increase in the testing capacity required to undertake these tests, although these costs will be passed on to businesses.

The impacts for customs authorities would be the same as in PO2b.

1.2. Economic operators – Administrative burden

A) Baseline

In the case of the Toy Safety Directive, the information obligations to be taken into account for the estimation of the administrative burden are the activities related to the **safety assessment**, such as the identification of the applicable safety requirements, generating the safety assessment, identification of the necessary tests and collecting all the necessary information – in particular from the supply chain – needed for the completion of the required documentation.

The safety assessment is performed by manufacturers for each toy. This requires considering all the hazards that a toy presents and that could lead to a risk when a child is exposed to a hazard during play. In the public consultation for the evaluation of the Toys Safety Directive (2020), manufacturers highlighted that taking into account all safety requirements causes significant costs and the safety assessment itself causes significant costs.

It is thus possible to identify three main classes of costs:

- **Certification:** which include all the activities related to the production of the safety assessment and the EC-type examination certificate. The actual testing of toys is not considered *per se* an administrative burden but is accounted in this study as an adjustment cost.[368] These certification costs can range between EUR 500 in case of self-assessment, and EUR 1000 in case of third-party assessment.

[367] See Table 21: Annual number of inspections

[368] *"Testing costs. When business have to submit their products & processes to a test in order to get an authorisation or a certificate, these testing costs are not considered as administrative costs.",* Better Regulation Toolbox, p.525

- **Technical Documentation:** including costs incurred in coordination with the supply chain and gathering of the information needed for the technical documentation of the toy. According to the TSD evaluation estimates, the production of the technical documentation would amount to approximately EUR 2,800 per new toy model.

- **Labelling:** labelling is also part of the administrative burden and would entail the activities related to the identification of the applicable rules on CE marking, on warnings and other toy markings. According to the estimates, the average cost for a company would amount to EUR 700 per new toy model.

The purpose of the following analysis is to estimate the potential changes in the administrative burden due to the application of the envisaged policy options. The information and data have been collected through multiple sources, including desk research, interviews and a survey with toy manufacturers and market surveillance authorities. The estimates provided in the different policy options are based on the information provided by consulted stakeholders and their expectations of the impacts based on the current descriptions of the policy options. The lack of definition of some details, prevented the possibility of having more specific estimates.

The purpose of the analysis of the policy options is to estimate the potential increment with respect to the current level of administrative burden (baseline) and the impact on the costs - increase or reduction – due to the specific provisions. In this section, we define the baseline against which the policy options are compared to.

According to the conducted interviews, the analysis of the responses to the SME survey and the data collected for the evaluation of the Toy Safety Directive (2020) it is possible to approximately estimate the current average administrative burden for a new toy model placed on the market:

- Approximately EUR 4,000 in case of self-assessment;
- Approximately EUR 4,500 in case of third-party conformity assessment.

Table 22: Detail of administrative burden and related monetary estimates

Type	Activities in scope	Source	
Certification:			
Self-assessment	• Generating the self-assessment	TSD evaluation / Interviews	500
3rd-party	• Review of the technical documentation by NB • Obtaining an EC-type examination certificate	TSD evaluation / Interviews	1000
Technical documentation:			
Self-assessment	• Familiarising with the information obligation • Retrieving relevant information from existing data • Generating technical documentation	TSD evaluation / Interviews	2800
3rd-party		TSD evaluation / Interviews	2800
Labelling:			
Self-assessment	• Application of the CE marking • Identification of applicable warnings and traceability elements	TSD evaluation	700
3rd-party		TSD evaluation	700

B) Policy options to strengthen the protection of children from harmful chemicals -

These policy options would not entail a direct increase of the administrative burden on companies since it does not entail any specific change in terms of information obligations for companies but focus on how the chemical composition of toys is. The indirect effect of these measures would most likely include an increase of the complexity of the technical documentation and the effort to familiarise with applicable safety measures, but these are considered to be marginal. In addition, there may be certain administrative costs from applying for derogations under option 1b, which will depend on whether the derogations are requested and for which specific substances. It has been estimated that these could range from EUR 100.000 to EUR 300.000 per year, for the whole industry.

C) Policy options to reduce the number of non-compliant toys

PO2a

Policy option 2a would entail the extension of pre-marketing conformity assessments to toys that are chemicals mixtures or substances for which there are higher risks of exposure; and that are marketed to under 36 months old or designed to be put in the mouth. Based on the responses obtained through the interviews and the SME survey by toy manufacturers, the administrative burden for conformity assessments would likely increase in comparison to the baseline. Currently only around 3% of toys have to undergo third party conformity assessments.[369] Under option 2a, considering the extension of the mandatory third-party conformity assessment to additional categories of toys, this proportion would likely rise to about 20% of new toys according to consulted stakeholders. Since third-party assessments are more expensive in comparison to self-assessments (at least EUR 500 more per new toy model) and companies consulted for this study reported a range of new toy models placed on the market every year ranging between 10 and 125 units (and in total 78,702), the expectations are an overall additional administrative burden of approximately EURm 7.8 per year.

PO2b

Policy option 2b involves the post-marketing facilitation of controls through the introduction of a digital passport that would require that the EU declaration of conformity is digitally accessible (via a machine-readable code) and the registration of the reference in a central registry (based on the Digital Product Passport of the ESPR).

Data on the administrative burden for Digital Product Passport, is still not available, and thus it is not possible to make a baseline estimate on this aspect. However, through the Impact Assessment on the Sustainable Productive Initiative (ESPR)[370], specific burdens have been identified in which businesses are most likely to encounter, these include:

- Administrative burden for businesses:
  - Setting-up of ICT systems that are compatible with the European Digital Product Passport;

[369] European Commission (2020). Evaluation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys.
[370] https://op.europa.eu/en/publication-detail/-/publication/8c3a27e6-b3fa-11ec-9d96-01aa75ed71a1/language-en

- The provision of information that is required in a digital format;

- Consolidation of information based on inputs of suppliers.

The implementation of the DPP, including the one-off costs (such as development of required IT tools, new procedures for the preparation of the product documentation, and potentially additional IT services) and recurrent costs (e.g. the FTE required to collect and provide electronically the required documentation) may generate additional administrative burden for toy manufacturers. According to consulted stakeholders, to adapt to the introduction of the DPP would generate internal, outsourcing and equipment costs. For the calculation of the overall market costs, SMEs have been assumed to incur in costs of EUR 3,000 per new toy model, while for larger companies, up to EUR 140,000. This calculation provides an estimate of around EURm 28.5. While there is no specific breakdown of these costs into one-off and recurring costs for the toy sector, previous research in other markets has found a split of 80% one-off vs 20% annual costs for large firms, and 62% one-off vs 38% annual costs for SMEs[371]. Applying this breakdown to the estimates for toys would suggest a total one-off cost of EURm 18, in addition to an annual recurring cost of EURm 10,5.

On the other hand, the provision of a digitalised and harmonised declaration of conformity and the availability of the compliance information online, is also expected to lead to savings y. Previous studies have suggested a benchmark of about 10-15% savings in administrative costs from the full digitalisation of product information (not only compliance but also user-related information)[372]. These studies also estimate the provision of compliance information at 0.4% of turnover of the sector.[373] Accordingly, savings could be estimated at around EUR 2.62 to EUR 3.93 million per year only from moving to the digital provision of compliance information.

The implementation of the DPP would also facilitate the control by market surveillance authorities of the existence of the required documentation for each toy model thanks to the immediate availability of these documents online. This would likely reduce the information obligations of companies to market surveillance authorities in case of inspections. According to the evaluation study of the toys directive, the average cost – per new toy model for an average importer or distributor – to *"ensure that the toy is accompanied by the required documents"*[374] amounts between EUR 548 and EUR 651. The Evaluation also estimated costs for "getting supply chain information" of EUR 700 per toy model.

In absence of a specific cost indication of this activities in case of inspections, but being a similar activity requested by market surveillance authorities to manufacturers, we assume the burden on companies to be on the same range. With the implementation of the DPP, this cost would likely

[371] Study to support the Impact Assessment on the use of digital labelling for EU fertilising products, European Commission's DG GROW, 2022

[372] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Supporting study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2873/625443

[373] 0.4% of turnover of EU toy industry in 2020 was EUR 26.2 million. The share of 0.4% is the result of a multiplication of the total cost of compliance (2% of annual turnover, based on previous literature) by the share of the total cost compliance related only to the cost of indicating compliance with EU harmonisation legislation (20%, based on stakeholder consultation in the study supporting the Evaluation of the New Legislative Framework referred to above).

[374] Evaluation of Toys safety Directive, p. 64

disappear for companies, since relevant documentation would be available online for market surveillance authorities.

Considering the annual number of inspections by market surveillance authorities in Europe is calculated to be around 25,000 (and may rise to 30,000 in case of implementation of the DPP), we can estimate that the average annual saving for EU companies could be between EURm 13 and EURm 16 in case of inspections remain at the same levels or increase slightly, or even up to EURm 20 in case of a significant increase in the number of inspections.

In addition, it is reasonable to assume that in the long term the internal costs for companies to implement the DPP will diminish thanks to economies of scale, while the benefit of less burdensome inspections for compliant companies will remain the same and lead to a visible economic benefit in terms of reduction of administrative burden for companies.

Some aspects of the DPP are very cost-effective. For instance, impact assessment studies on the digital labelling of fertilisers and chemicals have shown that the costs of generating unique QR labels containing extensive information are very small (i.e. 0.0016 EUR / unique QR code generated), with cost-efficiencies the more SKUs a producer has in its portfolio. This low cost was confirmed in an earlier McKinsey study, which estimated 0.001451 cost per unique identifier[375].

PO2c

Including both the extension of the conformity assessment procedures and the facilitation of control, entails that the administrative burden that will have to be incurred through this policy option would be the combination of both policy option 2a and 2b.

1.3. Economic operators – Adjustment costs

Beyond the administrative costs for economic operators detailed in the previous section, it is important to assess the **adjustment costs for companies** that could stem from the different policy options, as well as the possible indirect impacts on innovation, competitiveness, and the EU Single Market. The key adjustment costs to be considered are: i) the potential costs related to chemical substitutions or product withdrawal resulting from extended restrictions to the use of chemical substances and mixtures; and ii) increases in the costs associated with product testing.

The first set of policy options – i.e. those relating to improving toy safety – include a range of measures that will result in changes to the rules on the use of chemicals in toys:

- **Policy option 1a** would give the Commission greater regulatory powers to change Limit Values for any chemicals for any toys depending on scientific evidence presented regarding the safety of chemicals used in toys. It would also reduce the limit values for nitrosamines and nitrosatable substances, and require manufacturers to address combinations of chemicals in toys following guidance.
- **Policy option 1b** would, in addition to the measures under PO1a, extend the generic approach to risk management to introduce generic bans on additional substances classified among the most harmful hazard classes. PO1b would also remove the derogation based on

[375] McKinsey & C. "Want to improve consumer experience? Collaborate to build a product data standard", April 2020.

the relevant concentrations of the CLP Regulation, but it would allow for a quantification/testing limit and retain the other derogations.

- **Policy option 1c** would include all the measures under PO1a and 1b, whilst also removing the possibility of derogations to the generic bans detailed under PO1b.

Within this context, manufacturers of toys that use chemical substances that are subject to restrictions or bans under the above policy options would be required to either reduce the levels of chemical use, identify and use alternative substances or no longer make available the affected toys on the market.

No notable adjustment costs for companies have been assessed under policy options 2a, 2b or 2c.

Therefore, this section first considers background literature on the issue of **safe chemicals and substitution**, in particular, **how far this has served as a driver or inhibitor of innovation and competitiveness.** The review considers literature on the impacts of chemical substitution by industry generally, as more desk research is available on the generalised impacts on industry than on the impacts on the toy sector specifically. The impact this will likely have on costs for companies is then analysed, before the extent to which this may affect the competitiveness of the European toys sector (and international toy manufacturers exporting to Europe) and innovation in the toy sector is considered.

1.3.1. Chemical substitution: Context and mechanisms

Chemical substitution has become of increasing significance in the context of the development (and possible revision) of European chemicals legislation. In recent years, EU chemicals legislation has evolved, notably through the EU's **REACH Regulation** (EC/1907/2006) and the **CLP Regulation** (1272/2008)[376]. Additionally, the European Commission published the *Chemicals Strategy for Sustainability* in 14 October 2020[377].

Current EU chemicals legislation puts an emphasis on encouraging the substitution of chemicals by **incentivising producers to use safer chemicals through the system of the registration, evaluation, authorisation and restriction of chemicals**. If chemicals are banned, manufacturers are forced to either identify an alternative or to withdraw the product. Alternatively, if a particular chemical substance is restricted or requires authorisation from the European Chemicals Agency (ECHA), manufacturers are instead incentivised to explore safe alternatives, where available. They may also choose to continue using the same chemicals and to monitor the risks of that chemical no longer being available in future. EU chemicals legislation may therefore promote innovation but conversely, if no suitable substitutes are available, it may damage competitiveness as if toy manufacturers cannot get hold of or use a particular substance needed for the production of certain types of toys, this may lead to a product withdrawal.

One of the key differences between the positions of stakeholders towards the chemical substitution principle is whether it should be carried out based on a **risk-based or a hazard-based assessment,** with the hazard defined as a: 'potential risk'. The difference between the two approaches pertains to the fact that *hazard* 'refers to the inherent properties of the substance as such', whereas *risk* also

[376] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances

[377] European Commission, Chemicals Strategy for Sustainability (2020) - https://ec.europa.eu/environment/strategy/chemicals-strategy_en

considers issues of effective usage and exposure[378] [379]. The safety assessment of chemicals allowed to be used in toy products is relevant as this is an area where there have been disagreements between certain stakeholder groups, as it is **not always clear whether a given substance should be allowed for industrial use or not**.

An important consideration for the implementation of chemicals substitution as a policy change is that, according to Girling, they should be introduced slowly, and the policy development process should be based on scientific grounds, to ensure its transparency. This would also guarantee that it is not driven by a political rationale, hence, allowing for *'adequate time for the substitution of substances with genuinely safer alternatives.'*

Chemical substitution principles have some advantages, but also disadvantages as per the table below:

Table 23: Chemical substitution - advantages and disadvantages

Advantages	Disadvantages
• Improving the sustainability of chemicals in line with the EU chemicals sustainability strategy. • Strengthening the safety of chemicals used in toys, thereby promoting improved health and safety. • Improving competitiveness by promoting investment into R&D&I by industry into alternative chemicals and innovation (although this may take years for the substitutes to become available and produced in sufficient quantity.	• There may not be any suitable alternative chemicals leading to product withdrawal (or prospect of such substances being developed medium-term)[380]. • Alternative chemical substances can be costlier, at least in the short term. • Potentially, indirect costs for industry incurred due to the unpredictability of future development of EU regulations and the position on specific substances. • Controversial exclusions of some substances from usage from an industry perspective, particularly in cases where they are hard to replace with alternatives • If chemicals legislation is not well-implemented, or places insufficient attention on the scientific evidence as a rationale for changes, there may be disadvantages.

According to the ECHA: '*replacing unwanted substances might give a company competitive advantage*' […], especially if a given company adopts '*the strategy based on anticipating legal requirements*'. This is because *'better and safer alternatives may already be available, and they can open new opportunities for companies'.* The ChemSec Business Group argued that enforcement of the regulatory framework on chemicals replacement might boost industry innovation, forcing companies to adjust to the 'global move towards sustainability', and towards estimating the costs of

[378] Hansson, S.O., Molander, L., Rudén, C., 2011. *The substitution principle.* Regulatory Toxicology and Pharmacology 59, pp. 454–460. https://doi.org/10.1016/j.yrtph.2011.01.011, p. 456.
[379] Operationally, the first notion is a 'non-quantitative concept', and the latter is usually 'described by risk ratios, i.e. the estimated or measured exposure compared to the estimated or observed effect concentration/dose of a substance combined with assessment factors' which in some cases takes the form of 'probability assessment or similar descriptors'
[380] A frequently cited example during the interviews in this regard was titanium dioxide used in a wide variety of toys, covered in a case study later in this section.

chemicals replacement *'looking further than a simple kilo-by-kilo price comparison'* and anticipate the regulations which is seen as '*an extremely effective driver for innovation, which in turn is the foundation of economic development*.'[381,382]

However, policy theories regarding how chemical substitutes may drive firm-level innovation and competitiveness does not always match the practice. On the contrary, the **relationship between substitution and innovation was found to be complex and nuanced** in previous studies that have considered how far EU chemicals legislation has promoted competitiveness and innovation, including through chemical substitution. [383]

Specifically in the area of toys, there is a lack of available literature on the extent to which substitutes are available. However, this issue was probed through the interview programme in relation to the various policy options. The main stakeholder feedback from both large firms and SMEs is that, as the toy sector is a relatively modest intermediate user of chemicals compared with other sectors, it frequently purchases chemicals in smaller quantities than other sectors and is dependent on specialist substances. This creates particular risks for the toy industry's competitiveness as if these substances are subject to a ban or require authorisation due to a restriction, then many products would have to be withdrawn from the market. Related issues are explored in more detail under the analysis of POs below.

1.3.2. Costs of product adaptation and withdrawal for economic operators

This sub-section considers the costs of product adaptation for economic operators, mainly toy manufacturers, resulting from the different policy options under consideration. It also considers the percentage of toys which could no longer be made available on the market, if alternatives to the chemical substances are not found. It should be noted there is a close link with the previous sub-section, in that stakeholder views about the drivers of costs were already outlined, therefore the two should be read in parallel.

There are three main considerations in relation to chemicals substitution that will impact on the toys industry as a result of the policy options under consideration in 1a, 1b and 1c:

- **The impacts on regulatory uncertainty –** some costs could arise from the fact that changes to limit values will be difficult to anticipate for industry, and the extent to which it is realistic for toy manufacturers, especially SMEs, to comply with these.
- **The availability of substitute chemicals –** the main difficulty highlighted by industry stakeholders is that there are often no suitable alternatives for chemical substances or mixtures where alternative substances may need to be identified.
- **The cost of substitution** – where alternatives are available, the costs are typically higher during the early stages of substitution but may reduce over time. Nonetheless, there are costs of switching to more expensive substituted substances in the short to medium term.

One of the challenges is that, whilst a general analysis can be performed with selected examples, it is difficult to provide a comprehensive assessment as there are **considerable uncertainties**

[381] ChemSec (2016). *The bigger picture. Assessing economic aspects of chemicals substitution,* online: https://chemycal.com/dap/files/The_bigger_picture_160217_print.pdf, accessed: 30.05.2022, p. 31.
[382] ChemSec (2016). *The bigger picture. Assessing economic aspects of chemicals substitution,* online: https://chemycal.com/dap/files/The_bigger_picture_160217_print.pdf, accessed: 30.05.2022, p. 5.
[383] Study on Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, European Commission's DG GROW, 2015. Study by CSES, RPA and Okopol.

regarding the number of chemical substances and mixtures that would be impacted and the resulting impacts on market behaviours / toys (i.e. how will toy manufacturers respond to changes in limit values and / or to generic bans). This may vary between large firms and SMEs, and it would also vary by chemical as a very wide variety of chemicals are used in toy production. There is a **complex interplay of factors** determining whether chemicals producers decide to pursue substitution / reformulation or market withdrawal. This in turn will influence the behaviours of toy manufacturers who as intermediate users but purchasing in small quantities may not have much choice regarding whether chemical producers continue to supply them with the speciality chemicals needed.

In the IA of the CLP study[384], further estimates regarding costs are provided. Under PO1a in the possible revision of the CLP (adding new hazard classes), it has been estimated that the CLP — without considering the linked effect of the generic approach to risk management — would put indirect market pressure to substitute and reformulate or withdraw from the market **between 9-25% of the total chemical product portfolio in terms of turnover.** The IA study also recommends *"monitoring of the ECHA's registered substances database could provide information on the number of substances substituted or withdrawn from the market because of classification — or potential classification — for the new hazard classes"*. This would need to be carefully monitored in the toys sector to ascertain the impacts on competitiveness.

The CLP study also provides some quantitative estimates about the impacts of putting in new hazard warnings. Companies consulted in the context of a Ricardo (2021) study estimated that around 43% of product portfolios may be affected by the inclusion of new hazard classes to CLP and the extension of the generic approach to risk management (GRA). It moreover states that substances and mixtures reclassified for the new hazard classes would be affected by the application of the GRA, where a CLH triggers the restriction or ban of a classified substance for some specific or all uses. The study adds that whilst some products will not be directly affected by changes to the application of the GRA, *"CLP classification and labelling for the new hazard classes may still put pressure for market withdrawal or substitution and reformulation"*. [385]

In the CLP IA study, it is assumed that a range between 9% and 25% of the total number of mixtures have to be reformulated due to hazard classification changes, which although a horizontal piece of legislation will impact different industries including toys as intermediate users of chemicals. The costs of these changes are already in the several billions of EUR for industry as a whole.

Under the policy options being considered by this impact assessment study, potential changes to the Toy Safety Directive include granting the European Commission (or a delegated technical body) the possibility of tightening limit values for any chemicals, specifically reducing the limit values for N-nitrosamines and N-nitrosatable substances to the level of the EN standard (PO1a), introducing generic bans on additional hazardous substances and removing the derogations based on the 'relevant concentrations' of the CLP Regulation (PO1b) or introducing generic bans and removing derogations (PO1c). If these POs were to be adopted, then the impact would be that toy manufacturers would need to consider the identification of safe chemical substitutes or would need to withdraw particular product lines from the market.

[384] Technical and Scientific Support to the Commission's Impact Assessment for the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP), to be published.
[385] Idem. Pg 73 annexes to the CLP IA study.

The main finding is that the **costs of substitution are difficult to ascertain** for various reasons, such as the lack of available substitutes presently, the fact that there is considerable uncertainty (i.e. unclear when and which types of safe chemical alternatives will be developed in future and how relevant to the toys sector). As such, where no data is available, general observations regarding the nature and magnitude of costs is provided.

General discussion on the costs of substitution

A general discussion on the costs of substitution, relevant across the baseline scenario and all sub-options within PO1, is now provided. However, as explained further below, it is not possible to specify precise costs for most of the measures proposed under PO1, rather this section focuses on providing anecdotal data on the impacts and rough estimates of the costs based on consultation feedback.

The desk research and discussions with key toy manufacturers have shown that key factors determining the costs associated with increased restrictions to the use of chemicals are firstly the **availability of chemical substitutes** (as otherwise at least medium-to-longer term, there may be a need to cease making available certain products on the market, which has a different set of costs).

Secondly, where alternative chemicals are available, **substitution costs** compared with the chemical(s) currently being used need to be considered. A key consideration in relation to costs is that *"new alternatives are often expensive initially, while prices tend to decline as supply increases. Comparing prices of a hazardous substance and an alternative that has just reached the market, or doing so before the hazardous substance has been banned, can therefore be very misleading"*.[386]

Chemical substitutes are generally costlier than the original substance, according to literature. However, the prices of alternative substances can be expected to fall over time as the substance becomes more widely known, used and available. Among the concerns about chemicals legislation requiring substitutes is the potential increase in costs due to the necessity of relying on alternative substances. Oosterhuis, referring to the experiences of Scandinavian countries, argued that, whilst it might be the case that there are higher costs now, the price of chemical substitutes might be expected to decrease with time, as the "*growth in production of the alternative implies cost and price reductions, making it more attractive for an increasing number of actors*".

The same argument has been put forward by the ChemSec Business Group, who emphasised that prices are 'not stable, but market dependent'. However, this concern should not be entirely dismissed. A 2015 report from the European Commission emphasised that:

"the availability of private funding is crucial, [as] in the absence of supportive private investors, innovation, and therefore substitution of hazardous chemicals with safer alternatives, is not possible. An important role for public authorities would be to bridge the gap between SMEs and private investors: regulatory pressure without adequate financial incentives and subsidies is often negatively perceived by companies and does not trigger virtuous behaviour".

R&D&I processes may lead to the development of new alternative substitute chemicals at least in some industries (e.g. in Scandinavian countries, such as Sweden and Denmark). According to Oosterhuis: *'The introduction of new regulations can cause an initial 'innovation-shock' to industry*

[386] Chemsec (2016). The bigger picture: Assessing the economic aspects of chemicals substitution, https://chemycal.com/dap/files/The_bigger_picture_160217_print.pdf

which decreases the rate of innovation, but competitive and innovative firms survive through creative substitution and by moving into higher value markets'.

Furthermore, if appropriate chemical substitutes and appropriate incentives to identify chemical substances do not exist, toy manufacturers may be required to **withdraw products from the market** as a result of further restrictions on the use of chemicals.

Within this context, accurately calculating the product adaptation and withdrawal costs associated with each policy option would require data on: i) the precise number of chemical substances and mixtures impacted by each PO; ii) the type of restriction (e.g. reduced limit values, generic ban etc.); iii) the total number of new toy products placed on the market in a given year, as well as the number, types and values of products impacted by each PO; iv) the proportion of toy products currently making use of the existing derogations; v) the proportion of impacted products where adjustment, including the identification of chemical substitutes, would be attempted; vi) the proportion of impacted products that would be withdrawn from the market; vii) the costs associated with identifying product adjustments, including chemical substitutes (where possible), as well as the success rate of identifying appropriate alternatives; and viii) the costs associated with withdrawing products from the market, including industry behavioural responses to replacing withdrawn toy products and consumer behavioural responses to purchasing alternative toys.

Although data is available and has been collected on some of these elements (e.g. total number of new toy products per year), the quantitative estimates presented in the following analysis rely heavily on a range of assumptions, detailed throughout. This limits the certainty associated with the accuracy and precision of the estimates. As such, these **estimates should, at all times, be read in conjunction with information on the nature of the assumptions and the related caveats on data availability**.

A) Baseline

The evaluation of the TSD highlighted a range of challenges related to the protection of children that would **persist under the baseline situation**. These include:

- Additional limit values for chemicals can only be set for toys for children under 36 months of age and toys that are intended to be placed in the mouth.
- The TSD provides derogations that permit the use of CMR chemicals when they do not exceed certain concentrations detailed in the CLP Regulation. Although the necessity of such derogations is argued by industry, the evaluation concluded that the concentrations permitted currently were too high and still pose a risk to children.
- Limit values for nitrosamines and nitrosatable substances set by the TSD can reportedly still pose a threat to children and are not in line with the EN71-12:2017 standard or German law.

In this context, under the baseline the Commission will still be able to adapt the TSD's chemical restrictions and derogations in accordance with the provisions of Article 46:

- Through Article 46(1), the Commission will, amongst other possibilities, be able to amend the limit values for chemical substances listed in Annex II, Part III, point 13.
- Through Article 46(2), the Commission may adopt specific limit values for toys intended for use by children under 36 months or toys intended to be placed in the mouth and amend Appendix C of Annex II.

- Through Article 46(3), the Commission may adopt new derogations for CMR substances or mixtures and amend Appendix A of Annex II.

The following table summarises the amendments made to the TSD using the above provisions since its adoption.

Table 24: Summary of key amendments to the TSD chemical requirements

TSD Section	Overview of amendments
Appendix A	One amendment in July 2014 permitting the use of Nickel in toy components that are intended to conduct an electric current (i.e. derogation).
Appendix C	Nine amendments relating to the addition of specific limit values for 12 substances (e.g. Aniline, Phenol, Formaldehyde etc.) and the further amendment of the limit values for one of those substances (Bisphenol A).
Point 13	Five amendments reducing limit values for Cadmium, Barium, Lead, Chromium VI and Aluminium.

Amendments to limit values under the baseline scenario would result in new, ad hoc product adaptation costs for industry, while new derogations would limit such costs. However, although some information is available on the types of toys impacted by past amendments, limited data is available and limited input has been received from stakeholders on the scale of the adjustment costs that would result from future changes. This is primarily because the substances and mixtures that could be impacted by future amendments are unknown.

If we assume that the market for toys intended for use by children under 36 months and toys intended to be placed in the mouth accounts for 20% of the total toys market, the baseline scenario would **require product adaptation or withdrawal costs in 0.6-1.2% of toy models**[387]. Approximately 0.4-0.8% of toy models would be subject to adaptation, while 0.2-0.4% could no longer be made available on the market.

With these assumptions established, we now present the available data on costs of substitution, before extrapolating indicative industry-wide figures.

On the scale of the product adaptation costs, data has been collected from a range of relevant sources:

- The evaluation of the TSD reported data on the costs of the 12 amendments to the TSD implemented in the period 2012-2018. As highlighted above, these primarily aimed to strengthen the limit values for CMR substances. In its analysis, the evaluation found that stakeholders across all groups considered the amendments of the TSD to be costly. In addition, the evaluation calculated the average cost of the amendments to be **EUR 6,500 per toy model produced for large firms and EUR 7,700 per toy model produced by SMEs**.
- In response to the stakeholder consultations conducted for this impact assessment support study, one manufacturer noted that, in a previous situation, the process of identifying a replacement dye took the company five months and nine tests. Considering the costs of

[387] To derive these figures, the proportion of the total toys market accounted for by toys for children under 36 months and mouthing toys (20%) has been applied to the assumed proportion of toys impacted by PO1a (3-6% of toys), which was derived from stakeholder feedback and consultations with the Commission.

testing alone, without a detailed understanding of the other resources utilised, this **product adaptation challenge would have cost more than EUR 19,800** (based on estimated testing costs under the baseline scenario of EUR 2,200 per toy model).

- Furthermore, a small number of manufacturers provided estimates for the full costs associated with product redesign and redevelopment, specifically in response to the POs presented and analysed in this study. Considering staff, outsourcing and equipment costs, these estimates indicate a **total cost of product redesign and redevelopment at EUR 17,000-70,000 per product**. Given its position within the above range, the impacts on the costs of testing alone will be considered as a middle product redesign and redevelopment estimate.

Based on these figures, the **total one-off costs associated with product adaptation (including chemical substitution) across the toys industry under the baseline scenario could range from around EUR 2 million to EUR 44 million (see Table 25 below)**. This is based on 78,702 new toy models across all business sizes on which those percentages of toy models that may be impacted by substitution are applied. As highlighted above, the accuracy and precision of these estimates are limited by a lack of comprehensive data on the costs associated with product adaptation, as well as a wide range of other variables. As such, it is necessary to include product ranges that illustrate the possible variance in these costs. However, under the baseline scenario, it is anticipated that the costs of any new restrictions would strongly mirror the costs of the amendments made under the TSD in the period 2012-2018. As such, the costs to industry per toy type under the baseline are likely to be closer to the figures detailed in the evaluation.

Table 25: Cost estimates associated with chemical restrictions implemented under the baseline scenario

Estimated % of products impacted	Evaluation (large firms)	Evaluation (SMEs)	Total redesign / redevelopment (low estimate)	Total redesign / redevelopment (middle estimate)	Total redesign / redevelopment (high estimate)
Costs per toy type (EUR)	€6,500	€7,700	€17,000	€19,800	€70,000
% of products impacted (low estimate - 0.4%)	€2.05 m	€2.42 m	€ 5.35 m	€6.23 m	€22.04 m
% of products impacted (high estimate - 0.8%)	€4.09 m	€4.85 m	€10.70 m	€12.47 m	€44.07 m

Beyond the one-off product adjustment costs highlighted above, the below options will also impact **ongoing testing costs**. As such, it is necessary to establish the ongoing costs of testing within the baseline. Testing per toy has been estimated to cost around €2,200 (as determined in the Evaluation of the TSD). Considering the total number of tests to be conducted per year (approximately 86,024 across all sizes of business), the total ongoing costs of product testing per year are and will continue to be around EUR189.25 million.

In addition, in terms of product withdrawals, although the ultimate impact would depend on the value of the toy models impacted, it is possible to indicate an estimate based on the turnover achieved by the European toys industry. Considering the size of the toys industry in 2019, **an estimated EUR 16.5-33.0 million worth of toys could no longer be made available on the market**. **Based on 2020 provisional data, this could affect EUR 13.1 to 26.2 million worth of toys.** Given the time provided to accommodate such changes, the impact of such product

withdrawals would likely be mitigated by: i) the ability for producers to shift resources to the production and sale of alternative toy products; and ii) the purchasing decisions of consumers, who, instead of choosing not to purchase a product, will in many instances purchase an alternative product and still contribute to the toys market.

B) Policy options to strengthen the protection of children from harmful chemicals - PO1a

Under PO1a, all four of the following measures could result in adjustment costs for companies:

Limit values: Granting legal powers to the European Commission to make changes to limit values does not necessarily mean that a toy manufacturer will have to replace chemicals with a substitute and incur an adjustment cost. In some cases, they could instead continue using the same chemicals, but with the added risk that lower limit values will be more challenging to test for and comply with. Moreover, such restrictions and the related risks of generic bans could incentivise producers to search for alternative safe chemical substitutes.

However, in other cases, toy manufacturers highlighted that it may be impossible to continue to produce certain products in their current forms if they are subject to further chemical use restrictions. This could lead to the need for product adaptation or withdrawals from the market. An example provided was that a major reduction in limit values for nitrosamines beyond the reductions proposed below would result in the removal of balloon products from the market.

Considering the scale of the impact and related costs under PO1a, 17 amendments to limit values have been made under the TSD to date (see baseline scenario above), which could indicate the frequency of possible amendments to limit values under PO1a. However, most of these past amendments relate only to toys intended for children under 36 months and mouthing toys. This means that any limit value changes under PO1a, which will apply to all toys, will impact a much wider range of products and thus result in greater adaptation and withdrawal costs for manufacturers compared to the baseline.

Nitrosamines and nitrosatable substances: Most industry stakeholders interviewed noted that reducing the limit values for nitrosamines and nitrosatable substances to the levels already detailed in the EN standard and German law would have a minimal impact. In this respect, producers either make limited use of these substances or already use them at the lower limit values. However, certain manufacturers and SMEs in particular were concerned about the reduction of these limit values beyond the levels prescribed by Germany and the EN standard.

Combination effects: Although limited input was received on the impact of this measure, those manufacturers that did respond noted that it would have limited impact on their product portfolio as most reputable manufacturers already assess and address the risks stemming from the combination of chemicals.

Although the mechanisms of impact are clear across these measures, the precise **costs of product adaptation (incl. chemical substitution) and product withdrawal** are difficult to quantify. Many toy manufacturers and industry associations highlighted this point, noting that the scale of the potential impacts is difficult to assess given: i) the lack of information on the types of substances that could be subject to restrictions through limit values changes; and ii) the possible level of the restrictions and the specific requirements on assessing combinations of chemicals.

Furthermore, the scale of the impact would reportedly **differ significantly based on the make-up of a manufacturer's product portfolio**. For instance, industry estimates on the possible proportion of their product portfolio that would be impacted ranged from 0% to 20% to 100%.

While most manufacturers were unable to provide any insight, in line with the above reasoning, a small number of manufacturers provided rough figures on the potential impact of PO1a, allowing the calculation of indicative impact estimates. Based on stakeholder consultations, the below estimates assume that PO1a will either require **adaptation or withdrawal of 3-6% of toy models on the market compared to the baseline**. This is based on 78,702 new toy models across all business sizes on which those percentages of toy models that may be impacted by substitution or withdrawal are applied. Furthermore, we assume that 2-4% of toy models would require redevelopment to identify and use safe, alternative chemicals, while the remaining 1-2% could no longer be made available on the market. Some of the effects relating to product withdrawal would be partially mitigated in terms of the impact on the toy industry overall as consumers may instead purchase alternative products that meet more stringent limit value thresholds. However, these impacts are complex to assess as this depends on the toy product type in question and the extent to which there is easy substitutability for products using less harmful chemicals.

Based on these estimates and the cost estimates detailed above, the **total one-off costs associated with product redesign and redevelopment to adapt to greater restrictions could range from EUR 10.23 million to EUR 220.4 million compared to the baseline (see Table 26)**.[388] It is anticipated that the costs of any new restrictions under PO1a would strongly mirror the costs of the amendments made under the TSD in the period 2012-2018. As such, the costs to industry per toy type under the baseline are likely to be closer to the figures detailed in the evaluation.

Table 26: Cost estimates associated with chemical restrictions implemented under PO1a

Estimated % of products impacted	Evaluation (large firms)	Evaluation (SMEs)	Total redesign / redevelopment (low estimate)	Total redesign / redevelopment (middle estimate)	Total redesign / redevelopment (high estimate)
Costs per toy type (EUR)	€6,500	€7,700	€17,000	€29,700	€70,000
% of products impacted (low estimate - 2%)	€10.23 m	€12.12 m	€26.76 m	€46.75 m	€110.18 m
% of products impacted (high estimate - 4%)	€20.46 m	€24.24 m	€53.52 m	€93.50 m	€220.37 m

Industry stakeholders indicated that the unit costs of testing would likely increase within PO1a, as compared to the baseline. In particular, the increased complexity of testing for lower limit values would reportedly lead to increases in testing costs from EUR 2,200 to around EUR 3,300. Assuming that the 2-4% of toy models subject to adaptation efforts will be subject to these increased testing costs, applying the same percentages to the yearly number of tests (86,024), **yearly testing costs are estimated to incrementally increase compared to the baseline by around EUR 1.89-3.79 million**.

[388] These figures have been calculated using the following equation: total number of new toys in a given year (78,702) x the proportion of products impacted by product adaptation x the costs of testing/redevelopment. These figures are compared to the baseline while the main impact assessment report considers costs which are additional to the baseline.

In addition, 1-2% of toy models could no longer be made available on the market. Although the ultimate impact would also depend on the value of the toy models impacted, it is possible to indicate the impact based on the turnover achieved by the European toys industry. Using provisional Eurostat data from 2020, this impact could result in a **EUR 65.6-131.2 million worth of toys no longer available on the market, compared to the baseline**. Given the impact of COVID-19 on the 2020 figure, it is worth also noting the impact when applied to the 2019 industry turnover data. In this case, **EUR 82.6 – 165.1 million** worth of toys could no longer be made available under PO1a. However, as detailed under the baseline, these impacts would be mitigated by the time provided to adjust to the updated rules, which would allow producers to shift resources to the production and sale of alternative products, and the fact that, in many instances, consumers would choose to purchase an alternative toy product, rather than not purchasing anything, thereby ensuring the revenue to the toys market remains.

Although these figures should be read alongside the abovementioned caveats and the uncertain nature of the number of products impacted by PO1a, they illustrate the potential scale of the impact and how it might differ based on the proportion of products impacted.

PO1b

In comparison to PO1a, the **adjustment costs stemming from PO1b would be higher**, as, in addition to all the above measures, PO1b would involve a generic ban on additional chemical substances and the removal of the derogation based on the 'relevant concentrations' for CMR substances detailed in the CLP Regulation. This finding on adjustment costs was confirmed by many industry stakeholders. Below, we present the nature of the impacts per measure before discussing the overall adjustment costs for the option.

Extension of the GRA: PO1b would extend the existing general prohibition of CMR substances to a potentially significant number of other chemical substances, including endocrine disruptors, neurotoxic and immunotoxic substances (currently classified as STOT RE or STOT SE), as well as substances affecting the respiratory system. In total, this could mean an increase in the current list of substances restricted in toys by 10-30%[389].

Removal of CLP derogation: Although other derogations would be maintained, manufacturers noted that the removal of the derogation based on the relevant concentrations in the CLP Regulation could also have an impact on the use of chemicals in and the viability of certain toy products. A limit of detection or testing would still be allowed.

While the CLP-related derogation will be removed, manufacturers will still be able to apply for derogations under Article 46(3) where the following conditions are met: i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe; ii) the substance is not prohibited for use in consumer articles under REACH; and, iii) there are no suitable alternative substances or mixtures available. Although it is anticipated such applications would occur where the costs for manufacturers would be particularly high (and could result in products no longer made available on the market), only two derogations have been applied using this mechanism since the adoption of the TSD, for the use of nickel in stainless steel and in components that are used to conduct an electric current.

Beyond this limited use of Article 46(3), no feedback has been provided on the extent to which manufacturers are currently relying on the other two existing derogation possibilities (one based on

[389] See annex 10.d for an estimation of the number of substances that could potentially be affected by the GRA in toys.

CLP concentrations and one based on inaccessibility) . In addition to the other limitations highlighted previously, this makes it is difficult to assess the exact impact of this policy option.

Furthermore, the toy industry is an intermediate user of chemicals that often only makes small purchases of specialty chemicals. As such, toy manufacturers noted that they have limited market weight to influence the decisions of chemicals producers with regard to identifying chemical substitutes that are relevant and appropriate for use in toy products. This would have an impact on the number of products withdrawn rather than redesigned and redeveloped.

However, as for the baseline and the other sub-options, many manufacturers noted that the lack of clarity on which substances would be covered by the extension of the GRA and which products would be impacted by the removal of the derogation makes estimating the number of products impacted, as well as the other required data points, very difficult. The narrative on costs from industry was similar to PO1a; namely, PO1b has the potential to impact a large proportion of products, but the potential scale of the firm-level impact depends on the substances and mixtures banned, as well as the types of toys produced by a particular manufacturer.

In the same manner as for PO1a, we now present rough indicative estimates of the adjustment costs related to PO1b on the basis of available data. Given the increase in the impact of PO1b as compared to PO1a, we assume the following for the purposes of these estimates: a total of 9-14% of toy models will be impacted under PO1b compared to the baseline, with 5-8% subject to product adaptation efforts (including chemical substitution efforts) and 4-6% that could no longer be made available on the market. This is based on 78,702 new toy models across all business sizes on which those percentages of toy models that may be impacted by substitution or withdrawal are applied. The effect of product withdrawals on market contraction should be nonetheless mitigated, to a certain extent, in a demand shift to other toys remaining on the market.

Using the same data on cost estimates for product adaptation and redevelopment detailed above, PO1b could result in the costs for industry in the range detailed in the below table. More specifically, the estimated impact on 5-8% of all toy models could result in total one-off costs associated with product redesign and redevelopment of **EUR 25.6 – 440.7 million** compared to the baseline.[390]

While the costs of adaptation under the baseline scenario and PO1a were considered to mirror the adaptation costs identified through the evaluation, it is anticipated that the costs per toy type under PO1b will be more costly. This is because the types of adaptations necessary as a result of the measures implemented through PO1b are more likely to require the identification of substitute chemicals rather than only lowering the levels of the chemicals already in use.

Table 27: Cost estimates associated with chemical restrictions implemented under PO1b

Estimated % of products impacted	Evaluation (large firms)	Evaluation (SMEs)	Total redesign / redevelopment (low estimate)	Total redesign / redevelopment (middle estimate)	Total redesign / redevelopment (high estimate)
Costs per toy type (EUR)	€6,500	€7,700	€15,000	€35,100	€70,000

[390] These figures have been calculated using the following equation: total number of new toys in a given year (78,702) x the proportion of products impacted by product adaptation x the costs of testing/redevelopment. As indicated above, the main impact assessment reports costs additional to the baseline.

% of products impacted (low estimate - 5%)	€25.58 m	€30.30 m	€66.90 m	€138.12 m	€275.46 m
% of products impacted (high estimate - 8%)	€40.92 m	€48.48 m	€107.03 m	€221.00 m	€440.73 m

In addition, as for PO1a, the **costs of testing** products would reportedly increase under PO1b and PO1c due to an anticipate increase in the complexity of the testing required. Based on industry input, the costs of testing per product under PO1b and PO1c would increase to approximately EUR 3,900 per toy type. Assuming that the 5-8% of products subject to adaptation efforts will be subject to these increased testing costs, and applying the same percentage to the yearly number of tests (86,024), **yearly testing costs** are estimated to incrementally increase compared to the baseline by around **EUR 7.31-11.70 million**.

Product withdrawals: In terms of product withdrawals, although the ultimate impact would depend on the value of the toy models impacted, it is possible to indicate an estimate based on the turnover achieved by the European toys industry. This option could impact 4-6% of toy models that could no longer be made available on the market. **On the basis of 2020 data, PO1b could result in EUR 262.3-393.5 million worth of toys no longer being made available on the market.** Considering 2019 data, this value could be of EUR 330.2 – 495.3 million.

As detailed under PO1a, these figures should not be read in isolation, as they are subject to a range of important caveats. However, they illustrate the potential scale of the impact arising from the measures planned under PO1b.

Beyond these issues, it is important to note that, if PO1b is not implemented together with better enforcement, there is a risk that non-compliant toys and their manufacturers would become more competitive, as reputable manufacturers would have to comply with the extension of the GRA and the removal of CLP derogations, and thus incur the related costs, whereas non-compliant manufacturers do not presently comply with the essential requirements and would continue not to do so.

PO1c

While PO1b will lead to greater adjustment costs than PO1a, the removal of all derogations under **policy option 1c would implement further incremental adjustment costs on industry stakeholders**.

Many manufacturers and industry associations interviewed noted that the removal of derogations related to substances that are inaccessible or listed in Appendix A could **lead to extensive withdrawals of products**. While many stakeholders again highlighted the difficulty of assessing the scale of the impacts of this policy option due to a lack of detail, the following indications were provided:

- A large top 5 global manufacturer estimated that, under PO1c, 10-20% of toys would have to be removed from the European market, equating to up to 2000 Stock Keeping Unit (SKUs).
- Another manufacturer noted that approximately 20-30% of all their products would be impacted.

- Without offering precise figures, other manufacturers stated that the majority, if not all their products would be impacted under PO1c.

Notable impacts are anticipated under PO1c in relation to the use of nickel in toys and toy components made of stainless steel and in toy components which are intended to conduct an electric current, for example. . These changes will therefore not only bring a significant cost for manufacturers, but they could severely impact the competitiveness of the European toys industry.

Based on these figures and further discussions with industry stakeholders, we now present rough, indicative estimates of the potential adjustment costs related to PO1c. Given the incremental increase in the impact of PO1c as compared to PO1b, as well as the input on the balance between the relative impact on product withdrawals versus substitution efforts, we assume the following for the purposes of these estimates: a total of 20-30% of toy models will be impacted under PO1c, with 10-15% that could no longer be made available on the market and 10-15% subject to product adaptation efforts (including chemical substitution). In this case, as certain categories of products may be impacted by the restrictions, shift in demand to other products may be more limited.

Using the same data on cost estimates for product adaptation and redevelopment detailed above, PO1c could result in the costs for industry in the range detailed in the below table. More specifically, the estimated impact on 10-15% of all toy models could result in total one-off costs associated with **product redesign and redevelopment of EUR 51.2 – 826.4 million compared to the baseline**.[391] It is anticipated that the costs per toy type under PO1c will be more costly than under PO1a and the baseline scenario. As for PO1b, this is because the types of adaptations required as a result of the measures implemented through PO1b are more likely to require the identification of substitute chemicals rather than lowering the levels of the chemicals already in use.

Table 28: Cost estimates associated with chemical restrictions implemented under PO1c[392]

Estimated % of products impacted	Evaluation (large firms)	Evaluation (SMEs)	Total redesign / redevelopment (low estimate)	Total redesign / redevelopment (middle estimate)	Total redesign / redevelopment (high estimate)
Costs per toy type (EUR)	€6,500	€7,700	€15,000	€35,100	€70,000
% of products impacted (low estimate - 10%)	€51.16 m	€60.60 m	€133.79 m	€276.24 m	€550.91 m
% of products impacted (high estimate - 15%)	€76.73 m	€90.90 m	€200.69 m	€414.37 m	€826.37 m

In addition, as under PO1b, the costs of testing products would reportedly increase under PO1c due to an anticipate increase in the complexity of the testing required. Based on industry input, the costs of testing per product under PO1c would increase to approximately EUR 3,900 per new toy model. Assuming that the 10-15% of toy models subject to adaptation efforts will be subject to these

[391] These figures have been calculated using the following equation: total number of new toys in a given year (78,702) x the proportion of products impacted by product adaptation x the costs of testing/redevelopment.
[392] These figures have been calculated using the following equation: total number of new toys in a given year (78,702) x the proportion of products impacted by product adaptation x the costs of testing/redevelopment.

increased testing costs, and applying the same percentages to the yearly number of tests (86,024) **yearly testing costs** are estimated to incrementally increase compared to the baseline by around **EUR 14.62-21.94 million**.

Product withdrawals: In terms of product withdrawals, although the ultimate impact would depend on the value of the toy models impacted, it is possible to indicate an estimate based on the turnover achieved by the European toys industry. This option could impact between 10% and 15% of all toy models that could no longer be made available. On the basis of 2020 data, **PO1c could impact EUR 656 – 984 million worth of toys**. Considering 2019 data EUR 826 million and 1.24 billion worth of toys could no longer be made available. However, as mentioned throughout, this would not lead to a direct market contraction of that size, given 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. Nonetheless, the severity of the measures under PO1c will render certain categories of toys unavailable.

As detailed under the other policy options, these figures should not be read in isolation, as they are subject to a range of important caveats. However, they illustrate the potential scale of the impact arising from all measures proposed under policy option 1.

C) Policy options to reduce the number of non-compliant toys – Overarching analysis

There are no notable adjustment costs stemming from PO2a. All additional costs for industry are discussed within the above section on administrative burden.

For PO2b, there are no adjustment costs either as costs associated to the DPP are factored in as administrative burden above. There could be some cost synergies and savings in that product information digitalized through the DPP could be useful in demonstrating compliance with the toy safety rules, as well as for meeting the requirements set out in horizontal legislation (such as REACH and the CLP in relation to substances used in toys). The precise level of savings is not possible to estimate.

2. IMPACTS ON INNOVATION AND COMPETITIVENESS

As per the Better Regulation guidelines, it is important to assess the impacts of changes to the TSD and its possible transition to a Regulation on innovation, competitiveness and the single market.

In this section, we discuss how the proposed changes to the TSD outlined under the different policy options (POs) could potentially contribute towards the achievement of EU policy objectives relating to strengthening innovation and industrial competitiveness. A summary is provided here, before a more detailed analysis is presented below, by policy option:

- Under PO1a, the ability for the Commission to more easily change chemical Limit Values could impact the ongoing feasibility of continuing to use the same substances in toy production. There could be ongoing competitiveness risks related to the uncertainty of relying on substances if they can only be used safely in very small quantities with a risk of them being banned in future. This could incentivise producers to explore the use of chemical substitutes, which could in theory drive innovation. However, in practice, industry stakeholders note that, although the specific substances this option will impact are unknown, there are generally limited suitable alternatives available and the toy industry lacks influence

in the market to drive targeted activities by the chemicals industry to identify appropriate alternatives.

- Under PO1a, a reduction in the limit values stipulated in the TSD relating to N-Nitrosamines and N-nitrosatable substances to the levels already set out in the EN standard and in German national legislation, which are lower, was generally supported by large toy manufacturers on the basis that they largely already follow lower limit values compared with the TSD as per the EN standard. As such, toy producers would not need to use chemical substitutes even if limit values were reduced, as they are already below those reduced limit values anyway. However, an exception in this regard was producers of certain toy products, such as balloons, where SMEs were highly concerned that changes beyond the limit values detailed in the EN standard could result in them having to withdraw their products from the market.
- Under PO2a, if conformity assessment was to be extended, with additional pre-conformity assessment required through an EC-type examination, industry feedback was that this would result in considerable additional compliance costs during the conformity assessment process for the product types covered by the extended requirements. In case the measures would lead to an improvement in enforcement this would have a very positive effect on competitiveness of complying producers as they would win market share and the cheaper illicit competition will be curtailed.
- Under PO2b, the facilitation of controls, a Digital Product Passport would be introduced. This could facilitate the work of market surveillance authorities and customs authorities and lead to efficiency savings, but this would not necessarily impact directly on innovation and competitiveness *per se*. Again, in case the measures would lead to an improvement in enforcement this would have a very positive effect on competitiveness of complying producers as they would win market share and the cheaper illicit competition will be curtailed.

The impacts by policy option are now considered in detail:

A) Baseline

The current baseline situation in relation to competitiveness and innovation is as follows:

- Currently, a very selected number of derogations from restrictions on chemical substances are possible under the TSD under Appendix A. This allows the toys sector to avoid the costs of generic bans, given the absence of suitable substitute chemicals in many cases, which prevents product withdrawal.
- Limit values change rarely, and it can take considerable time to get limit values changed, therefore there is a challenge that no fast-track mechanism exists to respond quickly if scientific evidence suggests that limit values are unsafe. Whilst this avoids damaging competitiveness by avoiding a situation in which limit values change regularly, it is not ideal as the system for setting limit values is slow and inflexible, which may damage industry competitiveness in the medium-long term.
- The great majority of toys (around 97%) are not presently subject to an EC type examination. This is viewed as being cost-effective by industry, who have a strong preference for following Module A (internal production control).
- The very high number of non-compliant toys in the Union market create a competitive disadvantage for reputable manufacturers that spend a significant amount of resources in complying with the TSD.

B) Policy options to strengthen the protection of children from harmful chemicals - PO1a

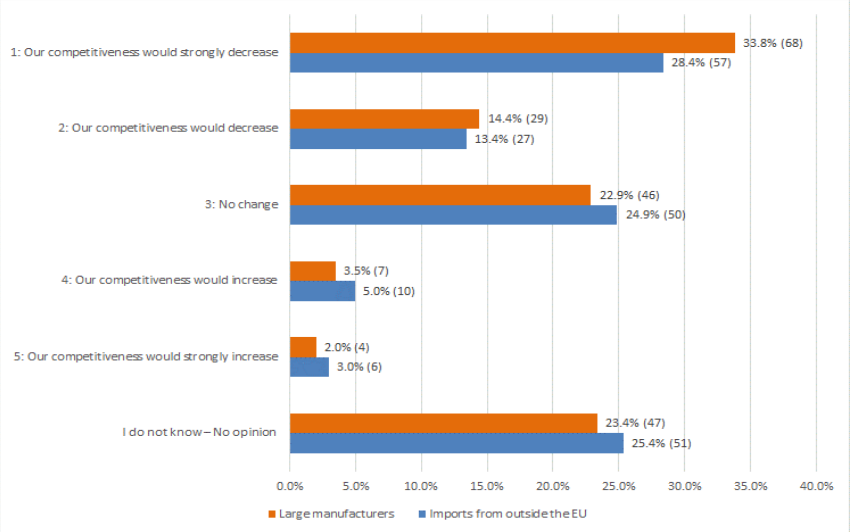
Strengthening the limit values for chemical substances could have mixed impacts, given that **tightening chemicals rules for toys is likely to serve as both a driver and inhibitor of innovation and competitiveness.**

Under PO1a, there would be an impact on innovation and competitiveness. In particular, the proposed changes would **incentivise, but not mandate chemicals substitution**. Reductions in limit values could require producers to reconsider which chemicals they use in toy production, for instance if they can only use these in small quantities to avoid exceeding new limit values. Whilst in some cases, they could continue to use the same chemicals, there could be an increased risk in terms of the supply of those chemicals in future if scientific evidence evolves and requires further changes to the limit values, or even the substance being banned. The nature and magnitude of impacts would depend on which limit values are put in place, which is not yet known at this stage, as PO1a is about giving regulatory powers to change limit values to be more flexible and quicker to reflect evolving scientific evidence.

Where no suitable alternative chemicals are available, this could lead to the withdrawal of particular products from the market. However, whilst there could arguably be some withdrawals of products from the market, estimated in the cost-benefit assessment at between 1% in a low case and 2% in a high case, regarding the impacts on industry overall, this would be partially mitigated through the effects of consumers switching to purchasing compliant products instead of a product they would have otherwise purchased had it not been withdrawn from the market, as well as the possibility for producers to adapt production through a sufficiently long transition period.

The SME survey examined views on what difference this package of options would make to competitiveness of products. It should be noted that the views expressed cover all sub-measures included in PO1a, which go beyond making changes to chemicals limit values alone.

Figure 18: *PO1a minimum changes. Impacts on SMEs – on a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would these measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?*



Source: SME survey

Regarding the SME survey results, interestingly, **SMEs are more concerned about the impact on their relative competitiveness in comparison to large manufacturers** compared with any concerns they might have regarding the impact on imports from outside the EU. However, this is not surprising, as any importers or toy manufacturers outside the EU would be subject to the same rules as manufacturers within the EU-27, whereas SMEs would arguably be more impacted by changes to limit values in chemicals as they lack the economic clout of large producers and are more at risk of speciality chemical producers discontinuing the production and supply of particular chemicals.

More positively, if limit values could be changed more easily by the Commission, this would promote adaptability in case particular concerns come to light regarding chemicals used in toys and allow for a rapid and flexible regulatory response to adjust limit values in light of any new or changed scientific evidence. It is difficult to anticipate the impact on competitiveness and innovation that this would have at a more granular level, as the precise chemicals whose limit values would be amended are not known at this point in time.

The **timing of changes to limit values could also impact on toy manufacturers' competitiveness**. If these occur at short notice, this would cause regulatory uncertainty and make it more difficult to adjust to the new limit values. This may hamper competitiveness and innovation in some cases. Conversely, if sufficient time is given to manufacturers (especially SMEs) to adapt to changes to limit values, then there would be fewer costs and adverse consequences on their competitiveness.

Balanced against this, if stricter limit values are introduced for certain chemicals used in toys, it could **incentivise toy manufacturers to search for safer chemical substitutes**, which in turn could drive innovation by spearheading investment in R&D&I. Some SME manufacturers interviewed (as well as those taking part in workshops on the possible revision of the TSD)

mentioned that, whilst changes to limit values could be managed, the impact would strongly depend on what changes are made to existing limit values, which is not yet known by the Commission as changes to limit values would be made in future depending on which scientific evidence emerges regarding the use of particular substances.

Moreover, large firms interviewed commented that, generally, where particular substances are under review or require authorisation under REACH, there could be a negative impact on their competitiveness for two reasons 1) the lack of suitable alternative substances (i.e. chemical substitutes) and 2) the impact of regulatory uncertainty, as this may lead to delayed investment, uncertainty about whether they can continue to produce certain product lines in future etc. Regulatory uncertainty will thus have a cost for toy manufacturers, although the precise level of cost is difficult to ascertain.

If limit values are made more stringent, in the short term, there could be negative impacts on innovation and competitiveness, as firms may have to consider not using particular chemicals in the manufacturing of particular toy product lines, and this could in turn lead to product withdrawals in instances where there are no safe substitutes available. In addition, any decision to focus resources on identifying chemical substitutes could also represent an opportunity cost for innovation, research and development in relation to other types of toys. However, the scale of this opportunity cost is also difficult to assess.

A 2021 *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability* undertaken by consultants for CEFIC, for instance, attests to the difficulty in predicting how far products will either be discontinued or substituted/reformulated. "The extent to which products will be discontinued or substituted/reformulated as a result of CLP changes only has not been investigated directly, although an assumption based on expert input has been considered".

Regarding the **innovation and competitiveness-related impacts of reducing the limit values for nitrosamines and nitrosatable substances,** these were seen as being neutral by many but not all industry associations and manufacturers. The measure to adjust the limit values for N-nitrosatable substances[393] and N-nitrosamines from the current level set out in the TSD to the levels already set out in both the EN standard and in German national legislation, which are considerably lower, would largely reflect current industry standards and not require much adjustment (apart from those producers not presently following the EN standard). Among large toy manufacturers interviewed and also during the stakeholder workshop on the possible revision of the TSD held in April 2022, there was a broad stakeholder consensus that the current limit values for nitrosamines and nitrosatable substances (0.5 mg of N-nitrosamines per kg of material) used in Directive 2009/48/EC are currently too high and should be reduced.

The rationale for reducing limit values under PO1a is for health reasons, as some N-nitrosamines are carcinogenic (Category 1B). However, as the limit values are widely acknowledged as being set too high, reducing the limit values to more realistic safety levels was not viewed by stakeholders (including industry) as causing problems from a competitiveness perspective.

In terms of the impact on innovation, arguably this could encourage manufacturers to reduce levels of nitrosamines and nitrosatable substances in existing products and / or to search for alternatives chemicals not containing such substances. However, there are limitations as to what is realistic. For instance, several SMEs responding to the survey mentioned that there are no alternatives to these substances for balloons.

[393] "N-nitrosatable substances" refers to any substances capable of being converted into N-nitrosamines;

An area where there could be a positive impact on innovation is not in manufacturing itself, but rather **improving the quality of test methods and the development of new equipment to test lower levels of N-nitrosamines and N-nitrosatable substances for certain types of toys**. EN 71-12 mentioned above provides test methods in support of the EU requirements for N-nitrosamines and N-nitrosatable substances in certain types of toys. However, there needs to be **new and more sensitive testing equipment and validation techniques developed** so as to ensure that limit values of these substances can be tested to lower levels. According to stakeholder feedback, current testing equipment is insufficient to test such substances to much lower limit values, which is a barrier to regulatory change but would also result in costs for toy manufacturers. Whilst larger firms may purchase the equipment themselves, SMEs would likely have to use a third-party testing house and pay for the costs of testing as they would be unlikely to purchase new highly sensitive testing equipment themselves as the costs could be prohibitive.

An SME responding to the SME survey agreed with other stakeholders interviewed (especially market surveillance authorities and notified bodies) that testing of nitrosamines and nitrosatable substances is presently unreliable, such that this causes uncertainty for business which can damage competitiveness. Regarding nitrosamine and nitrosatable substance testing, they stated that *"there are discrepancies at the testing level between different laboratories, and within the same laboratories themselves on chemically identical samples. We believe further work is required on why these discrepancies occur to ensure that tests are robust, reliable and fit for purpose"*.

PO1b

Many toy industry representatives and individual manufacturers interviewed (both large firms and SMEs) expressed major **concerns about the impacts on competitiveness of the extension of the GRA and the removal of derogations related to the relevant concentrations in the CLP Regulation so that certain chemical substances cannot continue to be used by the toy industry.**

Concerning the **extension of the GRA** to other substances, an industry association noted that, in their understanding, many reputable toy manufacturers do not use the materials that would be subject to generic bans under PO1b. However, this extension of the GRA could result in a 10-30% increase in the number of substances and mixtures banned under a future Toy Safety Regulation. In this context, other manufacturers noted that there would be an impact on their product portfolio, but the level of the impact is difficult to estimate due to the lack of clarity on the substances that would be covered. The removal of derogations related to the CLP will put an onus on individual firms to request derogations. Whilst some may do so, others may decide to withdraw their product from the market instead.

Manufacturers also anticipated some impact from the **removal of the CLP derogations**, given that residual presence of certain chemical substances is common in some toy products. Even though manufacturers consider such use safe, it would not be permitted under PO1b. However, the scale of such impacts was again difficult for industry to anticipate.

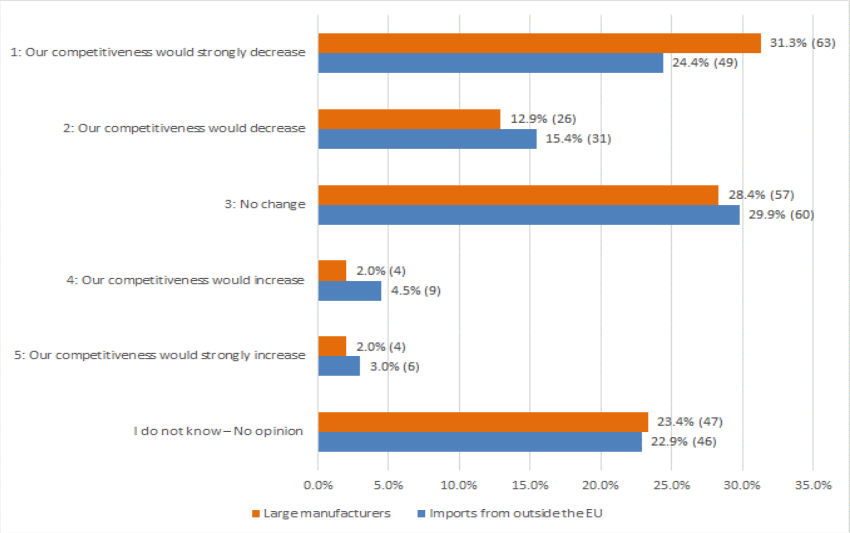
In this context, toy industry manufacturers detailed a further challenge related to the identification of appropriate chemical substitutes. More specifically, they noted that the toy industry is highly dependent on the chemicals sector as intermediate users for the availability of chemicals despite these being crucial to their competitiveness.

Feedback was that, in comparison with other sectors that are bigger intermediate users of chemicals, the toys sector (especially SMEs) **habitually purchase speciality chemicals in low quantity.** Therefore, their market power is not that strong and any changes in the availability of

particular chemicals due to the implementation of horizontal legislation through REACH would have a major impact if chemical producers decided to no longer produce particular substances, as there are often no substitutes available, and most toy manufacturers (except the leading global players) lack the market weight to work with chemical producers to carry out R&D&I into safe alternatives.

Some product withdrawals would occur as a result of this policy option, estimated as being equivalent to approximately 4% in the low case and 6% in the high case. The ultimate impact of product withdrawals on the size of the market would be mitigated to some extent by the purchasing of alternative toy products by consumers and the ability for manufacturers to shift resources to the production and sale of alternative toy products should sufficiently long transition periods be implemented. However, it is not clear that chemical substitutes will be available for all products affected.

***Figure 19**: PO1a On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would those measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?*



Source: SME survey

As for PO1a, the results show that a greater proportion of SMEs are concerned about the impact of the policy option on their competitiveness vis-à-vis large firms compared with their performance against imports from outside the EU. However, as can be seen, an overall negative impact on SME competitiveness is anticipated under PO1b.

PO1c

A large top 5 global manufacturer estimated that, under PO1c, an **estimated 10-20% of toys would have to be removed from the market**, especially electric toys. The precise percentage of toys that would have to be removed would depend on how rules on CMRs evolve in a future TSR. For example, some monomers are CMRs, but the toy industry uses them only as polymers. Previous

studies have found that the **migration of monomers from polymers has not led to children being exposed to hazardous substances**. This raises an issue as to the **imperative of scientific evidence being robust** otherwise it could damage the competitiveness of the European toys industry (including international toy manufacturers selling toys in Europe). This could be counter-productive from a safety perspective too, given that such firms invest significantly in regulatory compliance with the TSD in comparison with non-compliant firms in countries like China that may not be compliant with toy safety requirements.

A particular concern from a **competitiveness perspective** was that some monomers could also be banned, even though no safety issues have been shown when used in polymers (ABS). Such polymers have a significant mechanical impact on reliability and safety, and on the safety of users.

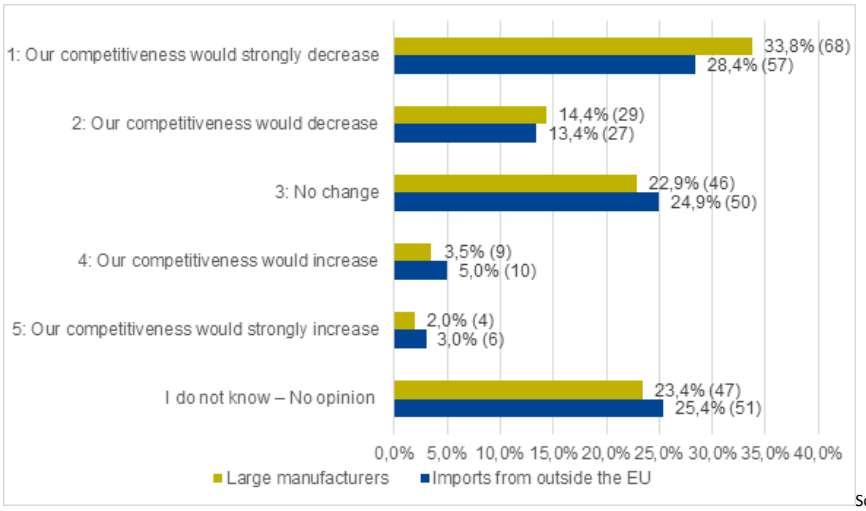
An example of a substance for which there is **presently a derogation under the TSD is nickel**, which is mentioned in Annex A of the TSD. Nickel is essential as a conductor of electricity and is extensively used in electric toys. Feedback from interviewees was that if such derogations were removed, it would also be very costly for industry. However, there was no data on the costs of substitutes, largely as there were not seen as being any viable alternative safe chemicals presently. Instead, the costs would relate more to the costs of product withdrawal.

As for PO1b, there will likely be some mitigation in terms of the ultimate impact of such product withdrawals on the overall toy market. However, certain product types would likely cease to be sold if appropriate substitutes cannot be identified.

Large industry players in chemicals can carry out periodic monitoring of the development of legislation concerning their area of business operations, which is **more difficult for SMEs**. Secondly, it has been pointed out that tightening the rules on chemicals under the TSD may not lead to a level playing field as non-compliant firms might be favoured, as they would not be expected to invest in compliance, whereas the 'fair' players would be forced to do so, which, again, would harm relative competitive position of the compliant SMEs.

In the following figure, feedback from SMEs regarding the impacts of PO1c is provided.

Figure 20: *PO1c Maximum changes. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would those measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?*



Source: SME survey

The concerns of SMEs regarding PO1c were captured in the responses to the SME survey. Nearly half of SME respondents (48.2%, 97) were concerned that their competitiveness would decrease (14.4%) or strongly decrease (33.8%) compared with large firms, with a clear indication towards stronger negative impacts. Although a negative impact on competitiveness is still anticipated, the responses in respect of the impact of PO1c on the competitiveness of SMEs compared with importers were lower, with 28.4% of SMEs responding that it would strongly decrease and 13.4% stating there would be a decrease.

However, it can be noted that there were a high percentage of 'I do not knows' for POs 1a, 1b and 1c, which suggests that the impacts on competitiveness are difficult to confirm without further information, for instance, on which chemical substances and mixtures would be restricted and to what extent.

In summary, the main industry concerns regarding the removal of all derogations under PO1c are:

- The general lack of suitable substitute substances for those presently the subject of a derogation in the TSD's Appendix A, which are permitted for specific use (example, the use of nickel in stainless steel used in electric toys).
- Whether if none of the existing derogations are permitted, substances will be available in a sufficiently cost-effective and timely manner; and
- Whether alternative chemicals can be supplied on a large enough scale for the purposes of their usage in toy manufacturing. Chemical substitutes are only any good to industry if they can be produced at sufficient scale.

C) Policy options to reduce the number of non-compliant toys

PO2a

It was estimated that this option would increase the costs of conformity assessment for manufacturers. Increasing the use of EU type examinations for products deemed higher-risk was viewed as costly in comparison to the self-declaration of conformity (SDoC). Secondly, it was perceived by large manufacturers interviewed that more extensive mandatory use of a notified body to perform an EC-type examination could lengthen lead times to market, which may undermine the competitiveness of the European toys market compared with third countries not having any such requirements. The percentage of toy products that would be affected by PO2a is difficult to estimate but evidence gathered through the interview programme and desk research suggests about 20% of toys would be affected in total (e.g. mainly those designed for the under 3s and to be put in the mouth plus toys such as slimes, clays and paints for children).

The impacts on competitiveness would vary, however, between each of the proposed areas to be covered as some situations in which conformity assessment would be extended are much more common than others. Feedback on the specific types of products that would be subject to additional conformity assessment procedures is summarised in the following table:

Table 29: PO2a – specific types of products subject to additional CA procedures

PO2a – extending conformity assessment	Baseline situation/ background	Feedback on impacts
Toys which are chemical mixtures or substances (i.e. e.g. slime, modelling clay or finger paint) for which there are higher risks of exposure to chemicals.	Many toy products are chemical mixtures or substances, as slime, modelling clay and finger paints are very popular among children. There are greater health risks associated with such products. Although the toys industry has argued (e.g. during workshops, interviews) that they proactively manage the risks of children ingesting chemicals used in toys by managing exposure risks.	Industry's main concern is that they would face higher costs of undertaking third-party conformity assessment.
Toys marketed at children under the age of 36 months old or designed to be put in the mouth.	Toys marketed at children under the age of 36 months old or designed to be put in the mouth are very common and industry stakeholders interviewed were concerned that this would lead to greatly increased testing and compliance costs as currently, only an estimated 3% of toys require an EC type examination.	The main feedback from industry was that they already implement risk management approaches for toys for the under 36 months and for those designed to be put in the mouth. They were concerned about the cost increase of having to carry out mandatory third -party conformity assessment for such toys. The concern was that this cost would be borne by reputable and already compliant manufacturers rather than by non-compliant manufacturers who do not carefully test the

PO2a – extending conformity assessment	Baseline situation/ background	Feedback on impacts
		chemicals used in such products. Any increase in costs may adversely impact on competitiveness.

Stakeholders were concerned about the impacts on competitiveness by the delays in marketing a toy. The costs of lead times to market are difficult to quantify, a leading top 5 global producer estimated that mandatory could third-party conformity assessment could add an additional 4-6 months in the process to place a product on the European market, with an adverse impact on competitiveness.

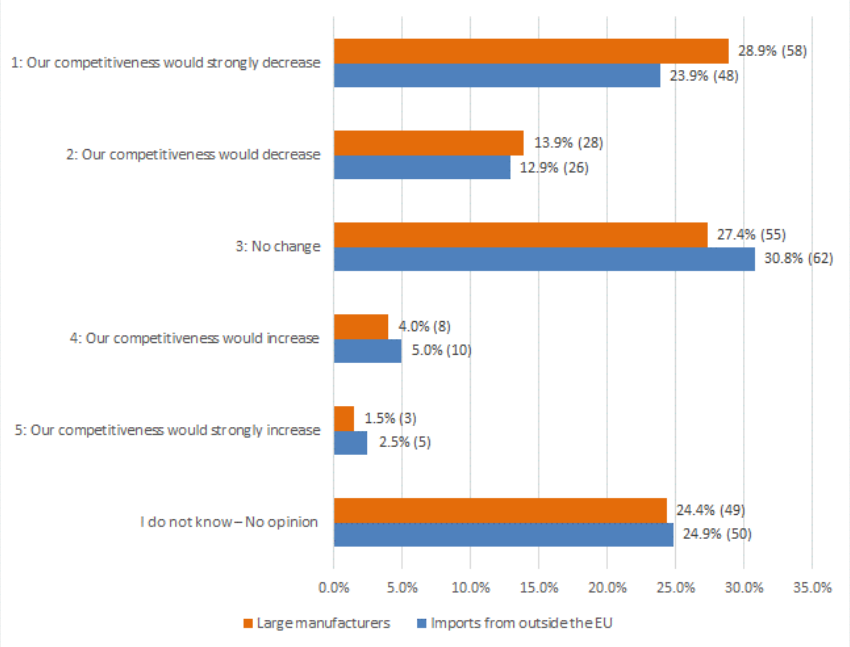
On a more positive note, stakeholders across a range of groups noted that any increase in costs for rogue traders and producers would have a positive effect on the competitiveness of compliant manufacturers, thereby improving the level playing field in the EU market and curtailing cheap, illicit competition. Although the European toys industry may experience some negative impacts on competitiveness through the above, PO2a should also help to strengthen the single market by promoting a more level playing field between reputable and rogue manufacturers placing products on the European market. However, PO2a would only have a positive effect on removing more non-compliant products from the European market if market surveillance authorities adopt a proactive approach in checking whether such products have been subject to a mandatory third-party conformity assessment or not. There would remain a risk that reputable manufacturers invest in complying with additional requirements which would impose additional costs, but rogue producers would still find ways to manage to get their products on to the market illegally.

However, some market surveillance authorities pointed out that it is more straight forward to check technical compliance and make a decision whether they need to investigate if a third-party conformity assessment body has already checked the product and the test results. This could save time for market surveillance authorities and therefore allow them to perform more checks, which in turn could help to reduce non-compliant products on the market. The positive impacts would be limited in this instance to the types of products covered by this measure.

Beyond the above general points, some targeted feedback through the SME survey was obtained regarding the impacts on SMEs of making mandatory third-party conformity assessment for certain higher-risk product categories. As shown below, nearly a quarter of respondents were unable to provide or did not have an opinion on the issue. This suggests that many SMEs found it difficult to conceptualise the impact of PO2a on their overall competitiveness.

However, of those SMEs that were able to respond, the figure illustrates a clear inclination towards a decrease in SME competitiveness as compared to both larger manufacturers and imports from outside the EU.

***Figure 21**: PO2a: Extending conformity assessment. Impacts on SMEs. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would these measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?*



Source: SME survey

Overall, this PO would have some benefits but relatively minor impacts in terms of their scale in reducing non-compliant products on the European market. Balanced against this would be a relatively significant increase in testing costs as many reputable producers would face both internal and external mandatory third party testing costs.

PO2b

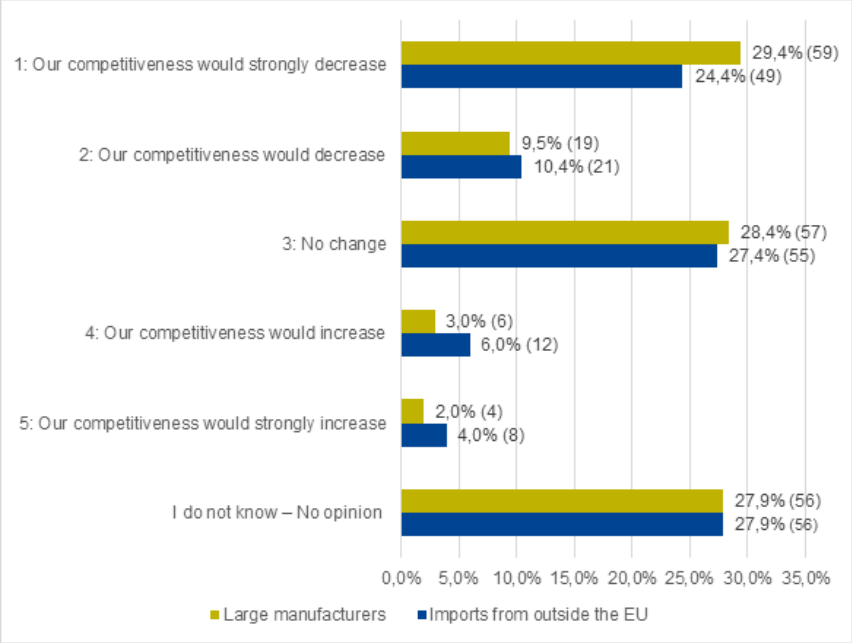
There would be benefits from this PO that contribute towards enhancing toy producers' competitiveness. Firstly, the digitalisation of product information (including regulatory compliance aspects) could lead to greater efficiencies and cost savings. A potential impact is that the information mandatorily required under the DPP could bring synergies if it also helps contribute towards meeting TSD compliance requirements. This PO is difficult to assess in detail as the precise information requirements of the DPP at the product level are not yet known.

However, it is highly likely that for instance, the chemical content of products will need to be disclosed in a toy producers' DPP. This could lead to cost savings for producers if having some of this information already available in digital form could also be useful to demonstrate compliance with the toy safety requirements.

Furthermore, stakeholders across a range of groups noted that any improvements in the functioning of market surveillance and enforcement within the EU, but also at the EU border, would improve the identification and control of non-compliant toys, thereby placing additional challenges and costs on rogue traders and producers. This option should have significant impacts in the reduction of non-compliant toys in the Union market. In turn, this would have a positive impact on the competitiveness of reputable and compliant manufacturers by improving the level playing field and curtailing cheap, illicit competition.

The views of SMEs, as expressed through the SME survey on this issue are now provided:

Figure 22: *PO2b: Facilitation of control. Impacts on SMEs. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would these measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?*



Whereas the EU's mandatory DPP initiative will require some investment by toy producers, they could potentially recoup some of this investment through cost savings as they would have the same product information already available under digital form under the DPP for compliance. Generally, the direction of travel is of increased digitalisation of product information, including to demonstrate regulatory compliance to customs and market surveillance authorities, and enhancing traceability within value chains. There could be potential cost savings for industry from digitalising product compliance information. Previous studies have suggested a benchmark of about 10-15% savings from full digitalisation, as the DPP will provide an alternative means to provide product compliance information digitally and as physical documents (e.g DoCs) will no longer be required, then there

would be greater savings.[394]. These studies also estimate the provision of compliance information at 0.4% of turnover of the sector.[395] Accordingly, savings could be estimated at around EUR 2.62 to EUR 3.93 million per year only from moving to the digital provision of compliance information.

Whilst 28.4% (57) of SMEs did not think this would lead to any changes in their competitiveness vis-à-vis large firms and 27.4% (55) compared with imported products, 29.4% (59) were concerned that this would strongly decrease their competitiveness compared with large firms. The rationale was that large firms are more easily able to invest in digitalisation and the digitisation of product information compared with SMEs.

In general, this PO of introducing a DPP for all toy products was seen very positively by industry, both by large firms and SMEs interviewed. This could provide a practical solution for toy manufacturers as over time, there is an increasing volume of information to be provided about products to different users and readers of product labels. market surveillance authorities require detailed product information to check regulatory compliance. Toy product information also needs to be communicated to other economic operators in the supply chain to ensure traceability. Lastly, consumers also need relevant product information about products, such as whether the product is intended for the under 3 years, and more generally, consumers increasingly demand more information about chemicals used in products, including toys.

PO2c

The impacts on competitiveness and innovation would therefore be similar to those described under PO2a and PO2b previously. However, there would also be the cumulative impacts on industry of both requiring more mandatory third-party conformity assessments under PO2a and the digitalisation of information under PO2b.

Moreover, as for PO2a and PO2b separately, the implementation of PO2c would likely improve the functioning of market surveillance and enforcement, thereby placing additional burdens on rogue traders and limiting their ability to place non-compliant toys on the European market. In this respect, reputable manufacturers would receive the benefits of a more level playing field and reduced illicit competition.

Stakeholders did not have particular views about 2c as a combined package. Instead, industry stakeholders reiterated their concerns about the increased cost of compliance under 2a and highlighted that this could lead to a significant increase in their conformity assessment costs.

3. IMPACTS ON THE SINGLE MARKET

Article 1 of the TSD establishes the focus of the Directive on ensuring the free movement of toys within the EU, supported by Recital 1 and Article 12. Although the evaluation of the TSD reported a generally positive assessment of the impact of the Directive on the European toys market, it did

[394] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Supporting study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2873/625443

[395] 0.4% of turnover of EU toy industry in 2020 was EUR 26.2 million. The share of 0.4% is the result of a multiplication of the total cost of compliance (2% of annual turnover, based on previous literature) by the share of the total cost compliance related only to the cost of indicating compliance with EU harmonisation legislation (20%, based on stakeholder consultation in the study supporting the Evaluation of the New Legislative Framework referred to above).

highlight a range of application and market development challenges that limited this effectiveness to some extent. Most prominently, the evaluation highlighted the presence of too many non-compliant toys on the market and the associated impact on market fairness and product safety, as well as the existence of implementation differences across the Member States in terms of both legal transposition and practical implementation (e.g. regarding surveillance and enforcement).

As the free movement of toys will remain as an important objective under the future proposal for a TSR, this section considers the impact of each policy option on the EU single market for toys and the related application challenges identified through the evaluation.

A) Baseline

The 2020 evaluation concluded positively on the achievement of the TSD in relation to ensuring the free movement of toys within the EU. In particular, manufacturers and other economic operators highlighted the harmonisation of procedures and requirements as highly effective in supporting the functioning of the single market.

However, the evaluation, as well as the research conducted for this impact assessment, identified a range of challenges in the application and particularly the enforcement of the Directive that act as barriers to the full realisation of the EU single market for toys:

Differences across the EU: In some cases, Member States have gone beyond the requirements of the TSD. The most prominent example is the 2011 application by Germany to maintain certain stricter national provisions on chemicals, including nitrosamines and nitrosatable substances. In 2012, this application was approved by the Commission.[396] In addition, under the current TSD, changes can be made to limit values, with some 17 changes having been made to the TSD since its adoption. However, there have been delays in the transposition of the different amendments to the Directive. The fact that the legal instrument covering toy safety is a Directive means that every amendment to the text must be transposed by all Member States. Significant resources are spent to ensure the transposition of amendments in a timely manner. The study underpinning the evaluation identified that the transposition of amendments of the TSD was excessively burdensome and time consuming.

Surveillance and enforcement challenges: Given market surveillance is the responsibility of the Member States, the resources allocated, and the approaches taken to surveillance and enforcement were found to differ across the EU based on the specific circumstances of each country. This included differences in the number and type of control procedures implemented, differing, and in some cases insufficient, financial means allocated, and differences in testing capabilities, including lack of appropriate testing laboratories in some countries. As a result, the evaluation found that the effectiveness of market surveillance can be considered as limited.

Beyond these challenges, the study supporting the evaluation highlighted key emerging market trends that impact the functioning and effectiveness of the single market, as well as the safety of toys and are thus important to consider within the baseline. These most prominently include an increase in online sales of toys, which has caused both enforcement and traceability issues, as well as a reported increase in counterfeit toys being placed on the EU market, bringing both product safety and IP risks.

[396] Commission Decision 2012/160/EU. OJ L 80, 20.3.2012, p. 19.

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1495625630954&uri=CELEX:32012D0160

Within this context, the evaluation noted the concerns of stakeholders that too many non-compliant products were being placed on the EU single market, stating that this can impact market fairness. Tackling this overarching challenge is a key policy objective for the possible revisions to the TSD.

One recent development that is important to note within the context of the baseline scenario is the adoption of the Market Surveillance Regulation (EU) 2019/1020, which has applied since 16 July 2021. More specifically, the Regulation aims to address key surveillance and enforcement challenges, including the challenges related to online sales and the role played by foreign manufacturers in the market. Given its recent application, the effectiveness of these measures is yet to be evaluated; however, the impacts on surveillance, and thus the functioning of the single market (including for toys), are anticipated to be positive.

B) Policy options to strengthen the protection of children from harmful chemicals – Overarching analysis

The proposed sub-options under PO1 aim to address problems of toy safety, rather than the functioning and effectiveness of the single market. However, as detailed in the above discussion on innovation and competitiveness, the introduction of further chemical restrictions through these policy options could lead to the need for toy manufacturers to identify chemical substitutes for use in certain toys.

Any changes to the limit values would continue to be applicable across the whole EU to all economic operators who would all be affected by the same set of changes to the limit values. However, there could be some disbenefits for the single market if the limit values are set in a very stringent manner, such that products would have to be withdrawn from the market, thus reducing consumer choice.

There would be some positive single market benefits by having a uniform approach across the EU to meeting the limit values for nitrosamines and nitrosatable substances in line with the German and EN standards.

C) Policy options to reduce the number of non-compliant toys

The proposed sub-options under PO2 aim to address challenges related to the functioning and effectiveness of the single market; namely, the existence of too many non-compliant toys on the market. According to stakeholders across all relevant groups (e.g. industry, national authorities, notified bodies etc.), this non-compliance is driven by products sold into Europe from economic operators based outside the EU and facilitated by increased access to the EU market through online platforms / marketplaces.

Although the SafetyGate alert data is not representative in this regard, due to the influence of differing approaches and priorities of Member State market surveillance authorities, the data do suggest that foreign-manufactured toys pose extensive safety and non-compliance problems. For instance, 85.6% of the toy-related alerts in the period 2016-2021 concern products originating in China (see full analysis in Annex 11).

Moreover, the SafetyGate data suggests that non-compliance in relation to specific types of product safety risk requires further attention within the TSD. In fact, over the period 2016-2021, the two most common toy-related risks – by a large margin – were choking risks (1,507 alerts, 37.7%) and chemical risks (1,404, 35.1%).

PO2a

Policy option 2a seeks to extend the list of toys for which mandatory pre-marketing third party conformity assessment is necessary. The logical mechanism for tackling the identified problem (i.e. too many non-compliant toys on the market) is that, for certain products that pose a particularly high safety and/or non-compliance risk, obliging manufacturers to independently test those products prior to placement on the market will improve compliance rates for those product types. The product types to would be subjected to mandatory 3rd party examination by a notified body under the policy option and commentary on their relevance is now provided:

- **Toys using chemicals mixtures or substances for which there are higher risks of exposure** – as highlighted by the abovementioned SafetyGate data, chemical-related risks are among the most common reasons for safety and non-compliance issues in toys. As such, their coverage through option 2a appears relevant.

- **Toys marketed to under 36 months old or designed to be put in the mouth** – as for chemical risks, such toys have been found to be particularly challenging from a compliance and safety standpoint. As highlighted in the SafetyGate data, choking (primarily on small parts) is the most common safety risk identified and alerted by market surveillance authorities, whilst the evaluation of the TSD noted that there is insufficient clarity regarding whether a toy is marketed to children under 3 years or not. As such, their coverage within this policy option appears relevant.

In terms of the functioning and effectiveness of the EU single market for toys, this policy option could improve compliance levels and product safety within the above categories by ensuring independent testing of these product types. Such an impact could benefit the single market by improving consumer trust, stimulating market growth and improving market fairness for these product types.

However, many stakeholders noted a dichotomy between compliant manufacturers, who already undertake appropriate compliance checks and report limited instances of identified non-compliance, and rogue economic operators, who place potentially non-compliant and unsafe products on the market will little chance of being identified and punished.

According to these stakeholders, this policy option would not improve the functioning of the single market but would in fact negatively impact market fairness. The rationale being that compliant manufacturers of these types of toys will bear the further costs (i.e. related to engaging a notified body), while rogue traders, who it is assumed are responsible for the vast majority of non-compliant and unsafe products placed on the market, will continue to operate in the market without fear of punishment (e.g. by using fraudulent test certificates).

In this respect, these stakeholders note that the primary factor limiting the effective functioning of the single market for toys is the lack of effective market surveillance, rather than any provisions within the TSD itself. Regulation 2019/1020 on market surveillance introduces measures aimed at tackling online sales and foreign manufacturers; however, it is not yet known whether these measures will have the desired impact on product compliance.

PO2b

Policy option 2b aims to facilitate controls by market surveillance authorities through the introduction of a digital product passport containing the EU declaration of conformity (DoC). This

would provide market surveillance authorities – with the support of customs authorities, who will verify the existence of the DPP – with more efficient access to the key information on which to assess the compliance of a toy product.

In practice, this improved access to information could enable market surveillance authorities to conduct more checks over a given time-period and improve cross-border circulation of toys, both into and within the EU. However, although the efficiency benefits for these stakeholders are clear, their potential effectiveness in tackling the key problem of product non-compliance was questioned by industry and market surveillance stakeholders.

PO2b would also have a beneficial impact on the level playing field as non-compliance with the mandatory requirement to ensure that a toy is accompanied by a DPP could lead to customs authorities preventing the free circulation of any product missing a DPP. Strengthening the transparency of product compliance information through its inclusion in a DPP would make it easier for market surveillance authorities to determine which products are non-compliant thereby improving efficiency and allowing for higher volumes of checks.

Conversion to a Regulation

In addition to the above measures, the proposed conversion of the TSD to a Regulation would bring single market benefits. As highlighted above, the evaluation of the TSD identified instances of inconsistency in the transposition and application of the Directive by the Member States. Through its direct application, the Regulation would remove the possibility for such inconsistencies, while also freeing up the resources currently used by Member State authorities and the Commission to ensure transposition and alignment. This could, for instance, allow for greater investment in market surveillance and enforcement

4. SOCIAL IMPACTS: IMPACTS ON HUMAN HEALTH

Seeing that the main objective of the TSD is safeguarding the health of children in their use of toys it is not surprising that the two main problems identified in the TSD evaluation of 2020 and this impact assessment are also very much linked to potential risks for human health.

- Scientific evidence on human health risks is constantly evolving and the TSD needs to keep pace with the available knowledge on human health risks of substances used for toys.
- Too many toys in the market are not complying with the TSD provisions and some of them pose an additional risk to children's health due to this non-compliance.

The impact assessment considers the following human health impacts to be the most relevant for the proposed policy options.

A) Baseline

The current problems identified in the protection of health of children will remain. The evaluation, stakeholders and the literature have identified several safety concerns from dangerous substances for children when using toys. Without a quick and regular update of substances and limit values these concerns will increase over time.
There is also significant evidence of remaining human health challenges caused by chemical hazards despite the existing regulatory frameworks and a significant number of them relate to

illnesses and risk for children too. A study[397] from 2017 listed the following relevant human health impacts:

- The costs of childhood asthma were estimated to be approximately EUR 1.6 billion per year. This is linked to the respiratory hazard class.
- 30,000 DALYs per year are estimated to be potentially caused by chemical exposure.
- Exposure to endocrine Disruptors are linked with several illnesses linked to children like childhood obesity and diabetes, autism and ADS. The costs of that are conservatively estimated to be between EUR 8-29 billion a year.

Establishing with precision the quantitatively exposure to harmful chemicals via toys is not possible as children are exposed to chemicals in many other ways. However, seeing the time that children spend with their toys every day it is likely that an important part of the exposure happens through them. For example in terms of metals, the main source of exposure of children is via the diet. Ingestion of metals through chewing toys will be an additional source. Under these circumstances the Scientific Committee (CSTEE, predecessor of SCHEER) recommended that the current maximum tolerable intakes or limit values for food should be used and 10% allowed as a maximum contribution from toys[398]. In practice, the limit values for other chemicals in the TSD are set at 10% of the tolerable daily intake set by the European Food Safety Agency (see for example the amendments to the TSD setting limit values for BPA) and for particularly toxic substances, at half of that level (5%) (see recital 22 of the TSD).

B) Policy options to strengthen the protection of children from harmful chemicals - PO1a

Lower limit values for nitrosamines and nitrosatable substances will align the limit values with other products relevant for children using similar substances (e.g. dummies). This could improve the safety especially of balloons and similar toys.

Many respondents also agreed with the need to amend the TSD to enable the Commission to introduce and change these limit values for all toys as scientific evidence evolves. Several examples were mentioned, where limit values for chemicals in toys for children above three years are necessary, e.g. preservatives and emission of volatile organic chemicals (VOCs). Most authorities therefore assessed that a modest increase in safety is likely if those limit values were introduced. At the same time, some authorities thought this solution would not their perceived challenge of regulatory processes being too slow and that it would take too long to reach the protection goals. There have been severe delays in updating annexes, as well as an inability in addressing emerging risks under the Toy Safety Directive as mentioned in a joint letter of several ministers to the Commissioner in 2019[399]. Some commentators therefore suggested to limit the annex to a reduced number of the most hazardous substances. In their view, the Commission would never have the time and resources to go through the full list of substances, which is why they support an umbrella solution limited to 40 or less specific items as opposed to thousands of substances.

[397] Study on the cumulative health and environmental benefits of chemical legislation, 2017.
[398] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on "Assessment of the bioavailability of certain elements in toys", June 2004, Opinion on bioavailability of certain elements in toys, CSTEE plenary, written procedure (europa.eu)
[399] Evaluation of the toy safety Directive 2019

Combination Effects: Not many interviewees had an opinion on the human health impacts of combination effects. One interviewee though argued that an inclusion would increase safety, as children are exposed to other chemicals with the same mode of action from other toys and other products and this exposure is not taken into account today.

There is by now a significant body of evidence[400] on the human health impacts of mixtures. For many mixtures the assessment by the risks of the single substances is appropriate as their combined risk levels are lower or equal to the additions of the risk of the single substances. But in some cases, the combined risk level can be higher and currently the TSD has no legal provisions to take account of those cases where the assessment of single substances leaves a significant risk factor out.

PO1b

The human health impacts of an extension of the GRA and the end of existing derogations on CRM substances would bring overall a positive impact on human health but the scale of this benefit was controversially discussed by stakeholders.

Currently the extension of the GRA approach is also discussed in the review of the REACH regulation. A use mapping was conducted in that Impact Assessment on the basis of the ECHA registration dossiers. For the most relevant product categories an assessment on the number of substances that would fall under specific hazard classes was developed. The results for 3 product categories particularly relevant for toys: PC 32: Polymers, PC9a: Finger paints and PC9c: Plasters and modelling clay have been considered. It is quite clear that many substances counted under this will not be used in toys but seeing the variety of toys and the polymer compounds used in them it is nonetheless a good approximation to understand the scale of the challenge. Another caveat is that the analysis eliminated as far as possible the overlap to substances already covered. But as the TSD and REACH do not have the same scope this might mean that some substances relevant for the TSD were eliminated while others should have been eliminated (as already banned in the TSD) but were not. An extension to all the hazard classes for the most harmful chemicals (EDs, respiratory sensitizers, immunotoxic and neurotoxic substances (currently under STOT) would mean that the number of substances covered might increase by about 10-30%[401]. That has of course implications for the costs of substitution, the cost of regulation and the human health and environmental impacts.

The evidence on existing chemical risks (although not directly linked to toys) on especially children's illnesses shows that especially the ban of endocrine disruptors and substances affecting the respiratory systems could be very relevant for toys. A significant amount of research has been conducted on the risks for human health of endocrine disruptors, immunotoxic, neurotoxic, STOTs and substances affecting the respiratory systems. Recent studies[402] have revealed alarming levels of cadmium and lead in products intended for children and compounds in plastics, such as phthalates and bisphenol A, that are suspected of harmful effects. Especially the risks of endocrine disruptors for children are set out in recent literature[403]. Given their capacity to mimic, obstruct and block natural hormones, exposure to even tiny amounts of EDs may result in severe and irreversible effects on human health, such as infertility, cancers, genital malformations, IQ loss or obesity. Other literature[404] showed that the exposure of children especially by mouthing to endocrine

[400] https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_mixtures.pdf
[401] See annex 10.D for the precise estimates.
[402] https://pubs.acs.org/doi/10.1021/es1009407
[403] https://www.beuc.eu/publications/beuc-x-2020-004_endocrine_disruptors.pdf
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disruptors does surpass safe levels in a very significant number of cases. A special focus of the research[405] has been the impact of phthalates and Bisphenol A in plastic applications.

The findings of the baseline show that especially two hazard classes might be most important for the Toy sector. Due to the closer link of endocrine disruptors and substances affecting the respiratory systems tor childhood diseases these hazard classes can be seen as the most urgent to be included in the GRA.

The not yet published impact assessment for the REACH revision on an extension of the GRA approach provides some interesting estimates on the impact of a generic ban on endocrine disruptors. The assessment of different health outcomes linked to endocrine disruptors in that IA brought the following results. Overall 11 health outcomes were identified, where a statistical relationship with the exposure to endocrine disruptors can be established (Very low birth weight, Intellectual disabilities, Childhood obesity, Male infertility, Cryptorchidism, Hypospadias, Testicular cancer, Autism Spectrum Disorder, ADHD in children and adolescents, ADHD in adults, Diabetes) . For those 11 health outcomes information on the prevalence , the costs per case and the PAF (Prevalence attributable Fraction) were available. For the attributable fraction the evidence was much less robust and therefore estimates of 1%, 2.5% and 10% were used.

The estimates show that exposure to endocrine disruptors causes very significant health effects that can be estimated on the basis of these 11 identified health outcomes to be at **around 24 billion EUR per year**). It is important to note that this annual benefit will be only reached after a very long time span as many of the avoided negative health outcomes will only not materialise in 50 years or more. This is especially true for endocrine disruptors and children where the costs of infertility or diabetes will show only many years after the exposure to EDs. So even a 20 year or even 30 year assessment period will not capture many of those benefits. On the other hand the costs for toy companies will happen in the very near future.

As explained above only a part of this exposure is linked to toys. The evidence on the share of exposure that is linked to toys is missing. On the one hand the type of adverse health outcomes are especially relevant to be avoided in children as they are linked to chronic illnesses like Diabetes or infertility. On the other hand children are only a smaller part of the population so many of the damages described above are happening to the adult population not much affected by toy legislation, but exposure to such substances at a young age can lead to such health problems. But certainly seeing the amount of time children spend with their toys and especially in young age how closely they interact with them may suggest that the fraction is not trivial. First of all, the specific limit values in the current TSD are based on the fact that toys should only contribute to 10% of tolerable daily intakes of harmful chemicals, and 5% for particularly toxic metals[406]. Furthermore, the limit values were also based on the assumption that a child would ingest per day 100 mg of dry, brittle, powder-like or pliable toy material, 400 mg of liquid or sticky toy material, and 8 mg of scraped-off toy material. These assumptions are based on a number of studies on children mouthing behaviour and have been validated by SCHEER[407].

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405 https://www.researchgate.net/profile/Valentina-Christova-Bagdassarian/publication/282972605_Phthalate_Plasticizers_and_Safety_of_Toys_-_Problems_and_Perspectives/links/56247c5c08ae93a5c92cbb0a/Phthalate-Plasticizers-and-Safety-of-Toys-Problems-and-Perspectives.pdf and https://drive.google.com/file/d/1FubTn67W1Y-mjpydS6OeFpaS68hjxQBv/view

406 Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on "Assessment of the bioavailability of certain elements in toys", June 2004, Opinion onbioavailability of certain elements in toys, CSTEE plenary, written procedure (europa.eu)

407 SCHER (Scientific Committee on Health and Environmental Risks), Final Opinion on estimates of the amount of toy materials ingested by children, 8 April 2016 Estimates of the amount of toy materials ingested by children (europa.eu)

Based on the overall figures above, if only 1-5% of the overall exposure to endocrine disruptors will be caused by toys that would mean that the damage caused by exposure to endocrine disruptors could be valuated at between **EUR 240 million and EUR 1.23 billion per year,** in terms of avoided health damage**.** This is certainly an estimate on the low side due to the lack of evidence on the attributable portion of toy exposure. It is also worth noting that this is only the estimate for the impacts of endocrine disruptors and the GRA will include other hazard classes too.

Table 30: Estimated values of current human health damages caused by endocrine disruptors

Hazard classes/ properties	Health outcome	Type of metric	2022 Value*	Prevalence / incidence	Population	Casses per year	Attributable cases of EDs per year (PAF: 1%)
Endocrine disruptors and reprotoxicants	Very low birth weight	Willingness to pay to avoid a case	€140,000 - €450,000	1% (incidence)	4,000,000 (EU 27 - live births in each and every year)	40,000	400
Endocrine disruptors and neurotoxicants	Intellectual disabilities	Average lifetime costs per case of intellectual disability	€ 1,700,000	1% (incidence)	4,000,000 (EU 27 - live births in each and every year)	40,000	400
Endocrine disruptors	Childhood obesity	Total lifetime excess cost per obese child	€ 160,000	12% (incidence)	4,000,000 (EU27 – number of 8 years old in each and every year)	480,000	4,800
Endocrine disruptors and reprotoxicants	Male infertility	Value of a statistical pregnancy among the general population	€25,000 - €45,000	7.50% (50% of prevalence of couple infertility)	2,000,000 (EU 27 - live male births in each and every year)	150,000 Men born with reduced semen quality resulting in infertility Fertility ratio: 1.50461 Number of children that will not be born naturally due to reduced semen quality: 230,000	2,300
Endocrine disruptors and reprotoxicants	Cryptorchidism	Direct, indirect and intangible costs per case	€ 40,000	1%	2,000,000 (EU 27 - live male births in each and every year)	20,000	200
Endocrine disruptors and reprotoxicants	Hypospadias	Direct, indirect and intangible costs per case	€ 45,000	0.2% (19.9 over 10,000 births regardless of sex)	4,000,000 (EU27 - live births in each and every year)	10,000	100
Endocrine disruptors and reprotoxicants	Testicular cancer	Direct, indirect and intangible costs per	€90,000	0.01% (incidence)	130,000,000 (EU27 – male adult population (20-69y))	10,000	100

Hazard classes/ properties	Health outcome	Type of metric	2022 Value*	Prevalence / incidence	Population	Casses per year	Attributable cases of EDs per year (PAF: 1%)
		case					
Endocrine disruptors and neurotoxicants	Autism Spectrum Disorder	Lifetime excess costs - Direct health care costs and indirect societal costs	€490,000	1% (incidence)	4,000,000 (EU 27 - live births in each and every year)	40,000	400
Endocrine disruptors and neurotoxicants	ADHD in children and adolescents	Average total ADHD-related costs per child / adolescent	€ 120,000	4.8% (prevalence)	66,000,000 children and adolescents (3-18 years old) in 2050 in EU27	3,170,000	32,000
Endocrine disruptors and neurotoxicants	ADHD in adults	Lifetime excess costs per case	€ 270,000	0.15% (prevalence)	240,000,000 work-age adults (19-65 years old) in 2050 in EU27	360,000	3,600
Endocrine disruptors	Diabetes	Lifetime direct and indirect healthcare costs per case	€ 55,000	10.4%	310,000,000 (EU27 adult population (20-79y) in 2050)	32,000,000	320,000
*Rounded to the nearest five thousand							

The increased speed of the regulation is the key benefit of this option too. By reaching the protection targets quicker than under the baseline or PO1a human health impacts could be achieved quicker too.

It is worth noting though that this increase in safety could only be realised for the compliant toys on the market. Without proper enforcement the higher risks of illicit toys would stay the same or even increase due to higher compliance costs of the compliant producers.

The human health impacts of the removal of the CLP-based derogation are hard to predict but would be potentially significant.

Another important condition is the link to the currently discussed implementation of the GRA in REACH. If the same hazard classes and substances are banned under REACH it will be much easier for the Toy industry to be compliant as chemical manufactures will need to adapt their practices.

PO1c

Most of the benefits for human health described above under PO1b are also relevant also for PO1c. The key difference is the number of derogations that can be expected. Under this option both the existing derogations for CRM substances and also potential future derogations on other hazard categories would be not implemented or abandoned.

Regarding the existing derogations, the evaluation of the TSD concluded that they do not pose an additional human health risk, beyond the CLP-based derogation.

Companies were very sceptical about the positive health impacts of removing derogations. Their argument was that if derogations follow the procedure and the risk can be clearly avoided following the conditions of the derogations, no extra human health risks are avoided by scraping the derogation. In their opinion, the existing derogations are not abused and do not result in additional risks.

Apart from the CLP-based derogation authorities did not point out either to another derogation that would cause additional risk to the health of children.

Consumer organisations considered that option 1c will give better tools to responsible authorities to protect children. It should ensure the higher possibility of safe toys present in the single market of the EU and if it will also implement new provisions which strengthen the requirements to ensure that only safe toys enter the market, this should significantly increase the protection of the children health.

Many commentators from all sides argued that the derogation criteria are an important factor in the choice between option 1b and 1c. If the derogation criteria can avoid all residual risks, no derogations would be a regulation overreach but if not the human health impacts of 1c compared to 1b might be significant. Yet, derogations for the most harmful substances under PO1b could be based on minimal effects as a means to determine the safe use and in that respect PO1c could be more protective of human health, as in that there could be no exposure to those substances.

Many commentators also formulated the concern that criteria that are too strict could inadvertently foster the illicit toys market and increase human health risks in this way.

C) Policy options to reduce the number of non-compliant toys

PO2a

Non-compliant toys are on average less safe for children. The available evidence and stakeholder comments showed that this PO is expected to lead only to a very limited improvement in the number of illicit toys is to be expected from the market and with that the risks of illicit toys would only decrease slightly. Both authorities and companies agree overall that even third party conformity assessments would be too easy to forge. Rogue traders could place their products on the EU market without complying with the third-party conformity assessment, as they do today for other requirements.

On the other hand the available evidence showed that the health risks of illicit toys are very substantial and any positive impacts on the market share of those toys could would have an important impact on human health.

PO2b

As this PO is expected to reduce significantly the number of non-compliant toys on the Union market, it would have significant impacts on the health risks of those. The introduction of a DPP would make it easier and less resource intensive for customs authorities and other market surveillance authorities to identify non-compliant products. Digital product passports would help in reducing the number of illicit toys in the EU as currently authorities needs to reach out to the seller, importer and manufacturer to collect all the necessary information, which can be a lengthy process. Withdrawing non-compliant toys from the market will be quicker with the digital product passport.

Finally, as the DPP will be required for toys coming from third countries to be placed on the Union market, it will prevent a significant number of non-compliant toys from reaching the Union market.

PO2c

Overall it is very likely that option 2c will be more effective than 2b and 2a in safeguarding and improving human health. The two options combined in option 2c could reinforce each other with more certainty on the assessments coming from third party conformity assessments and the information more easily available with the DPP a real improvement in surveillance and controls at customs could be achieved. However, seeing that the main impact will be expected from option 2b though it can be discussed whether the added impact of option 2c is (compared to 2b) more than marginal.

5. ENVIRONMENTAL IMPACTS

While the TSD concerns the safety of children and not environmental protection or sustainability aspects, certain indirect environmental impacts could be expected from the different policy options. Several environmental concerns linked to TSD can clearly be identified, such as the presence of hazardous substances (e.g., ED, CMR) in the toys that may be harmful not only for human health but also for the environment, the recycling process of these toys and the submission in paper of information on toys by the manufacturers.

A) Baseline

Under the baseline scenario, specific environmental concerns regarding chemical substances will be addressed by REACH. Sustainability requirements for toys may be set, as appropriate, under the ESPR even though this is not foreseen in the medium term.

Most information on the toy will continue to be provided on paper, such as the technical documentation or the Declaration of Conformity, upon request of the market surveillance authorities.

B) Policy options to strengthen the protection of children from harmful chemicals - PO1a

Policy option 1a could have a positive effect on the environment, notably because it could lead to less dangerous substances from toy materials and from recycled materials. This means that fewer harmful chemicals would reach the environment through end-of-life toys.

If depending on transition period requirements, already ordered and produced toys may need to be sent for destruction, and this could thus have a negative impact on waste.

As concerns the combination of chemicals under this option, it should be consistently approached across EU legislation on chemicals.

PO1b

The majority of stakeholders who expressed their opinion on the impacts of policy option 1b on the environment highlighted that the main environmental concern linked to toys is the presence of endocrine disruptors (EDs), PBT, vPvBs and CMR substances in the toys. These substances are indeed present in toys, but not mentioned in the TSD (apart from CMR substance) and they are not all regulated yet at the level of horizontal chemical legislation. Many of the chemical substances that would be covered by a generic ban in PO1b may not only be harmful for human health but also

for the environment. This PO will thus have greater benefits for the environment by addressing those.

If less chemicals are included in the toys produced, it could have a positive impact on the environment as less dangerous substances from toy materials and from recycled materials would reach the environment. As this option is expected to have more substances banned from the outset, it would have higher benefits on the environment than PO1b.

PO1c

Many of the impacts described above are relevant also for option 1c. The key difference is the number of derogations that can be expected. Under this option both the existing derogations for CMR substances and also potential future derogations on other hazard categories would be not implemented or abandoned. Less derogations could mean that less harmful substances would be present in the waste stream, which would thus have a positive impact on the environment, greater than for PO1b.

C) Policy options to reduce the number of non-compliant toys

PO2a

An increased number of third-party conformity assessment would allow to reduce the number of non-compliant toys. Non-compliant toys are likely to be more harmful to the environment, therefore, a reduction of the number of such toys would mean less pollution. Such a reduction would also favour recycling as safer materials could be used to produce recycled toys.

Additionally, toys found to be non-compliant would not be shipped to the EU (and in some cases not even produced) and this would have a positive impact on the environment as these non-compliant toys would not have to be destroyed. This would mean that less waste is created, and the environmental costs are also decreased due to the products not being transported.

PO2b

Illicit toys are more harmful to the environment, therefore, a reduction of the number of such toys would mean less pollution. It would also favour recycling for the production of toys as less harmful substances would be present in recycled materials.

A post-marketing facilitation of controls on toys through the introduction of the digital product passport could help reduce the number of non-compliant toys, and thus have a positive impact on the environment. It could also help reducing the packaging of toys, which is an important part of the waste creation linked to toys. Also, toys without proper documentation would not be shipped to the EU, so it would not have to be destroyed in the EU either.

Additionally, the digital passport for toys could help reduce the number of papers used by economic operators and national authorities. It could even incentivise toy manufacturers to use higher quality materials that do not have a negative impact on the environment.

In particular, policy option 2b would have overall a positive impact on the environment.

Less non-compliant toys: The introduction of a digital product passport for toys would facilitate the control of illicit toys as the EU declaration of conformity and information related to the toys could be consulted by the market surveillance authorities quicker and at the entry into the EU market. This would help to reduce the number of illicit toys on the EU market. As non-compliant toys have negative impacts on the environment due to the harmful substances contained in them, a reduced number of such toys would be beneficial for the environment.

Less waste: The introduction of a digital passport for toys would benefit the environment because digitalisation would reduce the packaging of toys, which is an important part of the waste creation linked to toys. Also, as toys without proper documentation would not be shipped to the EU, it would not have to be destroyed in the EU either. Thus, this would decrease overall the amount of waste produced in the EU and the amount of energy needed for the destruction of the products.

Paper savings: the digital passport for toys could help reduce the number of papers used by economic operators and national authorities. Indeed, if part of the information that accompanies the toys in a physical form now can be added to the digital product passport, it could reduce the amount of packaging and of paper accompanying the products.

Higher quality materials: A national authority added that the introduction of a digital passport for toys would incentivise toy manufacturers to use higher quality materials that do not have a negative impact on the environment.

PO2c

On the one hand, the digital product passport would facilitate the control of toys by allowing a quicker verification of market surveillance authorities and check before entering the EU market. On the other hand, more conformity assessments would make it more likely that toys are overall compliant and do not include harmful substances.

Both measures combined would thus allow to have fewer non-compliant toys in the EU market, and thus less negative impact on the environment. This would also incentivise recycling as the toys could use safer recycled materials.

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