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EVALUATION

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

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Glossary

Term or acronym	Meaning or definition
AdCo	Administrative Cooperation
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
DG	Directorate General
DG ENV	DG Environment
DG GROW	DG Internal Market, Industry, Entrepreneurship and SMEs
DG JUST	DG Justice and Consumers
DG SANCO	Former Directorate General for Health and Consumers
DG SANTE	Directorate General for Health and Food Safety
DG TAXUD	DG Taxation and Customs Union
DoC	Declaration of Conformity
EC	European Commission
EN	European Standard
ESO(s)	European Standardisation Organisation(s)
ETSI	European Telecommunications Standards Institute
EU	European Union
GPSD	General Product Safety Directive

IA	Impact Assessment
IoT	Internet of Things
JRC	Joint Research Centre
IDB	European Injuries Database
MS	Member State(s)
MSA	Market Surveillance Authority(ies)
NB	Notified Body(ies)
OJEU	Official Journal of the EU
PROSAFE	Product Safety Forum of Europe
R&TTE	Radio and Telecommunications Terminal Equipment
RAPEX	EU Rapid Exchange System for dangerous non-food products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
RPS	Regulatory Procedure with Scrutiny
SCCS	Scientific Committee on Consumer Safety
SCHER	Scientific Committee on Health and Environmental Risks
SG	Secretariat-General
SME(s)	Small- and Medium-sized Enterprise(s)
TIE	Toy Industries of Europe
UK	United Kingdom
US(A)	United States (of America)
WTO TBT	World Trade Organization – Technical Barriers to Trade

1. INTRODUCTION

Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys,[1] commonly known as the Toy Safety Directive, lays down the safety and other requirements that toys must meet before they can be marketed in the EU.

Directive 2009/48/EC replaced the former Directive 88/378/EEC in order to adapt the requirements for toys to technical and scientific developments and previously unknown safety issues. The application and enforcement are aligned with the so-called 'New Legislative Framework', adopted in July 2008 and laying down a horizontal framework of common principles and reference provisions intended to apply across sectorial legislation (such as the Toy Safety Directive). It defined all the necessary elements for an effective conformity assessment, accreditation and market surveillance, including the control of products imported into the European Union.[2]

The new Directive had to be transposed by the EU Member States into their national legislation by 20 January 2011[3] and was to be applied as of 20 July 2011, except for the chemical safety requirements which were to be applied as of 20 July 2013.[4]

Member States have to report every five years on the application of the Toy Safety Directive in their national territories. The first reporting exercise covered 2009 – 2013, the second 2014 – 2018.

1.1. Purpose of this evaluation

The overarching purpose of this evaluation is to assess the performance of the Toy Safety Directive since its entry into force in relation to its two objectives of (1) ensuring a high level of safety of toys with a view to ensuring the health and safety of children, and of (2) guaranteeing the functioning of the internal market for toys.

Following the 2014 Member States' reports on the application of the Directive during 2009 – 2013[5] and an external study by a consultant in 2014 and 2015 (2015 external

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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, p. 1) https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1403078123201&uri=CELEX:02009L0048-20181126

2 The New Legislative Framework relies on:
a) 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;
b) 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. https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

3 Article 54 of the Toy Safety Directive

4 Article 53 of the Toy Safety Directive

5 See the Commission Summary of Member States' Reports on the Application of the Toy Safety Directive 2009/48/EC at http://ec.europa.eu/growth/sectors/toys/safety/legislation_en

study)[6] analysing the performance of the Directive with regard to its effectiveness, efficiency, relevance, coherence with other legislation (whether EU or Member States' national legislation) and EU added value, the Commission considered it necessary, about five years after the full applicability of the Directive in the Member States, to conduct an own evaluation of the performance of the Directive, in order to consolidate the information collected so far and to complement it with its own observations.

This evaluation assesses the extent to which the Toy Safety Directive is fit for purpose, hence continues to deliver effectively and efficiently the intended benefits for consumers and business. It also assesses whether the Directive is relevant to stakeholder needs, coherent with other EU legislation (EU or Member States' national legislation) and whether it has an EU added value.

The evaluation provides conclusions on current drawbacks of the Toy Safety Directive that prevent it from fully achieving its objectives and generating the desired results.

1.2. Scope of the evaluation

The period evaluated starts from the entry into force of the Toy Safety Directive in 2009, bearing in mind that its provisions only started applying on 20 July 2011 (chemicals-related provisions: 20 July 2013), and covers all the Member States of the EU; and the world as a whole, since obligations for toy manufacturers apply to both EU and non-EU manufacturers whose toys are placed on the EU market. This evaluation covers the 27 EU Member States and the United Kingdom as during the period covered by the evaluation (2009 – 2018) the United Kingdom was still a Member of the European Union7. It should therefore be noted that when the document refers to EU Member States in the presentation of results these include also the United Kingdom. It focuses on the period from 2009 to 2018, seeking to understand trends over this period wherever possible.

2. BACKGROUND TO THE INTERVENTION

2.1. Description of the intervention and its objectives

2.1.1. Market evolution

The EU has the largest single market for goods and services worldwide. Toys valued at about € 18 billion were sold in the EU in 2016. Imports into the EU represented half of the sales (€ 9.1 billion). Most toy production takes place in China. Online sales are increasing and reach over 1 in every 4 toys in some countries[8].

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[6] 2015 Evaluation of directive 2009/48/EC on the safety of toys. http://ec.europa.eu/growth/sectors/toys/safety/legislation_en

[7] The United Kingdom withdrew from the European Union and became a third country as of 1 February 2020.

[8] 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

Almost 60,000 people are working in the EU toy sector and over 130,000 workers have an indirect role to play.[9] The EU toy industry is an international player: in 2016, toys worth € 1.91 billion were exported from the EU to third countries. Moreover, it is a dynamic and innovative industry: around one third of the toys on the market each year have been newly developed.[10]

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. About 99% of the EU's 5,900 toy companies are SMEs, most of which have less than 10 members of staff and account for 90% of the total number of manufacturers. Almost half of the EU toy manufacturers are located in four countries: Germany, France, Poland and the UK. It is a dynamic market with 900 new companies which joined the sector since 2013. The turnover of the industry in 2016 accounted for € 7.75 billion and steadily grew since 2009 by 16%.[11]

According to Toy Industries of Europe (TIE), the trade association for the European toy industry providing, amongst others, relevant information both for and on the EU toy industry, there were 18,680 specialised retailers in toys in 2016 compared to 19,083 in 2011.[12] According to the Retail-Index data, the biggest retailer in Europe was Amazon with € 45 million of turnover.[13]

The export from EU countries of toys covered by the Toy Safety Directive amounted to € 10.4 billion in 2018. This corresponds to 0.2% of the total EU exports. 86% of the export goes to other EU countries (intra EU trade), and the remaining 14% is sold outside the EU. Intra-EU export of toys covered by the Toy Safety Directive almost doubled since 2007 (real growth rate of 89%), while export of other toys grew by 12%, and the overall intra EU export of all goods grew by 9%.[14]

The traditional toys and games market shows moderate growth rates in Europe and the US and strong growth rates in China and especially in the rest of the world. Growth levels for traditional toys and games sales are higher than for the economy as a whole, offering a positive outlook for the toy sector with opportunities for expansion, especially for European toy producers, who are the second most important toy exporters after China.[15]

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9 The European Toy Industry (TIE), Facts and Figures. https://www.toyindustries.eu/resource/facts-figures-brochure/

10 The European Toy Industry (TIE), Facts and Figures. See footnote above.

11 Annual detailed enterprise statistics for trade (NACE Rev. 2 G) [sbs_na_dt_r2], Retail sale of games and toys in specialised stores.

12 The European Toy Industry (TIE), Facts and Figures. See footnote above.

13 Retail-Index. To note that the 5th retailer on the list, Toys R Us, declared bankruptcy in 2018. https://www.retail-index.com/Sectors/ToysGamesRetailersinEurope.aspx

14 Source: Eurostat, EU trade since 1988 by CN8 [DS-016890]

15 ECSIP Consortium (2013). Study on the competitiveness of the toy industry – Final Report, p. 19. https://ec.europa.eu/DocsRoom/documents/6653/attachments/1/translations/en/renditions/native

Figures from the association of the European toy industry suggest that 500 new companies have entered the sector between 2013 and 2017. This gave a total of 5,600 toy companies in the EU, of which 99% are SMEs.[16] It may appear therefore that the toy sector was attractive enough, in particular for SMEs, so that the number of toy companies increased by some 10% within five years This is also confirmed by the Eurostat data according to which in 2011 in EU there were around 5,000 companies "Manufacturers of games and toys". This number increased to around 6,000 in 2017[17]. There were only 33 large companies (0.6%) in the EU, the rest were SMEs (90.7% micro companies, 7.4% small and 1.3% medium-sized). The majority of companies were located in France, Poland, UK and Germany. The highest number of large companies was located in Germany.

Consumers are fairly price sensitive. In combination with a low concentration in the market, this means that producers face cost and price competition to a significant extent. This competition on costs is reflected in the production strategy of producers, with many producers offshoring and outsourcing production to China to reduce production costs. In toy production, margins in the entire sector are under pressure with long-term profit margins around 6% for the top 100 firms in terms of size. The margins are lower for small and medium sized (SME) firms than for large firms. Also, the profit margin for retail is lower than for the manufacture of toys.

The short product life cycle of toys drives the need for innovation and research and development (R&D). Innovation is widely acknowledged in the sector as essential to maintaining a competitive position. In addition, it allows manufacturers to experience (temporarily) reduced price competition for the innovative toys. Nonetheless, R&D expenditures in the sector may seem modest, with actual R&D expenditure amounting to 0.6% to 2.6% of total turnover. This range, however, is in line with the R&D intensity of the entire manufacturing industry in the EU. Also marketing strategies are very important to the toy sector. The key is market research and introduction of novelties.

2.1.2. The EU legislative context

The twofold objective of the Toy Safety Directive is (1) to maintain a high level of safety for children and protection against possible health threats from toys, while (2) allowing the free circulation of toys in the internal market.

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'.[18] 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

[16] Toy Industries of Europe. The European toy industry. Flyer designed in July 2017. https://www.toyindustries.eu/wp-content/uploads/2018/01/TIE-EU-Toy-Sector-Facts-and-Figures-FINAL.pdf

[17] Eurostat Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2], Last update: 21-03-2019

[18] Article 2.1 of the Toy Safety Directive.

small plush teddy bear attached to it is considered as a toy, or a toy plastic figurine with a pencil sharpener in its foot.[19]

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.[20]

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.[21] 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.

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 (REACH),[22] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances

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19 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/

20 Paragraph 5 of section 2 of Guidance document No 4.

21 Article 2.2 of the Toy Safety Directive.

22 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

and mixtures,[23] and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).[24]

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.[25] 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.

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).[26] 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 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 – 2019, the Directive was amended 14 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 annex 4.

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[23] 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

[24] 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

[25] DG ENTR (2014). 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

[26] Article 46 of the Toy Safety Directive.

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 (see annex 6).

European standards are developed by recognised European Standardisation Organisations (ESOs): CEN,[27] CENELEC,[28] and ETSI.[29] If developed following a request from the European Commission, the resulting standards are called European 'harmonised' standards.

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[30] is in Annex 7.

Conformity assessment

Conformity assessment is the verification whether a product complies with the applicable essential requirements. It 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.

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

[27] European Committee for Standardization. https://www.cen.eu/Pages/default.aspx

[28] European Committee for Electro-technical Standardization. https://www.cenelec.eu/

[29] European Telecommunications Standards Institute. https://www.etsi.org/

[30] Commission Implementing Decision (EU) 2019/1728 of 15 October 2019 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council, in OJ L 263, 16.10.2019, p. 32. https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=uriserv:OJ.L_.2019.263.01.0032.01.FRA&toc=OJ:L:2019:263:TOC

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,[31] 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.[32] 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 appears questionable since the study 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.

In this connection, it is important to consider that US attorneys can demand enormous sums on grounds of liability. This can put companies out of business if they cannot satisfy such demand. In contrast to this, the EU legal system is much less liability-prone. Therefore, any comparison between the EU and the US has to be considered with utmost care.

Restrictive measures against dangerous toys: EU Safety gate RAPEX

A EU wide Rapid Information Exchange System for dangerous products (RAPEX)[33] was established in 2001 under Directive 2001/95/EC on general product safety (GPSD).[34] Today the system is called Safety gate RAPEX.[35] It aims to ensure the exchange of information between Member States and the European Commission on measures that have been taken to prevent or restrict the marketing or use of products posing a (serious) risk to the health and safety of consumers or to other public interests. This not only applies to consumer products covered by the GPSD, but also to any product under sectorial legislation, such as toys. Data on those measures can therefore be used as a source of information on market surveillance activities on toys that present a (serious) risk and whose marketing has been restricted.

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31 A restriction may change or invalidate certain specification(s) in the standard referenced.

32 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

33 With the exception of food, pharmaceutical and medical devices, which are covered by other mechanisms.

34 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 January 2002, p. 4. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN

35 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

2.1.3. The intervention logic

The twofold objective of Directive 2009/48/EC is (1) to maintain a high level of safety for children and protection against possible health threats from toys, (2) while allowing toys' free movement in the internal market.

In order to ensure EU citizens' (and particularly children's) safety, the Toy Safety Directive lays down safety requirements and regulates the conditions for the manufacture and the trade of toys within – and across – Member States.

How does the Directive require manufacturers to ensure the safety of toys?

The Toy Safety Directive imposes considerable obligations on manufacturers in order that they ensure the safety of their toys and document that safety unambiguously.[36]

When developing a toy, the manufacturer, whether in the EU or elsewhere, has first to assess whether it will be safe. To this end he analyses the harm that the toy may cause when a child is playing with the toy. He analyses which mechanical, physical, flammability, chemical, electrical, hygiene or radioactivity hazards the toy may present, and subsequently how a child may be exposed to the hazards of the toy under the conditions of play. He not only considers the intended way to play with the toy, but also the reasonably foreseeable ways of how children may be (mis-) using the toy.

The manufacturer then has to document the toy's hazards and the exposure to them in the 'safety assessment' of the toy. The safety assessment should show why the toy can be considered to be safe, despite the hazards that it presents.

To substantiate his safety assessment, the manufacturer has to demonstrate that his toy conforms to the safety requirements that the Toy Safety Directive imposes on a toy with the identified hazards. He has the choice between two 'conformity assessments' (see above):

1. Self-verification. The manufacturer is allowed to verify the toy's conformity himself if all the requirements of the Directive, which apply to the toy, are represented in the relevant harmonised European toy safety standards the references of which have been published in the Official Journal (see above).

2. Third party verification. The manufacturer asks a 'Notified Body' to examine his toy. The Directive requires such third party's verification in particular when the toy presents one or more hazards that are not covered by harmonised toy safety standards referenced in the Official Journal.

   A notified body is a test laboratory of recognised quality, which has been accredited by a Member State (where the test laboratory is located) for carrying out a conformity assessment (the 'EC-type examination').[37]

   The Notified Body examines the toy and, if the toy passes all the tests successfully, issues an 'EC-type examination certificate' for the toy that the manufacturer had

[36] Steps for manufacturers. https://ec.europa.eu/growth/sectors/toys/placing-on-eu-market_en

[37] See Chapter V of the Toy Safety Directive: 'Notification of conformity assessment bodies'.

submitted for examination. The toy submitted is thus the 'type' for future routine production.[38]

The manufacturer then draws up the 'EC Declaration of Conformity' for his toy.[39] With this he declares that the toy conforms with all relevant requirements of the Toy Safety Directive. The Declaration has to be signed by the manufacturer, he thus takes over the responsibility for the conformity of the toy.

The manufacturer also draws up the 'Technical documentation' for the toy. Among others, the Technical documentation describes the toy and its manufacturing process, it includes the safety assessment and a copy of the EC Declaration of conformity, and it describes the conformity assessment used. In the case of third-party conformity assessment, the EC-type examination certificate is equally to be included in the Technical documentation.[40]

During routine production, the manufacturer has to ensure that each toy item produced is identical to the toy type that he submitted to the conformity assessment.

On any toy item produced, the manufacturer affixes the CE mark (either directly on the toy, on an affixed label or on the packaging)[41] and his address as well as an element allowing to trace back the toy (such as a serial number).

Finally, the manufacturer adds instructions and safety information to the toy, and the required warnings.

How does the Directive require importers and distributors to ensure the safety of toys?

Importers have fewer obligations than manufacturers.[42] An importer has to ensure that the manufacturer has fulfilled his obligations, such as carried out a conformity assessment demonstrating that the toy is safe. The importer further has to affix his own name and address on the toy.

Distributors have even fewer obligations.[43] A distributor has to verify that a toy bears the CE mark and a traceability number, that both the manufacturer and the importer have indicated their names and addresses (in the case of imported toys), and that instructions and safety information, including the required warnings, accompany a toy.

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38 See Article 20 of the Toy Safety Directive 'EC-type examination'.

39 See Article 15 and Annex III of the Toy Safety Directive.

40 See Annex IV of the Toy Safety Directive.

41 See article 16 and 17 of the Toy Safety Directive.

42 Steps for importers. https://ec.europa.eu/growth/sectors/toys/placing-on-eu-market_en

43 Steps for distributors. https://ec.europa.eu/growth/sectors/toys/placing-on-eu-market_en

How does the Directive ensure that its obligations are complied with by the economic operators?

The Directive provides for the obligation for Member States to perform market surveillance and test toys on the market as well as verifying the manufacturers' documentation, in order to take unsafe toys from the market and to prosecute those responsible for placing them on the market.[44] Traceability requirements and penalties support the enforcement.[45]

How is the Directive ensuring the free movement of toys?

The Directive requires Member States 'not [to] impede the making available on the market in their territory of toys which comply with this Directive.'[46] Thus, as long as a toy complies with the safety and other requirements of the Directive, no Member State is allowed to impose any other condition that would hinder the free circulation of the toy in the EU. The Toy Safety Directive is thus a 'maximum harmonisation' Directive. This eliminates all barriers for cross-border trade and guarantees the proper functioning of the internal market.

Overview on the intervention logic

Two strategic objectives were identified, namely the safety of toys and the smooth functioning of the internal market (see table below). They correspond to the areas of major concern that emerged from the 2008 Impact Assessment[47] (2008 IA) prepared to identify the possible impact of the then future Toy Safety Directive. While the two strategic objectives embrace long-term processes, the four specific objectives derived from them break them down into workable pieces.

In order to achieve the objectives, a number of provisions ('input'; for details see annex 5) were included in the Toy Safety Directive that address different issues that can emerge along the life cycle of a toy – from manufacture to marketing and use. The Directive's provisions are expected to lead to (short-term) output, (medium-term) outcome and (long-term) impact, thus eventually reaching the two strategic objectives as outlined in the table below.

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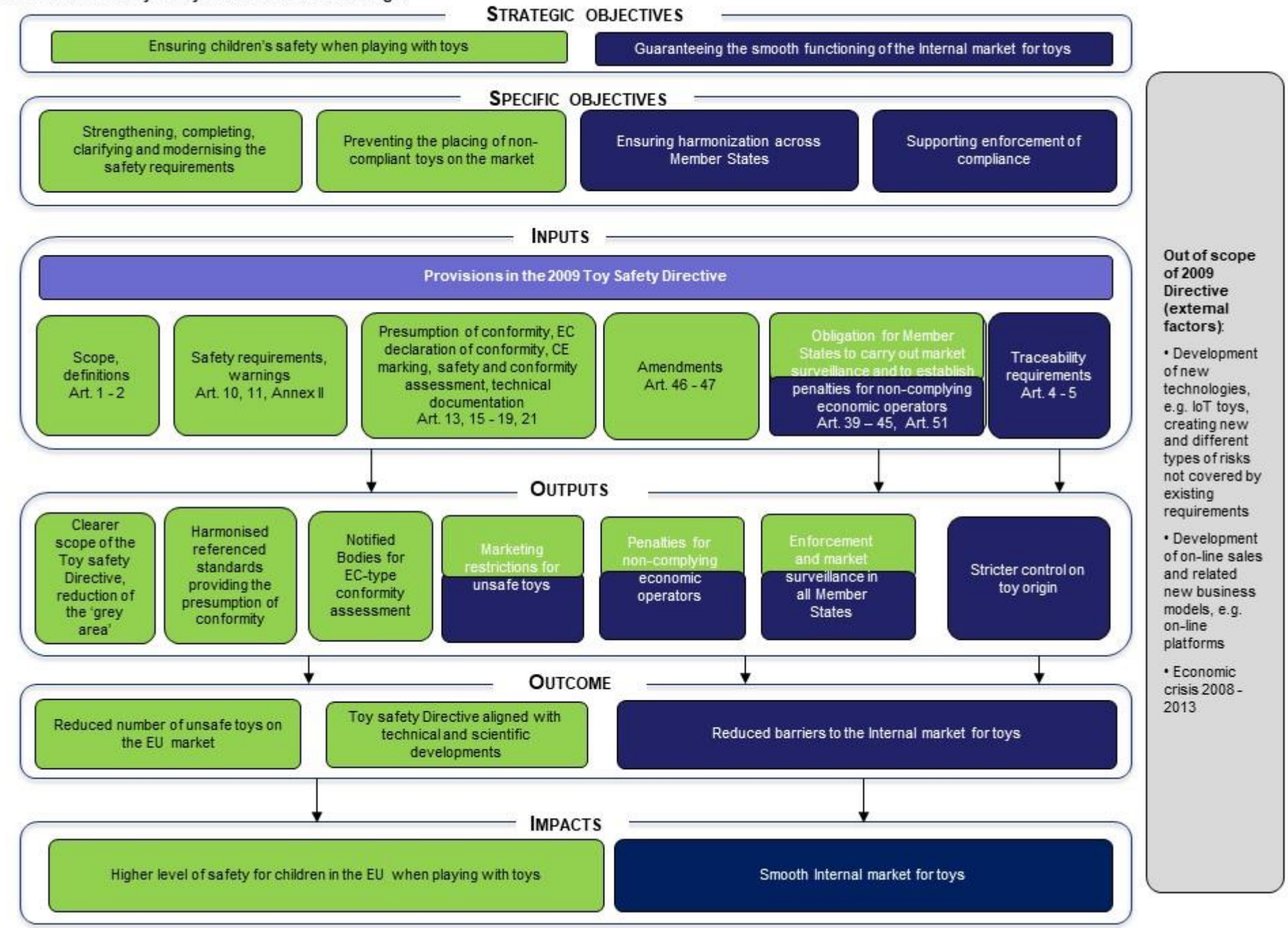
44 See Chapter VI of the Toy Safety Directive : 'Obligations and powers of Member States'.

45 See Article 51 of the Toy Safety Directive : 'Penalties'.

46 Article 12 of the Directive.

47 Commission staff working document accompanying the proposal for a Directive of the European Parliament and of the Council amending Directive 88/378/EEC on the safety of toys – Impact assessment. COM(2008) 9 final, SEC(2008) 38. 25.1.2008. Section 5.2.1 http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_0038_en.pdf

Evaluation of the Toy Safety Directive – intervention logic



Baseline and points of comparison

In the context of the internal market, the 1988 Toy Safety Directive[48] was adopted in order to harmonise the different safety levels across Member States. This was crucial as the lack of regulatory and enforcement consistency not only caused obstacles to the free movement of toys across Member States, but also hampered an effective protection of children against risks that may arise from toys.

The 1988 Directive was revised in 2009 based on a 2008 Impact Assessment (2008 IA)[49] that identified three main areas for improvement:

- Firstly, safety requirements were outdated and not fully responding to newly identified hazards, in particular those of chemicals. The limits for 8 'elements' (mainly heavy metals) were expressed in terms of bioavailability[50] in the 1988 Directive. The 2009 Toy Safety Directive added 11 further chemicals (mainly metals) and expressed the limits in terms of migration.[51]

  Warning requirements also needed to be refined. The provisions on warnings in the 1988 Directive presented gaps because they did not, in particular, provide that the warnings should always indicate appropriate user limitations such as those related to age, ability and weight of the user, as well as the need to ensure that the toy be used under adult supervision. These warnings, essential to the safe use of the toy, might have been lacking in some cases.

- Secondly, Member States highlighted the need for improving both the enforcement consistency and effectiveness of market surveillance and of the institutional framework concerning the implementation of the Directive and of toy-related information and traceability. For example, a specific problem linked to efficient market surveillance concerned the analysis of the hazards and risks that a toy may present. The 1988 Directive did not contain any explicit obligation for the manufacturers to carry out such an analysis. There was no requirement for them to document the hazard/risk analysis and to keep it available for inspection by the market surveillance authorities (in the technical file). Responsible manufacturers did already carry out a hazard/risk analysis. However, since the analysis was not mandatory, it was difficult for market surveillance authorities to check whether an analysis had been undertaken.

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48 Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ L 187, 16.7.1988, p. 1. https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31988L0378

49 Commission staff working document ... . See footnote above.

50 The 1988 Directive provided that the 'bioavailability of these substances means the soluble extract having toxicological significance.'.

51 'Migration limit' is the amount of an element that can be released from a toy material when (ingested and) present in the stomach (Matrix Insight (2012). Impact assessment study on the health costs due to children's exposure to lead via toys and on the benefits resulting from reducing such exposure. *Final Report*). https://ec.europa.eu/growth/sectors/toys/safety/legislation_en

– Finally, the scope and concepts of the 1988 Directive turned out to lack clarity. The 1988 Directive contained ambiguities, long and complicated sentences and internal and external cross-references. In addition, it needed a clarification on its relation with the General Product Safety Directive (GPSD).

Following the 2008 IA and the Commission proposal for a new Toy Safety Directive that it accompanied, the new Directive was adopted on 18 June 2009. Annex 8 provides an outline of the problems identified in the 2008 IA (on scope and concepts, on safety requirements and on enforcement) and where they have been addressed in the 2009 Toy Safety Directive.

In particular, the 2009 Toy Safety Directive puts in place stricter requirements for chemicals:

– Chemicals that are susceptible to cause cancer, change genetic information, harm fertility or harm an unborn child ('CMR substances' [52]) were no longer allowed in toys beyond the concentration limits set in the Regulation on Classification, Labelling and Packaging of substances and mixtures,[53] or unless they are inaccessible 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 the 'less concerning' CMRs category 2, no analysis of alternatives is necessary.)

– 19 'elements' such as mercury or cadmium were not allowed in toy parts accessible to children beyond the limits laid down in Toy Safety Directive.[54]

– Concerning the 19 'elements' 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.

– 55 allergenic fragrances were prohibited because the relevant Scientific Committee considered that they must not form part of cosmetic products due to their allergenicity in most cases (fragrances 1 to 31 and 36 to 40);[55] or they were (photo-) allergenic (fragrances 32 to 35);[56] or because they were most frequently reported as

52 Substances that are carcinogenic, mutagenic or toxic for reproduction.

53 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.

54 Annex II, part III, point 13 of the Toy Safety Directive.

55 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

56 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

contact allergens (fragrances 41 to 53);[57] or because they contain allergenic species (fragrances 54 to 55).[58] 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 11 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.[59]

- 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.

The law-making process that resulted in the 2009 Toy Safety Directive reinforced several chemical safety requirements in the proposal for the new Directive, and added further requirements:

- CMR substances are only allowed in toys beyond the concentration limits of the Regulation on Classification, Labelling and Packaging of substances and mixtures if they are entirely inaccessible to children, including by inhalation. The proposal had only referred to the inaccessibility of parts of toys containing CMR substances, which however does not take account of the inhalation of such chemicals;
- The limit values for the 'elements' 'arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, … should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.'[60] The proposal had not foreseen an extra role for the six afore-mentioned 'elements'.
- 15 allergenic fragrances proposed for labelling were moved to prohibition to give the total of 55. 13 [61] of the 15 had been 'most frequently reported as contact allergens' by the Scientific Committee, 2 [62] of the 15 were very strong allergens.

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57 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

58 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

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

59 Scientific Committee ... . SCCNFP/0017/98 final, 8.12.1999, Table 6b, p. 23. See footnote above.

60 Recital 22 and Article 46(1b) of the Toy Safety Directive, and Directive (EU) 2017/738 amending the Toy Safety Directive as regards lead.

61 Listed as numbers 41 to 53 in the Toy Safety Directive.

- Specific limit values for any chemical in toys can be set. These limit values 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. The proposal had not foreseen the establishment of such specific limit values;[63]
- Limit values for nitrosamines (0,05 mg/kg) and for nitrosatable substances (1 mg/kg) were added to the proposal.

There are no specific or quantified estimates published of the potential impact (i.e., the expected costs and benefits) of the 1988 Directive. The 2008 IA which accompanied the revision of the Toy Safety Directive provided quantification of costs and benefits related to planned chemical provisions and three illustrative case studies with large ranges of costs and a number of assumptions for multinational, SME and medium size manufacturers. The 2008 IA however did not foresee any monitoring and evaluation arrangements and did not provide a clear description of the baseline. Therefore, the baseline for this evaluation is the 2009 Directive and a comparison of data before and after the adoption of the 2009 directive was not possible. Therefore, it is difficult to identify clear points of comparison for the purpose of this evaluation, especially as concerns the main changes (outdated safety requirements or scope and concept clarification).

In the present evaluation the estimates of costs and benefits have been contrasted with the estimates from the 2008 IA where possible (see section 5.2). The reproduction of assessment of costs and benefits of chemical provisions for the purpose of this evaluation was considered disproportionate.[64] In the data gathering, it was decided not to artificially separate costs of chemical requirements and other provisions and instead to concentrate on one-off adaptation costs and recurring costs related to the Toy Safety Directive. The additional difficulty in relation to points of comparison relies in different dates of entry into force of different provisions (mid-2013 for chemical provisions and mid-2011 for the remaining provisions) and a number of amendments to the Toy Safety Directive adapting the chemical requirements between 2012 and 2019.

In the meantime, other EU initiatives have been adopted that may affect the functioning of the Toy Safety Directive, such as the EU Regulation on Market Surveillance and Compliance of Products,[65] which aims to improve market surveillance by strengthening controls by national authorities to ensure that products (including toys) are safe and comply with the rules. This new Regulation takes into account the increasingly complex supply chains, as well as the increase of products that are offered online to end users within the EU.

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62 Listed as numbers 51 and 55 in the Toy Safety Directive.

63 Recital 24 and Article 46(2) of the Toy Safety Directive.

64 The 2008 IA provided Life Cycle modelling of costs and benefits of chemical provisions based on DALY (Disability Adjusted Life Years). These analyses were outsourced. Moreover, given the number of amendments of the Directive, the cost estimates would not be comparable with those from 2008 IA.

65 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, OJ L 169, 25.6.2019, p. 1, see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020.

Practical experience of market surveillance has shown that such supply chains sometimes involve economic operators whose novel functions and activities do not allow to fit them easily into the traditional supply chain operators in the existing legal framework. Such is the case, in particular, with online sales platforms that qualify as 'fulfilment service providers', which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in EU law (and in the Toy Safety Directive). In order to ensure that market surveillance authorities can carry out their responsibilities effectively and to avoid a gap in the enforcement system, these fulfilment service providers have been included in the recent Regulation on Market Surveillance and Compliance of Products. They are part of the list of economic operators against whom it is possible for market surveillance authorities to take enforcement measures. Market surveillance authorities will be better able to deal with new forms of economic activity in order to ensure the safety of consumers and the smooth functioning of the internal market, including those cases where the economic operator acts both as an importer as regards certain products and as a fulfilment service provider as regards other products.

3. 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.[66] 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 detailed justifications including scientific studies on the health assessment of the concerned substances. The Commission acknowledged in a 2012 Decision[67] that the limit values for nitrosamines[68] 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.

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66 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

67 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

68 'Nitrosamines' is here understood to mean 'nitrosamines and nitrosatable substances'.

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.[69]

- The Expert Group on Toys Safety[70] 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 is 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)[71] 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 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.[72] 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

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69 See Articles 46 and 47 of the Toy Safety Directive.

70 Register of Commission Expert Groups and other similar entities. http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1360

71 The Toys-AdCo is the closed session of the Expert Group on Toys Safety (E01360) and comprises only market surveillance authorities.

72 Recommendations and Protocols under the Toy Safety Directive are available at https://ec.europa.eu/growth/sectors/toys/safety/guidance_en

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.[73] Harmonised standards translate the essential safety requirements of the Toy Safety Directive into detailed technical specifications for a large range of toys.

4. METHOD

This evaluation of the Toy Safety Directive 2009/48/EC began in 2014 with the work of an external consultant and continued until March 2020 with an internal evaluation by the Commission services.

It used two main sources of input: 1. studies, reports and databases, 2. stakeholder consultations. Output was aimed to be qualitative and, where possible, quantitative.

The evaluation was monitored by a steering group composed of representatives of several European Commission services, namely of the Secretariat-General and of Directorates-General Internal Market, Industry, Entrepreneurship and SMEs (GROW), Justice and Consumers (JUST), Health and Food Safety (SANTE), Environment (ENV), Taxation and Customs Union (TAXUD).

Details on the procedure are given in annex 1.

4.1. Supporting studies and reports

The 2015 external study, prepared by an external consultant in 2014 and 2015, analysed existing evidence relating to the functioning of the Toy Safety Directive, including literature data as well as views and suggestions of Member States in their five yearly reports 2009 – 2013 on the application of the Toy Safety Directive. Input from industry, a European consumer association, standardisation organisations and Notified Bodies were collected through interviews. For this evaluation, data from the 2015 external study have been updated and complemented as appropriate by the Commission services.

The Commission's Joint Research Centre (JRC) conducted a study on costs and benefits of the Toy Safety Directive (JRC study) for the purpose of this evaluation.[74] The study provided a review of quantitative literature data on the costs and benefits of regulation in the toys sector. The study deployed counterfactual impact analysis by looking at imports and at product restrictions under the Safety gate RAPEX data, and company level data from Bureau van Dijk[75] were used to analyse the possible cost impact of the Toy Safety Directive on manufacturers and distributors.

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[73] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/toys_en

[74] Joint Research Centre, Competence Centre on Microeconomic Impact Evaluation. Evaluation of the benefits and the costs generated by the Toy Safety Directive – A supply side analysis (October 2019).

[75] https://www.bvdinfo.com/en-gb/our-products/data

In addition, several Fitness Checks (FC) and related studies on chemicals legislation have been taken into account for the purpose of the present evaluation to the extent that they referred to toys or to the Toy Safety Directive.[76]

The present evaluation further takes account of the first five yearly reports 2009 – 2013 from the Member States on the application of the Toy Safety Directive, as well as of the second five yearly reports 2014 – 2018 as far as available.

4.2. Stakeholder consultations

Both a public and a targeted consultation of stakeholders have been carried out in the context of this evaluation. The table below gives an overview of the two consultations.

Table 4.1. Public and targeted online consultations carried out for this evaluation

	Public consultation	**Targeted consultation**
Data collection source	Public online survey	Targeted online survey
Expected outcome	Views of all interested parties	Industry feedback
Target	All stakeholders: – general public including consumers; authorities in 28 Member States and EEA-EFTA countries; – industry including SMEs: manufacturers, importers, distributors; – consumer associations: ANEC (The European consumer voice in standardisation), BEUC (The European Consumer Organisation); – Notified Bodies: NB-Toys Group; – European Standardisation Organisations: CEN, CENELEC.	Industry: manufacturers, importers, distributors
Number of responses	116 responses from: – 32 companies; – 12 business associations; – 7 Notified Bodies; – 31 public authorities; – 6 EU and national consumer organisations; – 26 citizens; – 2 others.	32 responses

[76] Cumulative Cost Assessment for the EU Chemical Industry - Final Report http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/
What the Commission is doing. http://ec.europa.eu/growth/sectors/chemicals/ec-support_en FC-chemicals_FR-3-AnnexVI_Final.pdf.
http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/
Study on the cumulative health and environmental benefits of chemical legislation. Final report – Study.
https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en
Towards a non-toxic environment strategy
http://ec.europa.eu/environment/chemicals/non-toxic/index_en.htm
Study supporting the Fitness Check on the most relevant chemicals legislation ('Fitness Check +'). Final report – Study. https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF

Moreover, within the framework of the 2015 external study, direct interviews with economic operators, consumer representatives, test laboratories' representatives and the relevant European Standardisation Organisations (ESOs) were conducted.

A synopsis summarising the different consultation activities is given in annex 2.

4.3. Limitations of available data

This evaluation covers the application of the Toy Safety Directive since mid-2011, when the Directive's provisions were to be applied in the Member States. The evidence is more recent for the chemicals provisions that were to be applied as of mid-2013, thus two years later.

Many of the elements assessed under the current evaluation, such as the principle of free movement of toys in the internal market, were already present in the 1988 Toy Safety Directive. Therefore, many observable outputs and outcomes cannot be attributed exclusively to the 2009 Toy Safety Directive.

It is important to highlight the limited availability of data and the limitations of the available data for the use in this evaluation.

4.3.1. Data on toy-related injuries

The number of toy-related injuries of children and their possible reduction could provide a quantitative analysis of the benefits of the Toy Safety Directive in terms of protection. However, already the 2008 IA pointed to the very limited availability of data related to such injuries. It was therefore impossible to quantify the benefits of the protective effect of the Directive:

- There were no consistent EU-wide statistics on toy-related accidents;
- Only three Member States – Denmark, the Netherlands and the United Kingdom[77] – had injury reporting systems with the potential to provide useful data. In these national systems, the exact cause of accidents was however not available, and the link with a toy or its manufacturer could not be established;
- Not all products included in these reporting systems were toys within the meaning of the Toy Safety Directive;
- Accidents and incidents not involving hospital visits or consultation of a medical doctor were not reported.

Another source that registers injuries with products is the European Injury Database (IDB);[78] it is the only 'EU wide' data base of this kind. It was set up by former Directorate SANCO (today: SANTE) under the Injury Prevention Programme since a better availability of injury and accident data was considered important for public authorities and other stakeholders to identify possible risks and to spot what types of products may pose a threat.

[77] The UK database was discontinued in 2002.

[78] EuroSafe (2016) EU-Injury Database: Operating Manual. http://www.eurosafe.eu.com/uploads/inline-files/IDB_operating_manual_Jan%202017.pdf .

The IDB however only collected data from around 100 hospital emergency departments across 20 EU Member States since the years 1990. Patients were asked about the cause of the injuries and accidents (activity when the injury occurred, area, unintentional, intentional injuries, etc.) and their socio-demographic characteristics (age, gender, country, etc.).

For this evaluation of the Toy Safety Directive the information in the IDB was analysed by the JRC to potentially quantify the impact of the Directive on the number of toy-related injuries. The JRC however concluded that the IDB contains too little usable information.[79]

The Susy Safe registry[80] aiming to establish an international surveillance system for suffocation injuries could not be used either, since, according to the JRC,[81] these injuries are reported on a voluntary basis by physicians, otorhinolaryngologists, pneumologists and general practitioners and will therefore not be representative of all injuries that occurred. Moreover, as the Susy Safe project is concerned with only a single, particular type of injury, an analysis would be too narrow.

The lack of available data on injuries has also been highlighted in various reports[82, 83, 84] and by several organisations.[85]

In 2010, twenty-two Member States signed up for a Joint Action for Injury Monitoring in Europe, with the aim of having a common hospital-based injury data collection system in place by 2015. However, several consumer and business associations pointed out that most Member States and the European Institutions have failed to give political commitment to the continued exchange of injury data after 2014. In addition, the same associations found that whilst injury data are available from several sources in Member States, they are usually limited in size and scope. Moreover, data are not comparable among Member States and are not exhaustive enough to identify the circumstances leading to accidents and injuries. Finally, a lack of coordination and funding at EU level has been pointed out as the root cause for the absence of consistent accident data.

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[79] The IDB was analysed by the Commission's Joint Research Centre, Unit Monitoring, Indicators and Impact Evaluation. The results were reported in a note to GROW, Unit 0.1, of 2 October 2019.

[80] www.susysafe.org

[81] See footnote on the IDB above.

[82] European Parliament (2008). Study On Safety And Liability Issues Relating To Toys, Policy Department Economic and Scientific Policy, (IP/A/IMCO/FWC/2006-058/LOT 4/C1/SC4). http://www.civic-consulting.de/reports/toys_study.pdf

[83] Impact Assessment for the revision of the 1988 Directive. See footnote 35.

[84] RPA (2004). Study on the Impact of the Revision of the Council Directive 88/378/EEC on the Safety of Toys, Final Report, DG ENTR. http://ec.europa.eu/DocsRoom/documents/1756/attachments/1/translations/en/renditions/native

[85] See for instance the joint call for action by consumer and industry associations. http://www.anec.eu/attachments/Joint%20call%20for%20a%20pan-European%20accident%20&%20injury%20data%20system.pdf

The use of US statistics in the 2015 external study on the Toy Safety Directive is limited to the identification of main toy-related issues. Toy-related injuries that occurred in the US may indeed contribute to provide a picture of major risk categories related to toys. However, taking account of the different contexts and legal frameworks in place in the US and in the EU, the relevance of these risk categories may be questioned.

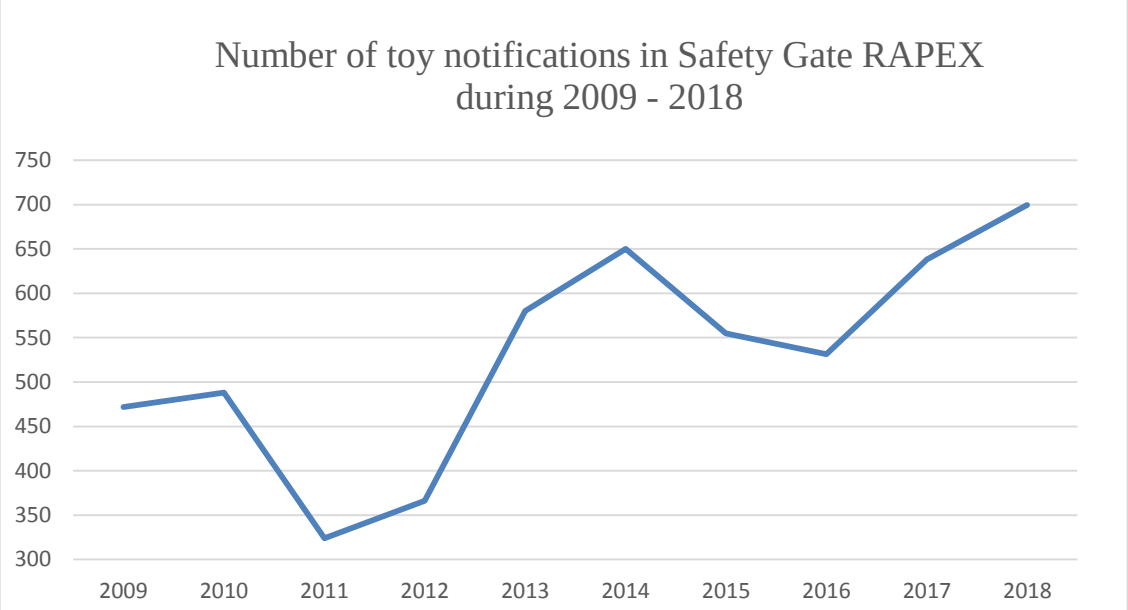
Finally, market developments may affect the number of injuries. The market of toys changes continuously, certain (dangerous) toys may flood the market in a specific year, such as fidget spinners in 2017 (with easy-to-open compartments for dangerous electrical button cells). The advent of such toy 'hypes' may contribute to an increasing number of injuries that interferes with the effects of toy safety regulation and its enforcement by market surveillance.

Thus, in light of the above, the possible impact of the Toy Safety Directive on injuries have been analysed only qualitatively.

4.3.2. Data on marketing restrictions for toys

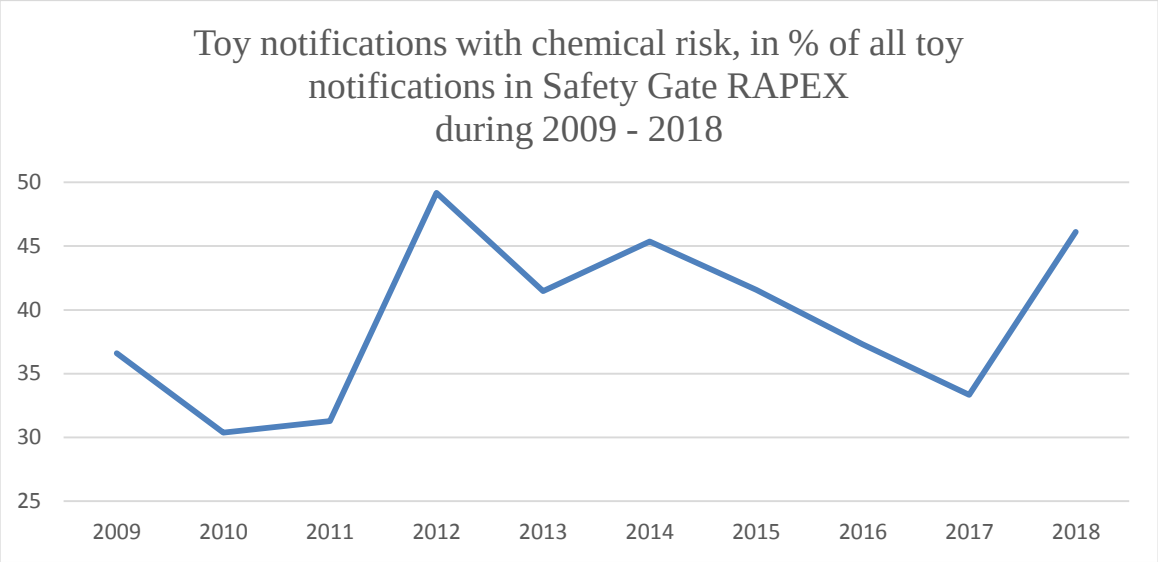
Also the number of toys banned or otherwise restricted from (further) marketing could provide a quantitative analysis of the benefits of the Toy Safety Directive in terms of protection. A higher number of dangerous toys that are no longer allowed on the market could mean a better protection of children.

Looking at the number of toys restricted from marketing and notified via the Safety gate RAPEX from 2009 to 2018 (see figure below)[86] however shows no unambiguous link to the application of the Toy Safety Directive. When its provisions (without the provisions on chemicals) became applicable in mid-2011, an expected rise in the number of notifications did not materialise in that year, and neither in 2012.



[86] Own analysis on 'Safety Gate - Search alerts'. https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=en

On the other hand, the number of toy notifications increased steeply in 2013. This might have been the result of the application of the many new chemical requirements in the 2009 Toy Safety Directive. However, the number toy notifications with a chemical risk went already up in 2012 and decreased in 2013, followed by a further downward trend in the following years before going up again in 2018 (see figure below).[87]



Thus, it appears that the Safety Gate RAPEX data are not useful to reflect an impact of the Toy Safety Directive.

It seems more likely that the yearly changing numbers of notifications may be heavily influenced by national market surveillance campaigns that target different types of toys in the course of the years, by changes in the number of market surveillance staff and of inspectors who actually take the samples, by more or less imports into the EU, by 'hypes' for certain toys which are easier (or less easy) to test for (non-) compliance, by new economic operators entering or leaving the toy market, and others.

It may also be that a new legal requirement for toys takes time to be applied in practice by market surveillance authorities, simply because no laboratories are yet known that are able to competently test toys against the new requirement. The impact of a new, stricter requirement may thus only be phasing in over time and therefore not be clearly discernible from the volatility effects of the 'remaining' market surveillance activities.

4.3.3. Data on toy trade

A further approach to measuring possible benefits of the Toy Safety Directive could be a comparison of the trade in toys before and after the application of the Directive. Manufacturing toys compliant with the more numerous and more demanding requirements of the Directive requires adaptation time and causes costs. This might cause a drop in toys trade until the adaptation is complete and trade returns to its usual pace.

[87] Own analysis on 'Safety Gate - Search alerts'. See footnote above.

An analysis[88] of the evolution of toy imports into the EU was contrasted with the imports of similar products. As a result, the introduction of the Toy Safety Directive in 2009 and the application of its chemical requirements since 2013 seem to have reduced the imports of toys. The effect was less pronounced between 2010 and 2013. Overall, the analysis suggested that the Toy Safety Directive may have reduced the imports of toys. Yet, the results should be interpreted with caution due to many confounding factors in the marketing of toys as described further above.

4.3.4. Data on costs related to toy production

Costs related to the Toy Safety Directive, in particular to the manufacture of toys, may be an indicator of the strictness of the Directive's requirements. Additional or more ambitious safety requirements may lead to higher costs.

The 2015 external study on the Toy Safety Directive mainly relied on data retrieved from stakeholders' qualitative perceptions gathered through interviews to assess costs (and benefits) of the Toy Safety Directive.

The lack of data on costs could perhaps have been compensated by a large survey, but this was not in the scope of the 2015 external study. As a result, the available data made it difficult to obtain exhaustive and comprehensive information on costs encountered by companies to comply with the Directive's requirements.

Furthermore, there are a number of factors that can influence manufacturing costs. Toy manufacturers will permanently seek to reduce costs by looking for cheaper sources for raw materials and by becoming more efficient in the manufacturing process such as when scaling up or automating more extensively the production processes, or by shifting manufacture to lower-wage countries. Also, a company may decide to develop innovative toys that are more expensive to manufacture but, if successful, allow higher profit margins. Taking manufacturing costs as an indicator for the impact of legislation may therefore have intrinsic limitations. As a consequence, economic operators in the 2015 external study were not always able to distinguish cost increases directly caused by the Directive from those induced by exogenous factors.

Also on the costs borne by Member States no quantification was possible in the 2015 external study since no related data were provided in the 2009 – 2013 national reports on the application of the Directive.

For the present evaluation of the Toy Safety Directive, in order to collect at least some quantitative information on the costs of the toy industry, a consultation was targeted to economic operators. It provided 32 responses (26 from toy manufacturers, 5 from toy importers and 1 from a toy distributor). Due to this limited number of responses, the analysis of costs presented in this evaluation should of course be considered with caution.

An effort was made in this evaluation to compare the present analysis, where possible, with the estimates in the 2008 IA. The 2008 IA estimates were however based on only a few case studies and a number of assumptions. Different cost categories and timeframes were used in the 2008 IA compared to the data collected for this evaluation. Therefore the comparison had to remain limited.

[88] See footnote on the Joint Research Centre supply side analysis (October 2019) above.

A counterfactual analysis of cost impacts on distributors and manufacturers[89] confirmed a possible cost impact of the Toy Safety Directive on economic operators. However the methodology applied did not allow to identify which elements of the Directive might have been particularly burdensome.

4.3.5. Lack of representativeness of the respondents in the stakeholder consultations

The more than 150 responses received through the different consultations[90] provided a good overall number of inputs for the analysis, taking into account that some of the respondents, such as TIE and consumer organisations (ANEC and BEUC) represented the views of all their individual corporate members and national associations. It can therefore be trustfully assumed that the input received represents the meaningful views of the stakeholders having toy safety as their core business. It should be underlined that the consultations reached all types of relevant stakeholders, ranging from industry, consumer organisations, public authorities and citizens.

The replies to the 2018 public consultation were mainly provided by companies/business organisations and public authorities, followed by EU citizens. Fewer replies came from business associations, Notified Bodies and consumer organisations.

It is evident that all these responses cannot be seen as representative from a statistical viewpoint. They represent opinions of those who decided to participate. Also, the robustness of the consultations that targeted industry and other economic operators may be influenced by these stakeholders' inherent interest to generally favour the status quo, because changes in the legislation can lead to additional costs which can hinder business.

Notwithstanding the above-mentioned limitations, partially compensated by the fact that replies came from those stakeholders that are really concerned with toys and whose input is most significant, the overall availability and reliability of data and the approach followed are generally considered as satisfactory. Care was taken to accurately report different opinions and findings while also ensuring that the evidence and sources can be traced back. Wherever possible the data gathered were cross-checked and validated against several sources in order to ensure reliability and robustness.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

5.1. Effectiveness of the Toy Safety Directive

5.1.1. Effectiveness in relation to the safety of toys

The safety of toys is one of the two key objectives of the Toy Safety Directive. Safety is the focus of the Directive, almost all provisions aim to ensure the safety of toys. The free movement of toys in the internal market is covered by a single provision: the Directive obliges Member States to not impede the making available on the market in their territory

[89] Joint Research Centre ... (October 2019) See footnote above.

[90] The consultation on the Roadmap, the 2018 public consultation and the 2019 targeted survey of economic operators.

of toys which comply with this Directive.[91] Thus, as long as toys are safe in accordance with the Directive, they can move freely in the internal market. This means that if the internal market provision is correctly implemented and enforced, the required high level of safety is ensured across the EU and no Member States is allowed to go beyond what is required.

This evaluation therefore focusses on the safety of toys, and less on the internal market.

5.1.1.1. Why focus on chemical safety?

According to the 2008 IA the safety requirements of the 1988 Toy Safety Directive had to be improved in particular on chemicals. Indeed, a range of chemical requirements were added to the proposal for the 2009 Toy Safety Directive, and they were further reinforced during the law-making process.

Furthermore, the 'subgroup Chemicals' was set up under the Directive to inform the Commission in particular about new limit values that were to be set for specific chemicals. All the 14 amendments of the Toy Safety Directive so far were based on the work of the subgroup.

Finally, chemicals deserve particular attention because knowledge about their toxicity may change. Even chemicals with a long-known toxicity may become 'more toxic' when new knowledge arises.

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.'[92] 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.[93] However, in 2013, the European Food Safety Authority (EFSA) issued a scientific opinion on lead providing that lead is more toxic than known before.[94] 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.[95]

In 2012 and 2013, the limit values for cadmium[96] and barium[97] had to be lowered, respectively, due to updated knowledge on their toxicity. For the same reason the limit

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91 Article 12 of the Toy Safety Directive.

92 National Institute for Public Health and the Environment (RIVM), Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM report 320003001/2008, of 2008, p. 182. https://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

93 National Institute for Public Health and the Environment (RIVM) ... p. 120 – 122. See footnote above.

94 EFSA Panel on Contaminants in the Food Chain (CONTAM), Scientific Opinion on Lead in Food. EFSA Journal 2010; 8(4):1570. www.efsa.europa.eu

95 Directive (EU) 2017/738 amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead. OJ L 110, 27.4.2017, p. 6. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017L0738&qid=1575370788272&from=EN

96 Commission Directive 2012/7/EU amending, for the purpose of adaptation to technical progress, part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council relating to toy safety Text with EEA relevance. OJ L 64, 3.3.2012, p. 7.

values for bisphenol A[98] and for aluminium[99] had to be lowered, respectively, in 2017 and 2019.

These examples show that chemical risks deserve permanent attention. For risks other than chemical, such as physical and mechanical risks, knowledge does not increase in the same way, if at all. When children under the age of three years choke on small parts, that risk will not change over time. Provisions addressing these risks therefore need less updating once they have been put in place. Mechanical and physical risks are thus covered by European toy safety standard EN 71-1.[100] Certainly, the standard is improved when new toys can cause new risks. This was the case in 2013 when more extensive specifications to limit the noise from toys were included in the standard.[101]

5.1.1.2.Is the Directive effective in protecting children from the risk of chemicals?

Chemicals in general

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 …'. [102] The reference to chemicals in toys was added during the law-making process, and thus considered as important by the EU co-legislators.

The Directive further lists a range of 'particular' safety requirements on chemicals in its Annex II, Part III, as described in section 'Baseline and points of comparison' further above. In addition, cosmetic toys have to comply with the compositional and labelling requirements of the Cosmetics Regulation.[103] Finally, toys that are themselves substances or mixtures have to comply with the CLP Regulation.[104]

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97 Commission Regulation (EU) No 681/2013 of 17 July 2013 amending part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys Text with EEA relevance. OJ L 195, 18.7.2013, p. 16.

98 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. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017L0898&qid=1580139759341&from=EN

99 Commission Directive (EU) 2019/1922 of 18 November 2019 amending, for the purposes of adaptation to technical and scientific developments, point 13 of part III of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards aluminium. OJ L 298, 19.11.2019, p. 5. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L1922&qid=1580139868389&from=EN

100 The choking risk from small parts is dealt with in clause 5.1 of EN 71-1.

101 See EN 71-1:2011+A2:2013, clause 4.20 Acoustics.

102 Article 10(2) of the Toy Safety Directive.

103 See footnote on Regulation (EC) No 1223/2009 further above.

104 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.

The many detailed safety requirements on chemicals in the 2009 Toy Safety Directive are based on the recognition in the 2008 IA that its predecessor, the 1988 Toy Safety Directive, needed additional safety requirements especially in the field of chemicals. In addition, during the law-making process the 2009 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 …'.[105]

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 4). However, experts in the subgroup Chemicals, but also in the Expert Group on Toys Safety,[106] repeatedly raised the need that children of 36 months and over be equally well protected as those under 36 months. Furthermore, in the 2018 public consultation, 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,[107] 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. In the 'Fitness check on chemicals legislation (excluding REACH)',[108] the supporting case study on toys[109] 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,[110] 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.

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105 Recital 24 of the Toy Safety Directive.

106 See footnote on the Register of Commission Expert Groups further above.

107 See footnote on the Commission Summary of Member States' Reports further above.

108 http://ec.europa.eu/growth/sectors/chemicals/ec-support_en. Click 'Supporting studies and consultations', click 'Annex VI'.

109 http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/

110 Letter of 25.4.2019, Ares(2019)2833234.

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.

In the Commission services' view, the distinction between (1) toys for children under 36 months and toys intended to be taken in the mouth, and (2) other toys, takes good 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, children may also be exposed to chemicals via the skin or via inhalation. Examples are the sensitising preservatives benzisothiazolinone,[111] chloromethylisothiazolinone and methylisothiazolinone[112] 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[113] 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.

Thus, in light of the above, it appears that the limitation of the scope of the specific limit values in Appendix C, both in terms of children's age and types of toys, hampers the effectiveness of the Toy Safety Directive.

CMR substances in general

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.[114] The hazardous effects of such substances can only be seen in the long term and can almost never be traced back to the chemical of origin,[115] and are often irreversible.

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[111] See the related amendment in annex 4.

[112] See the related amendment in annex 4.

[113] National Institute for Public Health and the Environment (RIVM) ... pages 120 and 123. See footnote above.

[114] See footnote on Regulation (EC) No 1907/2006 further above, Articles 55 and 57.

[115] A prominent exception is asbestos that causes '… mesothelioma [that] are very rare malignancies … '. IARC monographs, Volume 100C (2012) Asbestos (Chrysotile, Amosite, Crocidolite, Tremolite,

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[116] and mutagens[117] of categories 1 and 2, respectively, and 0.3% and 3% for reproductive toxins[118] 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 for establishing a safe level 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.[119]

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. 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.

Actinolite and Anthophyllite), p. 238.
https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-19/

[116] Table 3.6.2 of the CLP Regulation.

[117] Table 3.5.2 of the CLP Regulation.

[118] Table 3.7.2 of the CLP Regulation.

[119] See the related amendments in annex 4.

This likely inadequacy of the CMR derogation based on the CLP Regulation was referred to by public authorities and by consumer organisations in the 2018 public consultation. The fitness check on chemicals legislation (excluding REACH)[120] reported in its case study on toys[121] 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 safe 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.

In light of the above, the CMR provisions in the Toy Safety Directive can be considered not to be sufficiently effective to protect children's health. To note that, according to the 2008 IA, these provisions had been explicitly inserted in the Directive[122] because the 1988 Toy Safety Directive had no specific provisions on CMRs. It is however not clear why the inadequacy of such a prohibition, which does not take account of exposure, remained unrecognised before the adoption of the Directive.

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 inhalation, when children are playing with the toys. This derogation takes full account of exposure: When there is no exposure to CMRs, there is no risk. This derogation puts children's safety at the highest rank.

  This second derogation was possibly less strict in the Commission's proposal for the Toy Safety Directive, because the proposal allowed CMRs in toy parts 'that are not accessible to any physical contact by children.' The proposal thus clearly took account of oral and skin exposure, but it is unclear whether it also covered inhalation.

- 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 the 'weaker' 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.[123]

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120 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0264&from=EN

121 http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/ , p. 33.

122 COM(2008) 9 final. 25.1.2008.

123 Annex II, Appendix A of the Toy Safety Directive.

This third derogation in the Toy Safety Directive is the same as in the Commission proposal, however the Directive as adopted is more explicit, which makes its implementation easier.

From the above it appears that a generic approach to the risks of a whole class of chemicals could be missing effectivity if derogations are set that ignore one of the two constituents of risk, namely in this case the exposure to a vulnerable group of consumers. This calls for utmost attention when applying a generic approach to risk for example to newly identified groups of chemicals causing concern, such as endocrine disruptors. On the other hand, developing appropriate risk assessments for single chemicals has proven to be laborious, if not cumbersome, although ensuring tailor-made protection.

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.[124] Relevant nitrosamines may be genotoxic and very strong carcinogens. Nitrosatable substances can be converted into nitrosamines in the human body.

Limit values for nitrosamines and nitrosatable substances were added to the Commission's proposal for the Directive during the co-decision process. The amendment of the European Parliament[125] proposed to take over the limit values applicable to teats and soothers from the related directive, namely 0.01 mg/kg for nitrosamines, 0.1 mg/kg for nitrosatable substances.[126] That directive referred to an opinion of the Scientific Committee for Food recommending 'to keep the amounts of nitrosamines and nitrosatable substances migrating from such rubber articles below the detection limit of agreed appropriate sensitive methods.' [127] Indeed those migration limits were based on detection limits and not on toxicological evaluation, because for genotoxic carcinogenic

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

[125] European Parliament Report on the proposal for a directive of the European Parliament and of the Council on the safety of toys. (COM(2008)0009 – C6 0039/2008 – 2008/0018(COD)). 12.11.2008.
- Amendment No 85 of the Opinion of the Committee on the Environment, Public Health and Food Safety for the Committee on the Internal Market and Consumer Protection on the proposal for a directive of the European Parliament and of the Council on the safety of toys. (COM(2008)0009 – C6 0039/2008 – 2008/0018(COD)) 15.10.2008.
- Amendment No 124 of the Draft European Parliament legislative resolution on the proposal for a directive of the European Parliament and of the Council on the safety of toys. (COM(2008)0009 – C6 0039/2008 – 2008/0018(COD)).

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT%20REPORT%20A6-2008-0441%200%20NOT%20XML%20V0//en

[126] Directive 93/11/EEC concerning the release of N-nitrosamines and N-nitrosatable substances from elastomer or 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=1575564486032&from=EN

[127] Commission of the European Communities, Reports of the Scientific Committee for Food (20th series). Report EUR 11558 EN, p. 23: Nitrosamines in babies dummies and teats. (Opinion expressed on 10 December 1987)
http://aei.pitt.edu/40829/1/20th_food.pdf

substances no safe level of exposure exists; a toxicological evaluation by the Scientific Committee on Consumer Products (SCCP) concluded however that 0.05 mg/kg for nitrosamines in balloons was acceptable.[128]

The final position of the European Parliament[129] adopted the limit values as they are in the Directive eventually adopted in 2009, namely 0.05 mg/kg for nitrosamines and 1 mg/kg for nitrosatable substances.

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,[130] acknowledging that 'the German request is based on a real concern with regard to children's health …'.[131] 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.[132] – 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.[133] 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, that included lower limits for nitrosamines and nitrosatable substances in accordance with the Commission's mandate.

Thus, the Directive's effectiveness with regard to the protection from nitrosamines and nitrosatable substances is compromised. 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.

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[128] Scientific Committee on Consumer Products (SCCP) Opinion on the Presence and Release of Nitrosamines and Nitrosatable Compounds from Rubber Balloons. Adopted on 18.12.2007, p. 11, p. 23. https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_121.pdf

[129] Position of the European Parliament adopted at first reading on 18 December 2008 with a view to the adoption of Directive 2009/.../EC of the European Parliament and of the Council on the safety of toys (EP-PE_TC1-COD(2008)0018). 18.12.2008.

[130] See section on Implementation and State of Play above.

[131] 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

[132] 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

[133] Letter of 29.3.2012. ARES(2012)363020.

Finally, market surveillance authorities in the Member States continue to find both nitrosamines and nitrosatable substances in toys in excess of the current limits in the Directive, in particular in balloons, much less so in finger paints or other toys. Nitrosatable substances are more often found in toys than the nitrosamines themselves (annex 9).

In their letter of April 2019 to the Commission,[134] 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 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. The 2008 IA mentioned nitrosamines as an example of dangerous chemicals requiring regulation.

In conclusion, the Toy Safety Directive is less effective than required to ensure a high level of protection from nitrosamines and nitrosatable substances in toys. At the same time these carcinogens continue to be found in toys in excess of the limit values in the Directive.

Allergenic fragrances

The Toy Safety Directive prohibits 55 allergenic fragrances, with certain derogations, and requires to label a further 11 when used in toys;[135] in addition, specific labelling provisions apply to olfactory board games, cosmetic kits and gustative games.

Notwithstanding the prohibition of the 55 allergenic fragrances, the presence of traces of these fragrances is allowed if technically unavoidable under Good Manufacturing Practice and if they do not exceed 100 mg/kg.[136]

This tolerance of 100 mg/kg, corresponding to 0.01%, does not appear to compromise toy safety. The Scientific Committee on Consumer Safety (SCCS) noted, when assessing fragrance allergens in cosmetic products, that 'The studies available, however, indicate that a general level of exposure of up to 0.8 μg/cm² (0.01% in cosmetic products) may be tolerated by most consumers, including those with contact allergy to fragrance allergens. The SCCS is of the opinion that this level of exposure (up to 0.01%) would suffice to prevent elicitation for the majority of allergic individuals, unless there is experimental or clinical substance-specific data allowing the derivation of individual thresholds.'[137] Since

[134] See letter of 25.4.2019 … above.

[135] See section on Baseline and points of comparison above.

[136] Annex II, Part III, point 11 of the Toy Safety Directive.

[137] Scientific Committee on Consumer Safety (SCCS) Fragrance allergens in cosmetic products. Opinion adopted on 26 – 27 June 2012, p. 8. https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

cosmetic products such as face creams or hand creams will stay 12 hours or more per day on the skin, exposure to allergenic fragrances from such products will normally be more pronounced than from toys. The 100 mg/kg tolerance in the Toy Safety Directive, legally acceptable only if unavoidable under Good Manufacturing Practice conditions, therefore appears to go hand in hand with a high level of protection.

The only caveat to this could be the presence of allergenic fragrances in toys for children under 36 months of age, because those children take 'everything' into their mouth by bringing their lips and their mouth's mucous membranes in contact with a toy material.

On the other hand, allergies from the fragrances in question are caused by contact with the external skin, but not the (oral) mucosa, and exposure of the latter may therefore be tolerated. An example for this is the maximum limit of 1% for hydroxy-citronellal in cosmetics in general combined with a labelling requirement as of 0.001% in leave-on cosmetics and as of 0.01% in rinse-off cosmetics,[138] however no limit applies to oral cosmetics.[139] An analogous example is isoeugenol: maximum limit of 0.02% for cosmetics in general (plus the same labelling requirements), but unlimited use in oral cosmetics.[140]

The further 11 allergenic fragrances that may be used in toys if labelled above a concentration of 100 mg/kg in the toy or any of its components were less frequently reported as contact allergens.[141] In cosmetics they have to be labelled as of 0.001% (= 10 mg/kg) in leave-on products, and as of 0.01% (= 100 mg/kg) in rinse-off products. In this light the Toy Safety Directive appears to be sufficiently protective, since most toys will lead to a lower exposure than leave-on cosmetics, with a possible exception for finger paints, which may stay for several hours on children's skin, and thus rather resemble a leave-on cosmetic. This will require further expert consideration.

An exception amongst the 11 allergenic fragrances is methyl heptine carbonate that has a maximum limit of 0.01% in cosmetics in general,[142] but can be used without limit in oral cosmetics.[143] The maximum limit being based on a Scientific Committee opinion[144] and

[138] Scientific Committee on Non-Food Products (SCCNFP) An initial list of perfumery materials which must not form part of cosmetic products except subject to tge restrictions and conditions laid down. SCCNFP/392/00 final, 25.9.2001, p. 8. https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out150_en.pdf

[139] Entry 72 of Annex III to Regulation (EC) No 1223/2009 on cosmetic products. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1223-20190813&qid=1570630231024&from=EN

[140] Entry 73 of Annex III to Regulation (EC) No 1223/2009 on cosmetic products. See footnote 121.

[141] Scientific Committee on Non-Food Products (SCCNFP) Fragrance allergy in consumers. Opinion SCCNFP/0017/98 final, 8.12.1999. Table 6b, p. 23. https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf

[142] 0.08% when used in combination with methyl octine carbonate.

[143] Entry 89 of Annex III to Regulation (EC) No 1223/2009 on cosmetic products. See footnote 121.

[144] 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, p. 8. https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out150_en.pdf

corresponding to a prohibition under the Toy Safety Directive, the transfer of methyl heptine carbonate to the group of 55 prohibited allergenic fragrances in the Toy Safety Directive is under preparation.

Finally, for amending the specific labelling provisions for olfactory board games, cosmetic kits and gustative games in the Toy Safety Directive[145] Council and Parliament have to decide in an ordinary legislative procedure. This is time consuming and seems disproportionate given that amending the list of allergenic fragrances follows the regulatory procedure with scrutiny which requires much less time. This appears to be an in-built design defect of the Toy Safety Directive which could reduce its effectiveness.

Setting limit values for chemicals

Under the Toy Safety Directive, limit values for the (mostly heavy metal) 'elements' have been set at 10% of the toxicological reference value, as recommended by Scientific Committee opinions.[146, 147] This takes satisfactory account of the intake of elements from other sources, in particular from food, reported to be generally between 20% and 70%.[148]

The 10% have to be reduced to half (i.e., 5%) when such an element is 'particularly toxic', as provided for in the Directive[149] and applied to the adaptation of the limit values for lead.[150]

The 10% allocation has also been used in the case of bisphenol A.[151] In other cases, such as on highly allergenic preservatives,[152] the limit values were set so low that even sensitised individuals would not suffer if exposed to a toy complying with the limit values. At the same time these preservatives would have no preserving effect in a toy. The limit values thus effectively prohibit the use of those chemicals while allowing legal certainty when testing for compliance.

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145 Annex II, Part III, point 12 of the Toy Safety Directive.

146 Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) Assessment of the bioavailability of certain elements in toys. Opinon of 22.6.2004. https://ec.europa.eu/health/ph_risk/committees/sct/documents/out235_en.pdf

147 Scientific Committee on Health and Environmental Risks (SCHER) Evaluation of the migration limits for chemical elements in toys. Opinion of 1.7.2010. https://ec.europa.eu/health/sites/health/files/scientific_committees/environmental_risks/docs/scher_o_126.pdf

148 See footnote on National Institute for Public Health above.

149 Recital 22 of the Toy Safety Directive.

150 See the related amendment in annex 4.

151 See the related amendment by Commission Directive (EU) 2017/898 in annex 4.

152 See the related amendment by Commission Directive (EU) 2015/2117 in annex 4.

On the other hand, in the case of chromium-VI the toxicological assessment would require limit values[153] that are so low that they cannot be tested for compliance. The chromium-VI limit value for scraped-off toy material in the Toy Safety Directive has thus been adapted to a level that can reliably be tested with the most recent standard test method[154] referenced in the Official Journal.[155]

In conclusion, limit values in the Toy Safety Directive are normally set at levels that leave a sufficient reserve against the background exposure from sources other than toys. Where this is not possible due to modern test methods not being sufficiently sensitive, they are set at a level that allows compliance testing and unambiguous enforcement.

Identifying chemicals for limit setting

Chemicals to be considered for setting specific limit values in the Directive have regularly been identified by the dedicated subgroup Chemicals. Its chemical experts from several Member States, the toy industry and a consumer organisation have identified (and have been working on) chemicals that are particularly hazardous, such as CMRs or very strong sensitisers, or on chemicals recognised to be more toxic than previously known, such as aluminium. Suggestions (and work) of the subgroup have also concerned chemicals newly identified in toys, such as volatile chemicals in squeezing toys made from foam materials. Furthermore, opinions of the Commission's independent Scientific Committees, such as the Scientific Committee on Consumer Safety (SCCS), that is primarily working on cosmetics, or of the European Food Safety Authority (EFSA) have constituted a source of advice, normally via the subgroup. Finally, the subgroup has been discussing 'Anything to signal on risks from chemicals in toys?' at its meetings, this being an opportunity to bring up any relevant aspect on chemical risks in toys. – Chemical issues are also discussed in the Expert Group on Toys Safety, which has equally been suggesting chemicals for limitation, such as for certain allergenic fragrances.

Thus the identification of chemicals for potential limit-setting in toys has so far been based on expert advice regarding existing or new concerns, and the opportunity for experts to raise any concern they may have. So far there has been no oversight of a risk from chemicals in toys, and the absence of an explicit, more systematic link to activities elsewhere in the EU or worldwide has shown to be sufficient.

5.1.1.3. Is the Directive effective in protecting children from risks other than chemical?

The safety requirements in the Toy Safety Directive for hazards other than chemical have not led to any major discussion with Member States or stakeholders about their effectiveness, it seems that they can be applied in practice without further ado.

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[153] Scientific Committee Health and Environmental Risks (SCHER) Chromium VI in toys. Opinion of 22.1.2015. https://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_167.pdf

[154] EN 71-3:2019 Migration of certain elements.

[155] See footnote on Commission Implementing Decision (EU) 2019/1728 above.

The only safety requirement triggering almost permanent discussion is the 'small parts requirement': 'Toys, 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.' [156]

This requirement is based on the fact that children under 36 months put 'everything' in their mouth to explore the world. They therefore run the highest risk of choking on a small part that they have swallowed. This mouthing behaviour fades out with the completion of their 36 months. Nevertheless, toys or their components that are intended to or may be put in the mouth continue to present the 'small parts risk': for those toys the safety requirement applies regardless of the age of children. An example for the latter are suction cups at the tip of a toy arrow that children may wet in their mouth (so that it sticks better when shot onto a surface).

Manufacturing toys that comply with the small parts requirement is a challenge, because the toys have to be particularly resistant to mechanical stress.

The demanding specifications are circumvented by some manufacturers who disregard the rules and who, although their toys are apparently for children under 36 months, claim that they would be for children of 36 months and over. Such cases have led to discussions amongst Member States' authorities in the AdCo about the sometimes fine line between toys for children under 36 months and toys for older children. A toy mouse with a wind-up mechanism to be activated by simply pushing the mouse over the ground was thus considered to be for children under 36 months, whereas a pony with a mechanism to be winded up with the fingers was seen by some as too complex for the dexterity of such children, and thus categorised for children of 36 months and over.

A guidance document on the classification of toys intended for children under 36 months of age has been developed by Member State authorities and eventually adopted by the Expert Group (which also includes the stakeholders) in 2009.[157] Nevertheless, discussions are taken up when necessary, and a once-for-all remedy for this less-than-optimal effectiveness of the Toy Safety Directive does not appear to exist: new toys with new features are continuously being placed on the market, which requires a case-by-case approach.

5.1.1.4.Are standards effectively supporting the safety of toys?

The specifications in the harmonised toy safety standards referenced in the Official Journal cover a wide range of requirements of the Toy Safety Directive.[158] Only hygiene specifications are limited to 'Material cleanliness' in clause 4.1 of EN 71-1, without further details. Details on the maximum presence of specific microorganisms can however be taken from Protocol no 2 on the microbial safety of toys, drafted and adopted

[156] See Annex II, Part I, point (d).

[157] Guidance document No 11 on the classification of toys intended for children under 3 years of age. http://ec.europa.eu/growth/sectors/toys/safety/guidance_en

[158] See annex 7.

by the Notified Bodies under the Directive.[159] The radioactivity requirement in the Toy Safety Directive refers to the Treaty establishing the European Atomic Community.

So far the harmonised standards referenced in the Official Journal appear to have effectively supported the Directive and thus the safety of toys. There have been no major incidents with toys complying with such standards.

Also, on only very rare occasions did Member States object to a standard for being insufficient[160]. For example, a formal objection in 2016 from a Member State regarding EN 71-1 (mechanical and physical properties) considered that specifications for balance bikes were missing, and another formal objection from a Member State regarding EN 71-2 (flammability) in 2012 considered not to cover the easily flammable plastic puffer balls.

Furthermore, toy safety standards delivered by CEN are normally of a quality that allows the Commission to reference them without further ado in the Official Journal. Only the 2018 publication of the references to toy safety standards[161] had to be completed by the Commission with a note on the maximum concentration of a preservative in finger paints. The note limited the preservative to the maximum concentration recommended by the Scientific Committee on Consumer Safety (SCCS) for leave-on cosmetics (such as hand creams). CEN was not able to amend the standard on time because the SCCS opinion was published only shortly before the standard publication by CEN.

Harmonised referenced standards play a major role in the conformity assessment of toys (see '*Conformity assessment*' in section 2.1.2). They appear to help manufacturers to bring their toys more swiftly to the market, by avoiding the extra effort in time and money that an EC-type examination requires in comparison to self-certification.

5.1.1.5.Is the Directive effective in defining its scope?

The Toy Safety Directive defines toys as '… products designed or intended, whether or not exclusively, for use in play by children …'. Thus, products may be considered as toys subject to the Directive when they have a play value for children, although children's play may not be the main intended use ('not exclusively').

Due to this wide definition some 15 guidance documents on the related Commission web site[162] are dealing with the distinction between toys and other products, such as dolls (dolls for play by children or for adult collectors; the latter are not toys), toys used in and on the water (such as inflatable plastic animals or inflatable life-saving rings; the latter are not toys), pools, books, musical instruments, and so on. These guidance documents have been primarily developed by the AdCo and eventually agreed by the majority of all

[159] Protocol No 2 : Microbiological safety of toys (Rev 3). https://ec.europa.eu/growth/sectors/toys/safety/guidance_en

[160] Notifications from Member States on formal objections to standards are published at https://ec.europa.eu/growth/single-market/european-standards/notification-system/

[161] Commission communication in the framework of the implementation of Directive 2009/48/EC on the safety of toys. OJ C 282, 10.8.2018, p. 3.

[162] http://ec.europa.eu/growth/sectors/toys/safety/guidance_en

stakeholders in the Expert Group on Toys Safety, they thus indicate the view that has been generally adopted in the EU. Nevertheless these guidance documents are not binding and do not relieve national authorities from their obligation to determine for any individual product, on a case-by-case basis, whether it falls within the scope of application of the Toy Safety Directive or within the scope of application of other sectorial legislation.

The guidance documents are valued by all: Member States, the toy industry, notified bodies, and others. Updates of existing guidance documents is a recurrent task, such as on pools or on musical instruments, and new guidance documents are being drafted, such as on puffer balls and similar toys, or soother holders.

Still, the classification of products as toys (or not) is a permanent, almost daily task for market surveillance authorities, which they are discussing via email exchanges amongst themselves, with the Commission taking the role of an observer to ensure that the provisions of the Directive are not infringed.

Experience with the AdCo exchanges shows that products, which previously had never been classified as toys, are suddenly given a child-attractive design by manufacturers. This may give them a play value for children and thus may make them subject to the Toy Safety Directive. Those 'grey zone products' lead to hesitations, inquiries and exchanges between the authorities.

These hesitations have been confirmed by the 2014 – 2018 national reports of Member States,[163] where many countries referred to difficulties on how to interpret the provisions of the Toy Safety Directive, in particular as concerns the concept of play value and the foreseeable use of a toy. Also the classification of products as toys or not was raised as an issue, as was the classification of toys as being for children under 36 months of age and/or toys for children of 36 months of age and above. The 2014 – 2018 national reports called for more guidance and for more targeted guidance documents in this regard. The quest for related meetings with the Commission and the other countries to find agreed views was less pronounced, but still well noticeable.

Despite these discussions, triggered by new market developments, there has been no call to amend the definition of 'toy', and thus the scope of the Directive. The need to comprehensively protect children has been recognised by everyone in the stakeholder consultations.

Also under the predecessor Directive the main difficulty was the concept of 'use in play' or 'play value'.[164] This has not changed but is being monitored via the continued exchange of views between the Member State authorities and with the Commission.

5.1.2. Effectiveness related to the free movement of toys in the EU

The free movement of toys placed on the market in the EU is the second key objective of the Toy Safety Directive. The Directive is a maximum harmonisation directive: toys that

[163] The Commission is to provide a summary of the 2014 – 2018 national reports in accordance with Article 48 of the Toy Safety Directive.

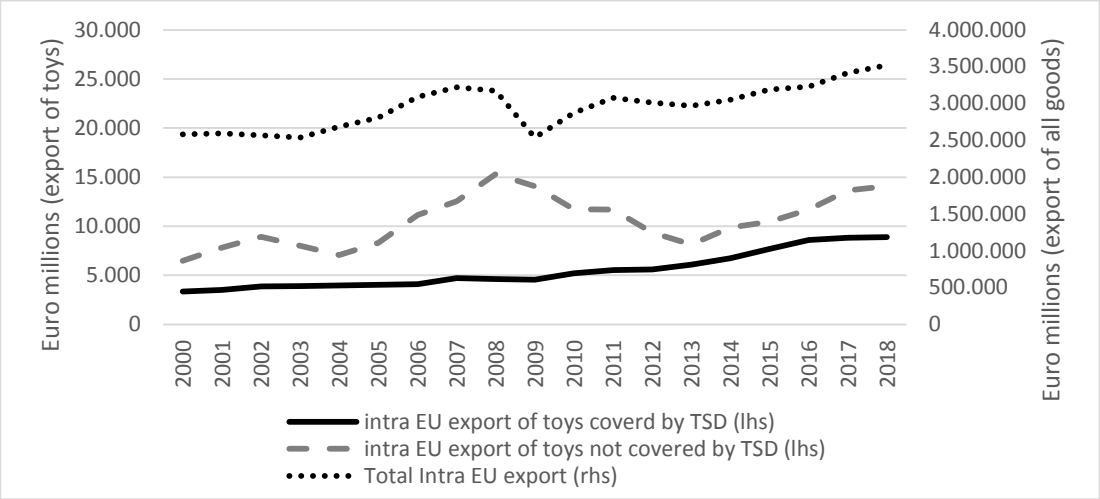
[164] Section 4.2.3 of the 2008 IA.

comply with all applicable requirements of the Directive can move freely and be made available throughout the EU.[165] There is therefore no need for other provisions on the free movement.

The effectiveness of the Directive related to the free movement of toys could be analysed by looking at the intra-EU trade of toys and its evolution over the years.

Export of toys covered by the Toy Safety Directive[166] from EU countries amounted to €10.4bn in 2018. This corresponds to 0.2% of total EU exports. 86% of the export goes to other EU countries (intra-EU trade), and the remaining 14% is sold outside the EU (Fig. 5.1.).

Fig. 5.1. Evolution of intra EU export of toys since 2000



Note: Toys covered by the TSD are classified under CN9503, toys not covered include categories CN9504, 9505 and 9506. Values presented in 2018 prices.
Source: Eurostat, EU trade since 1988 by CN8 [DS-016890]

The intra-EU export of toys covered by the Toy Safety Directive increased slightly but steadily since the year 2000. A steep increase started however in 2012/2013 (Fig. 5.1). Since the Toy Safety Directive started to apply fully in mid-2013, namely including all its new chemical requirements, this increase suggests that the Directive does not appear to have been a hindrance to intra-EU export.

The intra-EU export of toys covered by the TSD almost doubled since 2007 (real growth rate of 89%), while export of other toys grew by 12 % and the overall intra-EU export of all goods grew by 9% (Fig. 5.2). In particular, the intra-EU export of toys covered by the Toy Safety Directive saw a remarkable increase since 2012/2013. This again supports the

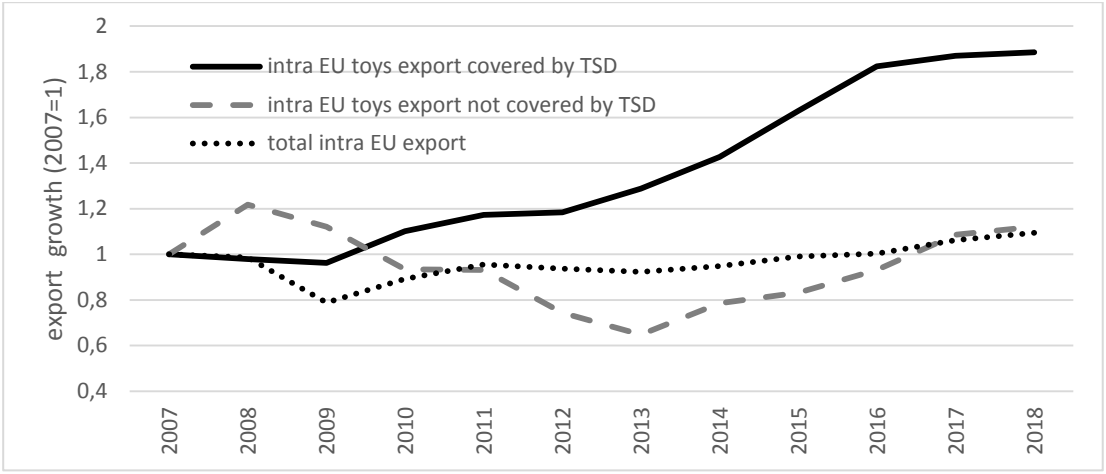
[165] See Article 12 of the Toy Safety Directive.

[166] Toys classified under category CN9503 of trade statistics. Products under this category include "tricycles, scooters, pedal cars and similar wheeled toys; dolls' carriages; dolls; other toys; reduced-size ('scale') models and similar recreational models, working or not; puzzles of all kinds". Source: EU trade since 1988 by CN8 [DS-016890].

above suggestion that the application of the Directive with all its requirements since mid-2013 did apparently not hamper the increase of intra-EU toy exports.

Seen from a different angle, the steep increase of intra-EU toy exports from 2012 – 2016 (Fig. 5.2) could make it plausible that economic operators increasingly seized the business opportunities offered by toys during that time period that started with the full applicability of the Toy Safety Directive's provisions.

Fig. 5.2. Real growth of intra EU export of toys since 2007



Note: Toys covered by the TSD are classified under CN9503, toys not covered include categories CN9504, 9505 and 9506
Source: Eurostat, EU trade since 1988 by CN8 [DS-016890]

During the slight decrease of toy imports into the EU between 2010 and 2013,[167] possibly related to the application of the Toy Safety Directive, intra-EU toy exports increased by some 20%. This might suggest a potentially higher competitiveness of EU toy manufacturers during the first years of application of the Directive, presumably through their better access to first-hand information and their subsequent quicker adaptation to the requirements of the new Directive.

Stakeholders in the public consultation also highly rated the effectiveness of the Directive in relation to the free movement of toys in the internal market. The majority of **consumer organisations** all agreed that the Toy Safety Directive definitely has helped to ensure the free movement of toys throughout the EU by harmonising rules and procedures for placing toys on the market. Half of the business associations agreed that the Toy Safety Directive has helped to ensure the free movement of toys in the EU, however, differences in interpretation and national deviations are still to be solved. Two thirds of the responding **companies/business organisations** considered that the Toy Safety Directive has helped to improve the placing on the market of toys and their free movement throughout the EU to a large or moderate extent.

An effective internal market for toys also requires a strong level of enforcement of the Directive by competent authorities (both market surveillance and customs) in all Member

[167] See footnote on the Joint Research Centre supply side analysis (October 2019) above.

States. Where a toy does not comply with the requirements of the Directive, its movement in the internal market is to be restricted.

In this light it is not relevant in which country of the world a toy for the EU market is manufactured. Whereas a large majority of the toys in the EU are said to originate from far east, all toys have to comply with all applicable requirements, whether in the Toy Safety Directive or in other pieces of legislation, in the same way as any toy manufactured in the EU.

From the same perspective it is of no relevance whether toy designers or the actual toy manufacturers have the largest influence on toy safety. When placed on the market the toy has to fulfil all requirements for toys, regardless of the efforts that many may have invested into it beforehand.

As a consequence, compliant toys can move freely and be made available throughout the EU. There is no need for other provisions on the free movement: the current provisions have proven to be effective in ensuring the smooth functioning of the internal market for toys which is further confirmed by the intra-EU trade data and stakeholder perception presented above,

5.1.3. Is the Directive effective with regard to market surveillance?

Market surveillance is the exclusive competence of Member States: they determine the resources that they put into market surveillance and how these resources are employed; they set the priorities about the types of toys they inspect; they decide against which requirements they test the toys, and they decide about the action they take on non-compliant toys in accordance with their national laws, including with regard to fines and penalties.

The Toy Safety Directive only obliges Member States generally to organise and perform market surveillance of toys placed on the market[168] in accordance with the relevant provisions in Regulation (EC) No 765/2008. The Directive further limits itself to 'the usual' general rules on penalties ('effective, proportionate and dissuasive') and sanctions. Also, the Directive obliges market surveillance authorities to report measures only on toys that pose a risk beyond their national territory. No reporting is necessary for risks limited to the national territory, and none is necessary either on toys that have been found compliant. All this considerably limits the Commission's knowledge about the reality of market surveillance, and this consequently hinders the assessment of the Directive's effectiveness with regard to market surveillance.

Nevertheless, under their obligation to report on the application of the Directive,[169] 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[170]) provided for the first time data on marketing restrictions of

[168] Article 40 of the Toy Safety Directive.

[169] Article 48 of the Toy Safety Directive.

[170] 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.

toys that could be consistently evaluated. The data reported by the other Member States were too complex to be included in this evaluation.

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.

Although these numbers would approximately increase by half if all 28 Member States could be included, they only represent a very tiny amount of the toys placed on the EU market. With the 'Sales of traditional games and toys' projected to between € 18 billion and € 20 billion per year between 2014 and 2016,[171] it can easily be assumed that the number of toys placed on the EU market every year may be counted in billions. Compared to the figures in the 2014 – 2018 reports above, market surveillance could appear to be ineffective.

On the other hand, 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. [172]

By comparison, four joint market surveillance actions on toys,[173] supported by the Consumer Programme of the European Commission,[174] showed non-compliance rates for

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https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D2076&qid=1571646130303&from=EN

171 ECSIP Consortium study …, p. 29. See footnote further above.

172 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

173 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

174 Consumer Programme 2014-2020. http://ec.europa.eu/chafea/consumers/programme/index_en.htm

the tested toys between 10% and 96%, with an average of 43%. This is somewhat higher than the 33% reported by Member States for 2014 – 2018, but can be considered comparably good since the chance of identifying non-compliant toys at first sight can vary considerably. A higher effectiveness in this regard would rather suggest that market surveillance would just focus on toys that are apparently non-compliant, without protecting from the risks that can only be identified following testing, such as those from intrinsic material defects or from chemicals.

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 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 present evaluation.

Overall and on a large scale, however, and in particular in light of the assumed billions of toys on the EU market, the effectiveness of market surveillance can be considered as limited.[175] This was confirmed in the 2018 public consultation: both public authorities and consumer organisations deplored that market surveillance is understaffed; they suggested more staff for authorities, including customs. Already in the 2015 external study, a lack of adequate financial resources and competences available to market surveillance was highlighted.

Many of the 2014 – 2018 national reports on the application of the Toy Safety Directive highlighted that the EC Declaration of conformity is difficult to obtain and equally often incorrect or of questionable quality and/or only drafted when requested by authorities. A similar situation was reported regarding the safety assessment and the technical documentation, which 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. With all this, the replies provided in the reports confirmed the unfortunate situation reported in the replies of market surveillance authorities' in the 2018 public consultation.

In that consultation, companies and business associations claimed that market surveillance authorities work differently in different Member States. Similarly, consumer organisations thought that authorities do not work sufficiently together. However both are difficult to verify since no details were given.

[175] See Communication from the Commission of 28 October 2015 'Upgrading the single market: more opportunities for people and business'.COM(2015)550 final, page 19. https://ec.europa.eu/transparency/regdoc/rep/1/2015/EN/1-2015-550-EN-F1-1.PDF

In any case, to counteract the above the Commission has, under the Consumer Programme,[176] made funding available for Member State authorities to jointly carry out market surveillance projects,[177] including on toys.[178] These projects foster the cooperation between Member States' market surveillance authorities who generally appreciate the collaboration with colleagues from other Member States.[179]

In addition, Regulation (EU) 2019/1020 on market surveillance and compliance of products provides for binding and detailed EU wide rules on how to carry out market surveillance and make it function effectively, including through cooperation of market surveillance authorities. The Regulation covers a wide range of products subject to EU harmonisation legislation, including toys, and it also provides rules for the effective surveillance of online sales. Once applied as of 16 July 2021, it can be expected to harmonise and improve the effectiveness of market surveillance further.

Interestingly, companies and business associations in the 2018 public consultation claimed that market surveillance would not always target the 'bad guys', namely those economic operators that may not be complying with the rule of law. Already in the 2015 external study, it was noted that 'several Market Surveillance Authorities seem to focus their checks on large, reputable companies who are more keen to provide technical documentation and pay due fines … .'

This appears to be contrary to market surveillance authorities efforts to use their limited resources most effectively. Guidance developed at EU level and building on best practices suggests that 'When targeting Economic Operators in a given sector, priority should be given to those that are most likely to break the rules, that do not follow the rules, or that have a history of non-compliance rather than targeting Economic Operators based on random selection … .' [180]

In conclusion, the effectiveness of surveillance under the Toy Safety Directive appears to be less than optimal. The Commission has engaged in improving the effectiveness of market surveillance throughout the years (also with regard to other product legislation) and continues to do so. On the legislative side, the recent Regulation on Market Surveillance and Compliance of Products can be expected to improve the effectiveness of surveillance and harmonise surveillance further through its binding and detailed EU wide rules on how to carry out market surveillance.

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176 Consumer Programme 2014-2020. See footnote above.

177 PROSAFE (Product Safety Forum of Europe): http://www.prosafe.org/index.php?option=com_content&view=article&idcontent&view=article&id=33&Itemid=128 http://prosafe.org/

178 http://prosafe.org/index.php/toys-gpsd-actions-by-product

179 In the 2018 public consultation, 29 of 31 responding public authorities answered that 'Meeting market surveillance colleagues from other Member States is useful for my own work.'

180 Good practice for market surveillance … , p. 49. See the footnote above.

5.1.4. Does the legal form – Directive or Regulation – impact the effectiveness?

In order to be fully effective, the Toy Safety Directive as well as all its amendments have to be transposed into national legislation by the required deadline(s). Only then can all provisions be concurrently enforced in all Member States. Delays in the transposition in one or several Member States would in particular be detrimental to the protection of children in those States.

Delays in the transposition could also affect the free movement of certain toys, namely those using permitted substances. For example, the CMR substance nickel was permitted for use '[i]n toy components which are intended to conduct an electric current',[181] such as toy railway rails. Such toy components could not be placed on a national market if that permitted use was missing in the national legislation.

Thus, the Member States' obligation to transpose the Directive and its amendments have to be closely monitored and, where necessary, enforced by the Commission services.[182] This requires resources in staff and time, which are both scarce however. Investing those resources in the management of the Directive, such as the organisation of joint market surveillance projects, the exchange of best practices or the development of guidance documents, could in practice be more beneficial for children's safety and for the free movement of toys.

As concerns the legal form of the toy safety rules (directive or regulation), it has to be considered that the Toy Safety Directive is a maximum harmonisation directive: Member States are not allowed to adopt any different requirements than those provided in the Directive. There is therefore no room for any national specificity.

This is not different from a Regulation on toy safety that is directly applicable in the Member States and does not need any transposition nor any related checks.

As reported in the 2015 external study, national transpositions of amendments to the Directive often turn out to be excessively burdensome and time-consuming (finding 31). According to a few Member States and stakeholders, this would not occur with a regulation, as amendments would then be directly applicable at national level.[183] The preference for a regulation is motivated by the desire to avoid delays by national transpositions and to ensure consistency in all Member States, thus preventing differences in the application of provisions on the safety of toys (finding 16, finding 17).

Some other stakeholders and Member States believed that a directive grants much more flexibility without regulating into detail, leaving technical specifications to harmonised standards, and the transposition of amendments into national laws constitutes a benefit, since it provides all interested parties with enough time to become aware of - and monitor - the legislative process.

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[181] See the related amendment in annex 4.

[182] See section on Implementation and State of Play further above.

[183] Whereas directives require EU countries to achieve a certain result and set out general rules to be transferred into national law by each country as they deem appropriate, regulations are legal acts that apply automatically and uniformly to all EU countries as soon as they enter into force, without needing to be transposed into national law, see http://ec.europa.eu/legislation/index_en.htm

In the 2018 public consultation, a majority of public authorities, Notified Bodies and consumer organisations were in favour of converting the Toy Safety Directive into a Regulation. They commented that a regulation would be more effective and be applicable at the same time in all Member States; it would also create clearer conditions for all Member States and avoid a cumbersome transposition into national law.

Companies and business associations were less in favour of a regulation; they considered that the Directive was actually working effectively and sufficiently well, and that an improvement of the current rules would be more efficient.

Although the 2015 external study had not raised any major need to change the legal form of the Toy Safety Directive, clear majority views in favour of a Regulation were expressed in the 2018 public consultation by public authorities, consumer organisations and business associations.

To note that the Toy Safety Directive and its amendments (in the form of directives) have always been applicable at the same date in all Member States and have always created the same effective conditions for all Member States. The difference with a possible Toy Safety Regulation would be the Regulation's direct applicability in all the Member States, thus avoiding the transposition into national law.

All the above suggests that it may be appropriate, in particular considering the delays in the transposition of the Directive that have led to the opening of infringement proceedings (see section 3), that the effectiveness of the Toy Safety Directive could benefit from a conversion into a Regulation, by freeing up resources that are currently bound by the transposition in the Member States and by the ensuing checks of the Commission services required in dealing with infringements. Such a choice of the legal form would be even more justified by the considerations above that, given the maximum harmonisation underpinning the Toy Safety Directive, any national specificities would not need to be taken into account.

5.1.5. Has the law-making process affected the effectiveness of the Toy Safety Directive?

The European Parliament inserted several provisions in the Commission's proposal for the 2009 Toy Safety Directive. These provisions were the only changes to the proposal in the law-making process.

The provisions inserted by the European Parliament can be considered to increase the effectiveness of the proposal. To quite an extent these are linked to the protection of children from chemical risks:

- The key safety requirement, namely that toys shall not jeopardize the health and safety of users, was completed with a specific reference to chemicals. The adopted Directive provides that 'Toys, including the chemicals they contain, shall not jeopardize … .'[184] The European Parliament thus attached a particular importance to the protection from chemicals;

[184] Article 10(2), first paragraph of the Toy Safety Directive.

- The possibility to add specific limit values for any chemical in toys involving a high degree of exposure, namely those for children under 3 years of age and those that are placed in the mouth (such as a toy flute), has equally been added by the European Parliament.[185] Indeed, up to the time of writing this provision has been used in eight cases to add specific limit values to the Directive;[186]
- Also the limit values for nitrosamines and nitrosatable substances[187] have been added by the European Parliament during the law-making process;
- From the allergenic fragrances proposed to be labelled on toys, the European Parliament shifted 15 to the list of allergenic fragrances prohibited in toys, namely fragrances number 41 – 55 of the adopted Directive. Also the 'tolerance level' of 100 mg/kg for prohibited allergenic fragrances was inserted by the European Parliament, this adds more clarity to the practical implementation of the prohibition. – The detailed labelling rules for allergenic fragrances in toys, including in olfactory board games, cosmetic kits and gustative games, equally inserted by the European Parliament, also clarify the implementation of the rules on prohibited fragrances and on the fragrances to be labelled.

The European Parliament also added provisions on warnings that are to be placed on toys. They can equally be considered to increase the effectiveness since they draw attention to dangers that may not always be evident:

- specific warnings for imitations of protective masks and helmets (since these do not provide protection),[188] toys intended to be strung across a cradle (since the related cord could lead to entanglement),[189] and the packaging for fragrances in olfactory board games, cosmetic kits and gustative games (since the fragrances may cause allergies);[190]
- a provision that aims to prevent the misuse of warnings.[191] A commonly known misuse concerns the warning that a toy is not to be used by children under 3 years of age,[192] because small parts may come off the toy and could be swallowed by a child under 3 years and lead to choking. This warning has been repeatedly found on soft-filled toys such as plush animals. Since plush animals, or plush toys in general, are without doubt intended for children under 3 years, the warning is not appropriate. The truth may be that the manufacturer wants to circumvent his obligation that, for example, the tip of the nose of a plush dog does not detach, and thus be exempted from his liability for using detachable small-parts in toys intended for children under 3 years.

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185 Recital 24 and Article 46(2) of the Toy Safety Directive.

186 See Annex 4.

187 Annex II, Part III, point 8 of the Toy Safety Directive.

188 Annex V, Part B, No 8 of the Toy Safety Directive.

189 Annex V, Part B, No 9 of the Toy Safety Directive.

190 Annex V, Part B, No 10 of the Toy Safety Directive.

191 Article 11(1), 3rd paragraph of the Toy Safety Directive.

192 Annex V, Part B, No 1 of the Toy Safety Directive.

The European Parliament further required manufacturers to ensure that the instructions and safety information for toys are written in a language (or languages) 'easily understood by consumers, as determined by the Member State concerned.'[193] These language obligation certainly contribute to make the Toy Safety Directive more effective in the various Member States.

In conclusion, a number of provisions have been added in the Toy Safety Directive during the law-making process on initiative of the European Parliament, thus increasing the effectiveness of the Directive.

5.2. Efficiency of the Toy Safety Directive

The 2009 Toy Safety Directive assigns clear roles and responsibilities to toy manufacturers, their authorised representatives, importers and distributors. These responsibilities not only include documentary obligations regarding the toy manufactured, imported or distributed, but also obligations to prevent potentially non-compliant toys from accessing the market and obligations to follow-up on non-conformity.

This section will shed some light on the costs, but also on the benefits of manufacturing toys and placing them on the market under the 2009 Toy Safety Directive.

5.2.1. Costs related to the Toy Safety Directive

5.2.1.1. One-off costs for adapting to the Toy Safety Directive

With the adoption of the 2009 Toy Safety Directive with its increased number of detailed safety requirements for toys, in particular on chemicals, companies had to invest in technical and human resources to adapt to the new requirements. These additional costs had already been reported in the 2015 external study.

In the 2018 public consultation, 29 (out of 32) company respondents agreed to this, or even agreed entirely. Based on the replies to a targeted survey of economic operators, this one-off adaptation cost was on average about 2% of the annual turnover (1.7% in case of large companies, and 2.4% in case of SMEs).[194] The median cost was around 1% for all and for large companies, and 3% for SMEs.

The 2008 IA accompanying the Toy Safety Directive did not indicate clearly any one-off adaptation costs and only concentrated on production costs. The only references in the 2008 IA to costs that could be considered as one-off costs are costs related to the need of altering 90% of moulds in the range of € 500 to € 1,000 per mould and changing the text on the packaging of € 0.05 per product.[195]

In monetary terms the median value of this one-off cost amounted to an average of € 17 million per large firm in the survey, and € 110,000 per SME. Relating to the number

[193] Article 4(7) of the Toy Safety Directive.

[194] Averages, based on 12 responses, exclude two extreme values of 30,000% and 30%.

[195] See 2008 IA, p. 80.

of toy types produced this meant an average of € 150,000 per toy type produced by a large firm and € 12,000 per toy type produced by a SME[196] (Table 5.1). This one-off cost was on average recovered over 2 years and 10 months (3 years in case of SMEs).[197]

Table 5.1. One-off cost of adapting to the requirements of the 2009 Toy Safety Directive

	All manufacturers	Large companies	SMEs
% of turnover (average*)	2%	1.7%	2.4%
% of turnover (median)	1%	1%	3%
Euro per company		€ 17 million	€ 110,000
Euro per company per toy type		€ 150,000	€ 12,000

Note: Average values based on 12 replies for all, 3 for large companies and 9 for SMEs
* excludes two extreme values of 30,000% and 30%
Source: Own analysis based on targeted survey

Using Eurostat data on turnover and number of companies, the one-off cost for the whole toy manufacturing industry amounted to between € 140 million and € 200 million (see annex 3).

Technical resources such as software to measure chemical substances or an IT system were the most costly investments that companies had to make to comply with Toy Safety Directive, followed by updates of internal procedures and guides and training of staff. Among other investments, companies mentioned training of foreign suppliers and review of raw materials and product portfolio (Table 5.2). Large companies considered these investments as more costly than SMEs.

Table 5.2. Response to the question: Prior to / With the full applicability of the Toy Safety Directive in July 2013, my company had to invest in the following areas: 5 = very costly, 1 = not costly

Investment	Average reply*
Technical resources (such as software to measure chemical substances, or an IT system).	3.9
Update of internal procedures and guides.	3.7
Training for staff.	3.6

*Weighted average, number of replies per investment between 20 and 24
Source: Own analysis based on targeted survey

More than half of manufacturers reported having to hire new staff to comply with the requirements of Toy Safety Directive. Almost all large companies did so, while the majority of SMEs did not (Table 5.3).

Table 5.3. Response to the question: Did you hire new staff to comply with the requirements of the Toy Safety Directive?

	All manufacturers	Large	SMEs
Yes	58%	90%	38%
No	42%	10%	63%
No. of replies	26	10	16

Source: Own analysis based on targeted survey

[196] Calculated average value based on responses to the question on percentage of turnover (excludes two extreme values of 30,000% and 30%) and reported turnover in 2017, based on 9 responses (3 from large firms and 6 from SMEs).

[197] Respondents were asked to choose one of the following time ranges: 1 year, 2 – 3 years, 4 – 5 years, more than 5 years. In order to calculate the average time the middle of range was used, there were two responses in the last open range to which value of 5,5 years was arbitrarily assigned.

Respondents mentioned engineers, chemists, technicians, administrative personnel and lawyers as the hired personnel.

Around two thirds of the respondents used outsourcing to comply with the requirements of the Toy Safety Directive. It was more often used by large companies than SMEs (Table 5.4). Activities such as testing and risk/safety assessment were most often outsourced.

Table 5.4. Response to the question: Did you have to outsource any activities due to the new requirements of the Toy Safety Directive?

	All manufacturers	Large	SMEs
Yes	65%	80%	56%
No	35%	20%	44%
No. of replies	26	10	16

Source: Own analysis based on targeted survey

5.2.1.2. Recurring costs for manufacturers

The Toy Safety Directive with its increased number of detailed safety requirements, in particular on chemicals, is causing higher costs than the predecessor Directive. Companies' replies in the 2015 external study had reported major costs related to the Toy Safety Directive's chemical requirements.[198]

More specifically, in the 2019 survey targeted to economic operators, almost all manufacturers (91%) stated that their production costs had increased since July 2013, while the remaining (9%) said the costs had not changed.[199]

New requirements of the Toy Safety Directive were quoted as the most significant reason for production cost increases. These were followed by an increase in the cost of materials, fixed costs, salaries, energy and transport cost. Two respondents stated that the cost of testing has increased substantially (Table 5.5).

Table 5.5. Reasons for production costs increases since 2011.
5 = most significant, 1 = least significant

Reason for cost increase	Average reply*
New requirements of the Toy Safety Directive (in addition to the former Toy Safety Directive).	4.4
Increase in cost of materials.	3.6
Fixed cost increase.	3.0
Wages / salary increase.	2.9
Energy cost increase.	2.6
Transport cost increase.	2.3

*Weighted average. The number of replies per reason was between 10 and 12
Source: Own analysis based on targeted survey to economic operators

[198] See the 2015 external study. Table 7, p. 79; section 6.3.1.2, p. 86.

[199] 21 answers and 2 answers, respectively.

The reported average cost increase due to Toy Safety Directive was around 6.8% for all manufacturers, and 7.4% for those who reported cost increases. Large companies (7 replies) reported a cost increase of 5.8%, SMEs (16 replies) one of 7.4%.

The JRC study[200] confirmed the increase of materials costs for manufacturers in the period 2009 to 2013 and after 2013. In both time intervals results show an increase in cost of materials of 13% and 14% due to Toy Safety Directive in small and medium firms, however leaving large and micro firm unaffected. An absence of effects on large firms, as identified by the study, could be explained by market power considerations and by the ability to accommodate cost increases. The cost effect of the Directive is statistically significant from 2011 onwards. This could reflect an anticipation of the effect of the considerably increased chemical requirements of the Toy Safety Directive that were to be applied as of July 2013.

These estimates are broadly consistent with the 2008 IA which estimated the increase of costs due to chemical provisions for multinationals of 4.8% and 7.6% for SMEs and the cost of other provisions for multinationals in the range of 0.56% – 11.4% and 2.3% – 12.5% for SMEs.[201]

5.2.1.3.Costs related to different provisions of the Toy Safety Directive

When developing toys, manufacturers have to generate a safety assessment for each toy. This requires to consider all the hazards that a toy presents and that could lead to a risk when a child is exposed to a hazard during play. Taking account of all safety requirements causes significant costs: 24 (out of 32) respondents indicated this in the 2018 public consultation, and also the safety assessment thus causes significant costs (18 out of 32 respondents). − On the other hand the safety assessment is also beneficial since it allows to limit toy testing to the necessary minimum when demonstrating that the toy is safe (see the benefits section further below).

Manufacturers had to spend on average around 485 man-hours to comply with all the requirements of the Toy Safety Directive when developing a toy. It took more time for SMEs – around 520 man-hours – than for large firms with 440 man-hours. This included both internal staff time and time of external contractors (Table 5.6). For instance, one very large international company reported employing 30 full time persons in its product safety and compliance department.

Table 5.6. Cost of developing a toy in percentage of man-hours per toy type

	% of man-hours		
Activity	**All**	**Large**	**SMEs**
Safety aspects			
Identifying all applicable safety requirements.	8	8	8
Generating the safety assessment.	6	6	7
Applying a chemical amendment of the Toy Safety Directive or a new specification in a standard.	7	9	7
Identifying the necessary tests.	5	4	5
Getting supply chain information.	6	8	5
Total Safety aspects:	**33**	**34**	**32**

[200] JRC study ... (October 2019). See footnote further above.

[201] See 2008 IA, p. 64 and p. 66.

Testing and documentation			
Testing the quality and compliance of the raw materials for the toy.	7	8	7
Testing the toy.	9	10	8
Generating the conformity assessment.	6	4	7
Obtaining an EC-type examination certificate.	5	7	4
Generating the EC declaration of conformity.	5	4	5
Generating the technical documentation.	12	15	10
Total Testing and documentation:	**43**	**48**	**40**
Labelling			
Identifying how to apply the CE mark on the toy and affixing it (Article 17 of the Toy Safety Directive).	2	1	3
Identifying the applicable warnings and marking the warnings.	3	2	3
Identifying the traceability elements and marking the toy.	2	1	2
Total Labelling:	**7**	**5**	**9**
Packaging			
Designing the packaging.	6	4	6
Selecting the packaging material.	3	3	4
Testing that the packaging is fit for purpose.	3	3	4
Total Packaging:	**12**	**10**	**13**
Other			
Other man-hours (e.g. filing documents)	4	3	6
Total Other:	4	3	6
Total all activities	**100**	**100**	**100**
Total man-hours for all activities for developing a toy type	**485**	**438**	**516**

Note: average number of man-hours (both internal staff and external consultants) per year devoted to each activity per toy type. Distribution per activity based on weighted average of ranges selected by respondents (available ranges 0-4 man hours, 5-10, 11-20, 21-35, >35). Middle of range used. Open range value selected to keep the sum of activity equal to average reported man-hour for a given activity group (extreme values were eliminated from the average).
Source: Own analysis based on targeted survey

Also the technical documentation causes significant costs to companies, as confirmed by 24 (out of 32) respondents in the 2018 public consultation. It includes the safety assessment, conformity assessment documents and supply chain information, and has to be kept up-to-date. If not all of a toy's risks are covered by harmonised standards the references of which have been published in the Official Journal, an EC-type examination by a Notified Body is necessary to carry out the conformity assessment of the toy. Also EC-type examination was considered to be costly by 24 (out of 32) respondents in the 2018 public consultation.

There are 10 toy safety standards in the EN 71 series that provide detailed specifications on the safety requirements that toys have to fulfil and which are referenced in the Official Journal. Adding up to this is standard EN 62115 on electrical toy safety, equally referenced. All standards, which to a large extent describe the technical details of test methods, have been repeatedly amended to adapt them to technical and scientific developments and to take account of the hazards of novel toys placed on the market. Standards are available for purchase from the national standardisation organisations.[202]

In the 2018 public consultation, respondents considered standards to cause significant costs. This was noted by companies (20 out of 32 respondents), public authorities (20 out of 31 respondents), but also consumer organisations in light of their testing activities

[202] http://standards.cen.eu/dyn/www/f?p=CENWEB:5

(4 out of 6 respondents). Also the 2015 external study on the Toy Safety Directive reported that standards were claimed to be expensive.[203]

On the other hand, comparing the prices of standards with other costs may lead to a different conclusion. A set of all non-electrical toy safety standards, the references of which have been published in the Official Journal,[204] is available for less than € 180 from a 'low-price standards organisation' in a certain EU Member State, and for around € 1,300 from 'high-price standards organisations' in other EU Member States. The cost for the electrical toy safety standard EN 62115 is difficult to estimate due to the complex system of updates actually valid, but can be estimated to be no more than € 300 from a 'high-cost standards organisation'.

In addition, the permanent updates of standards may require to purchase those updated standards. Assuming that the three most expensive standards would be updated once every year this could lead to yearly costs of € 70 ('low-price standards organisation') to € 600 ('high-price standards organisations').

In comparison, staff-costs (in man-hours) for developing a new toy amount to approximately € 11,000 (Table 5.7 further below). This is remarkably higher than the above cost estimates for standards, even more so as a new toy may only require the application of a few standards, because the majority of standards are targeting specific toys. Also, knowing that the toy industry is innovative, with around one third of the toys on the market each year being newly developed,[205] the estimated yearly costs for updated standards appears in a different light, in particular if a company develops several new toys every year.

On the other hand, missing standards, respectively standardised test methods, equally cause significant costs. Without standardised test methods, EC-type examination is necessary if a certain hazard in a toy cannot be tested with a method included in a harmonised standard referenced in the Official Journal. Companies replying to the 2018 public consultation confirmed these costs of missing standards (16 out of 32 respondents), and the results of the 2019 survey of economic operators confirmed that view. More specifically all respondents to the survey agreed that a lack of standards or standards that are not referenced on time is causing additional cost because EC-type examination becomes necessary.

Testing of toys, as of any other product, entails considerable laboratory costs. This includes the operation and maintenance of the laboratory and its equipment as well as costs for hiring the appropriate staff. Tests need normally sophisticated, specialised equipment and machines and, in the case of chemical tests, a permanent input of chemicals, some of which can be very expensive.

An EC-type examination by a Notified Body is more expensive than testing by a 'simple' test laboratory, because at least the costs for the review of the Technical documentation have to be added. Those are typically in the order of € 500.- . If test methods or test

[203] 2015 external study, Table 7, p. 79; p. 95. See footnote further above.

[204] EN 71-1, EN 71-2, EN 71-3, EN 71-4, EN 71-5, EN 71-7, EN 71-8, EN 71-12, EN 71-13, EN 71-14.

[205] The European Toy Industry (TIE), Facts and Figures. See footnote further above.

protocols have to be developed, such as for innovative features in toys, costs will further increase. There is however no general estimation of such costs. [206]

The higher testing costs are however not the most important issue. Toys requiring EC-type examination are often innovations and a manufacturer may already have invested a lot into its development. The biggest problem is the time to the market. The market is used to getting quick results, but EC-type examination is often considered too long a process for manufacturers. The main issue is to collect and complete the Technical documentation, which can cause delays.[207] On the other hand, collecting the documents necessary for the Technical documentation is also required when a manufacturer is self-certifying his toys.

The responses to the 2018 public consultation noted that testing costs under the Toy Safety Directive have considerably increased compared to the predecessor Directive (7 out of 7 responses from Notified Bodies). This is certainly due to the increased safety requirements, in particular on chemicals, under the Toy Safety Directive.

The Toy Safety Directive requires a range of documents accompanying a toy to be translated in a language that is well understood in the Member State(s) in which the toy is placed on the market. This includes instructions and safety information on the toy,[208, 209] information and documentation on the conformity of the toy,[210, 211] warnings and the safety instructions,[212] the EC declaration of conformity,[213] the technical documentation and correspondence relating to the EC-type examination,[214] and finally relevant parts of the technical documentation.[215]

Nevertheless, translation costs were not signalled as a major cost in the 2018 public consultation. Only the costs for affixing warnings in different languages were commented as costly by companies who indicated that warnings should therefore be replaced by pictograms.

An attempt was made to quantify the costs related to different requirements of the Toy Safety Directive. According to the results of the 2019 targeted consultation of economic operators (37 respondents in total, but only 32 replies could be taken into account),

[206] Information from the NB-Toys group.

[207] Information from the NB-Toys group.

[208] Article 4(7) of the Toy Safety Directive.

[209] Article 6(4) of the Toy Safety Directive.

[210] Article 4(9) of the Toy Safety Directive.

[211] Article 6(9) of the Toy Safety Directive.

[212] Article 11(3) of the Toy Safety Directive.

[213] Article 15(2) of the Toy Safety Directive.

[214] Article 20(5) of the Toy Safety Directive.

[215] Article 21(3) of the Toy Safety Directive.

testing and documentation activities require on average around 43% of the total man-hours. These activities include: testing the quality and compliance of the raw materials for the toy; testing the toy; generating the conformity assessment, obtaining an EC-type examination certificate, generating the EC declaration of conformity and generating the technical documentation.

Around one third of the time is devoted to safety aspects such as identifying all applicable safety requirements, generating the safety assessment, applying chemical amendments of the Toy Safety Directive or new specifications in standards, identifying the necessary tests and obtaining supply chain information.

Activities connected to packaging take around 12% of the time (designing the packaging, selecting the packaging material and testing whether the packaging is fit for purpose). Labelling takes 7% of the time. This includes identifying how to apply the CE mark on the toy and how to affix it (Article 17 of the Toy Safety Directive); identifying the applicable warnings and the marking of the warnings; and identifying the traceability elements and marking them on the toy. Other activities include the filing of documents.

Table 5.7. Cost of developing a toy in percentage of man-hours per toy type

Activity	% of man-hours	Cost in Euro
Safety aspects		
Identifying all applicable safety requirements.	8	900
Generating the safety assessment	6	700
Applying a chemical amendment of the Toy Safety Directive or a new specification in a standard.	7	800
Identifying the necessary tests.	5	500
Getting supply chain information.	6	700
Total Safety aspects:	**33**	3,600
Testing and documentation		
Testing the quality and compliance of the raw materials for the toy.	7	800
Testing the toy.	9	900
Generating the conformity assessment.	6	700
Obtaining an EC-type examination certificate.	5	500
Generating the EC declaration of conformity.	5	500
Generating the technical documentation.	12	1,300
Total Testing and documentation :	**43**	4,700
Labelling		
Identifying how to apply the CE mark on the toy and affixing it (Article 17 of the Toy Safety Directive).	2	200
Identifying the applicable warnings and marking the warnings.	3	300
Identifying the traceability elements and marking the toy.	2	200
Total Labelling:	**7**	700
Packaging		
Designing the packaging.	6	600
Selecting the packaging material.	3	400
Testing that the packaging is fit for purpose.	3	400
Total Packaging:	**12**	1,400
Other		
Other man-hours	4	500
Total Other:	4	500

Total all activities	**100**	10,900
Total man-hours for all activities for developing a toy type	**485**	

The average number of man-hours per activity per imported/distributed toy type is assumed to be the same for all EU countries, multiplied by an adjusted average hourly wage (adjusted by price change to 2017 levels, non-labour costs and 25% overhead) of Technicians and associate professionals ISCO 3; for Croatia wage data of Slovenia is used.

Source: Own analysis based on targeted survey

The 2008 IA provided some illustrative estimations of cost impacts for different economic operators and identified a number of factors that can determine the extent of the costs faced, including:

- product type: a large disparity was found in the costs of CE marking between companies producing plush or wooden toys and toys that are manufactured from plastic or metal;
- volume produced: the higher the turnover and the higher the volume a company produces, the lower the cost impacts will be, due to economies of scale in production; and
- number of product lines: the larger the number of different products produced, the higher the costs, as risk and conformity assessment procedures have to be carried out for each product separately.

The 2019 targeted consultation of economic operators confirmed some of these assumptions. Manufacturers confirmed that costs increase with stricter requirements and with the number of different toys they produced. To a lesser extent producers agreed that compliance cost diminishes with higher production volume or turnover. There was general agreement that SMEs have difficulties dealing with costs imposed by the Toy Safety Directive. (Table 5.8)

Table 5.8. Costs caused by the Toy Safety Directive in general

	All answers	
	% agree*	**% disagree***
SMEs have difficulties dealing with the costs induced by the Toy Safety Directive.	100	0
The constant changes to the Toy Safety Directive cause continuous costs to a company.	96	4
The stricter the requirements, the larger the costs.	95	5
The larger the number of a company's product lines, the larger the costs.	90	10
The larger a company's production volume, the smaller the costs.	75	25
The larger a company's turnover, the smaller the costs.	57	43

*Agree combines 'agree entirely' and 'agree' answers, Disagree combines 'disagree entirely' and 'disagree' answers, 'Neither agree nor disagree' and 'no opinion' answers ignored; number of replies per reason was between 18 and 24.

Source: Own analysis based on targeted survey

Importers spent on average 110 man-hours per toy type to comply with the Toy Safety Directive requirements which cost them about € 2,500. This time is evenly spent on ensuring that: appropriate conformity assessment procedures have been carried out by the manufacturers; that the manufacturer has drawn up the technical documentation; that the toy bears the required conformity marking; that the toy is accompanied by the required documents; and that the manufacturer has complied with the traceability requirements (identification of the toys, manufacturer's name and address).

The one **distributor** who replied spent 86 man-hours per toy type (i.e., the cost estimated at about € 1,950) to verify that: toys bear the required conformity marking; that toys are accompanied by the required documents and by instructions and safety information in a language or languages easily understood by consumers in the Member State in which the toy is going to be sold; that the manufacturer and the importer had complied with the traceability requirements (identification of the toys, manufacturer's name and address, importer's name and address) (table 5.9). This estimate cannot be compared with the 2008 IA where the increase of costs for chemical provisions for importers was estimated at 6%.

Table 5.9. Cost of developing a toy in percentage of man-hours per toy type

Activity	% of cost	Cost, €
Importers		
Ensuring appropriate conformity assessment procedures have been carried out by the manufacturers.	21%	516
Ensuring that the manufacturer has drawn up the technical documentation.	21%	516
Ensuring that the toy bears the required conformity marking.	17%	418
Ensuring that the toy is accompanied by the required documents.	22%	548
Ensuring that the manufacturer has complied with the traceability requirements (identification of the toys, manufacturer's name and address).	21%	516
Total man-hours and cost for importers:	110	2,514
Distributors		
Verifying that toys bear the required conformity marking.	33%	651
Verifying that toys are accompanied by the required documents and by instructions and safety information in a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market.	33%	651
Verifying that the manufacturer and the importer have complied with the traceability requirements (identification of the toys, manufacturer's name and address, importer's name and address).	33%	651
Total man-hours and cost for distributors:	86	1,953

Note: average number of man-hours (both internal staff and external consultants) per year devoted to each activity per toy type. Distribution per activity based on weighted average of ranges selected by respondents (available ranges 0-4 man hours, 5-10, 11-20, 21-35, >35). Middle of range used, no replies in the open range.

Source: Own analysis based on targeted survey

The average number of man-hours per activity per imported/distributed toy type is assumed to be the same for all EU countries, multiplied by an adjusted average hourly wage (adjusted by price change to 2017 levels, non-labour costs and 25% overhead) of Technicians and associate professionals ISCO 3; for Croatia wage data of Slovenia is used.

Values for importers are based on responses of only five firms (all SMEs), and values for distributers are based on replies of only one micro firm.

Source: Own analysis based on targeted survey and Eurostat Structure of Earnings Survey 2014

For distributors the Toy Safety Directive has produced a significant increase in costs according to the JRC study. This increase was observed both in the period 2009 − 2013 (about 14%) and from 2013 onwards (about 10%). The increase in costs is significant in 2011 – 2012, and a strong impact was detected for the group of small and micro distributors (about 15%) in both 2009 and 2013. This suggests that the increased costs incurred by the manufacturers has been passed on to distributors / importers in the form of an increased price of the final product.

Public authorities are burdened with getting the documentation that has to accompany a toy from the economic operators. In the 2018 public consultation with 31 responding

public authorities, 16 considered it costly or very costly to get the safety assessment, 14 to get the technical documentation, 13 to get the EC-type certificate and 11 to get the EC declaration of conformity. These results were confirmed by the 2014 – 2018 national reports of the Member States, most of which observed that economic operator (and specifically the SMEs) have difficulties in identifying their obligations under the Toy Safety Directive.

It appears therefore that in the above cases, economic operators save on the costs for the required Technical documentation, thus increasing their competitiveness, unless they are caught by market surveillance authorities. On the other hand, authorities have to bear costs that would be unnecessary if all economic operators would play by the rules.

Finally, enforcing the Toy Safety Directive in online sales causes significant costs, as signalled by 16 (out of 31) responding public authorities in the 2018 public consultation. These costs result among others from the extended time needed to get hold of online providers who place non-compliant products on the market, sometimes in vain. Online toy surveillance was also identified as a concern by different Member States in the national reports they submitted for 2014 – 2018. However, a comparison with results from the previous reporting period (2009 – 2013) was not possible, since data on online sales were not reported in that period.

Market surveillance authorities do not have available the necessary tools for checking online sales as they have them for traditional sales. An improvement of the situation can be expected from the Regulation on market surveillance and compliance of products that will be applicable from 2021, because it includes binding obligations for economic operators in order to support authorities in their work. According to Article 7(2) of the Regulation, '[i]nformation society service providers shall cooperate with market surveillance authorities … to facilitate any action to eliminate … the risks presented by a product … offered for sale online …'.

5.2.1.4.Costs related to amendments of the Toy Safety Directive

In the period of 2012 − 2018 there have been 12 amendments of the Toy Safety Directive (see annex 4), which have been primarily strengthening the limit values for CMR substances. In the 2018 public consultation, all stakeholders, in particular companies and business associations, signalled that amendments of the Toy Safety Directive are costly (Table 5.10).

Table 5.10. It is costly to adapt to amendments of the Toy Safety Directive (% of respondents*)

Stakeholders responding**	Agree entirely/ Agree	Neither agree nor disagree	Disagree/ Entirely disagree	No opinion
Companies (32)	80	10	0	10
Business associations (12)	80	0	0	30
Notified bodies (7)	100	0	0	0
Public authorities (31)	50	30	10	10
Consumer organisations (6)	70	20	0	20

* Rounded to the nearest 10%, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

This was also confirmed by the results of the 2019 targeted consultation of economic operators. The reported average annual cost caused by amendments to the Toy Safety

Directive (such as the introduction of new restrictions on chemicals that can be used) was on average 1.4% of the annual turnover[216]. It amounted to 1.7% in case of SMEs and 0.6% in case of large companies. The median value was lower and stood at 1% of the turnover for all companies and for SMEs, and at 0.4% for large companies.

In monetary terms this cost amounted to € 3.3 million per large firm in the consultation, and € 207,000 per SME. Or taking into account the number of toy types produced by companies: € 6,500 per toy type produced by large firm and € 7,700 per toy type produced by SMEs[217] (Table 5.11).

Table 5.11. Cost of implementation of amendments to Toy Safety Directive

	All manufacturers	Large	SMEs
% of turnover (average*)	1.4%	0.6%	1.7%
% of turnover (median)	1%	0.4%	1%
Euro per company		€ 3.3 million	€ 207,000
Euro per company per toy type		€ 6,500	€ 7,700

Note: Average values based on 16 replies for all, 2 for large companies and 11 for SMEs
* Excludes two extreme values of 10% and 15% reported by SMEs.
Source: Own analysis based on targeted survey

5.2.2. Costs for SMEs

From the different sources of information used for this Evaluation, it appears that in general SMEs have difficulties dealing with costs imposed by the Toy Safety Directive. SMEs' low production volume fails to reap economies of scale benefits and to compensate initial investments. The costs in terms of turnover thus might affect SMEs disproportionately.

Also SMEs themselves denounced the high costs caused by the Directive. This concerned the one-off adaptation costs to the 2009 Toy Safety Directive as well as a higher cost increase due to the Directive (compared to the predecessor Directive), in particular due to the safety requirements and the safety assessments as such. Also the amendments to the Toy Safety Directive (such as the introduction of new restrictions on chemicals that can be used) costed more to SMEs in terms of annual turnover than to large companies.

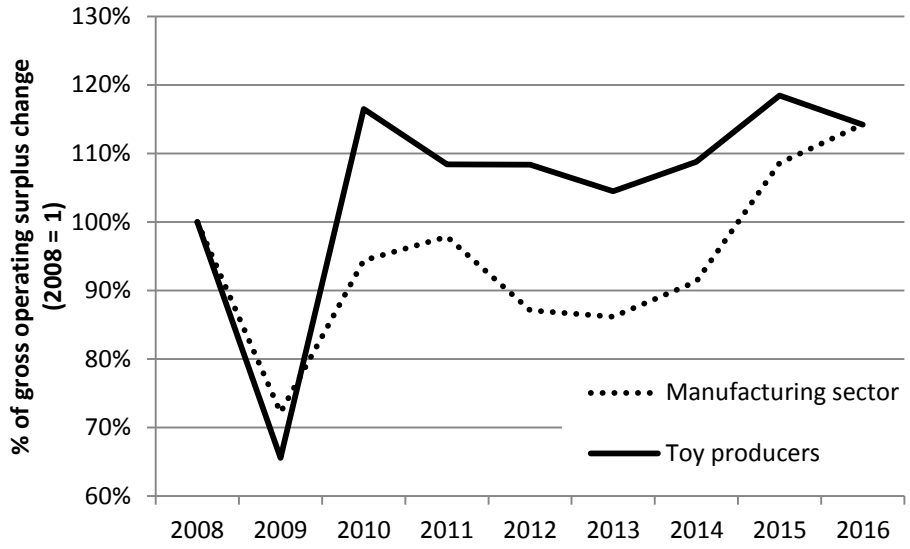
The increase of costs due to the Directive could have had an impact on the profits of the firms which in 2009 dropped even deeper than for the whole industry (Fig. 5.3).[218] However, from 2010 to 2015 the profits of the toy industry were systematically higher than for the manufacturing sector as a whole, suggesting that the full applicability of the Toy Safety Directive since mid-2013 did not hinder the cost competitiveness of the toy industry.

[216] Based on 16 observations. Excludes two extreme values of 10% and 15% reported by SMEs.

[217] Calculated average value based on response to question on percentage of turnover (excludes two extreme values of 10% and 15% reported by SMEs) and reported turnover in 2017, based on 13 responses – 2 large and 11 SMEs.

[218] Please note that there may be many other factors explaining that difference.

Fig. 5.3. Development of profit per firm since 2008 for toy producers and manufacturing sector



Note: Gross operating surplus[219] per firm in NACE C324 "Manufacture of games and toys" and NACE C "Manufacturing", 2018 prices.
Source: Eurostat, [sbs_na_ind_r2], [prc_hicp_aind]

SMEs were reported to have limited staff, lacking specific skills such as those of legal experts or chemists. Therefore, identifying their obligations under the Toy Safety Directive is difficult and, when faced with new legislative requirements, SMEs turn to external consultants, significantly increasing overall costs. Also, due to the limited capacity of their laboratories – as regards both economic resources and competences – SMEs have to recur to external testing laboratories or Notified Bodies to ensure compliance with the Directive. This again increases the costs.

However, there is no evidence on a possible reduction of these costs by means of national legislation – instead of an EU Directive – on the safety of toys, nor do SMEs point to any benefit stemming from national rather than EU rules. National rules were not considered to be more beneficial.

Finally, figures from the association of the European toy industry[220] suggest that 500 new companies have entered the sector between 2013 and 2017. This resulted in a total of 5,600 toy companies in the EU, of which 99% are SMEs. It may appear therefore that, despite the high(er) costs for SMEs, the toy sector was attractive enough in particular for SMEs, so that the number of toy companies increased by some 10% within five years.

[219] Gross operating surplus or profits is defined, in the context of structural business statistics, as value added minus personnel costs. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Gross_operating_surplus_-_SBS

[220] The increase in number of SMEs in the sector is also confirmed by the Eurostat data. See section 2.1.1.

5.2.3. Are there any costs of consumers

Almost all manufacturers (91%) responded in the 2019 targeted consultation of economic operators that their production costs had increased since July 2013. It may thus be argued that prices for toys could consequently increase. However, only ¼ of the economic operators reported a significant price change in general; more than one third considered that prices had remained approximately unchanged, and some more gave no answer.

On average, the respondents to the consultation reported a 2.9% toy price increase since 2013. According to Eurostat between 2013 and 2018 all prices rose by 5% while prices of 'games, toys and hobbies' declined by 2%.[221] To note that the reported cost increase was higher and amounted to 6.8%. This suggests that not all costs were transmitted to consumers, and companies internalised 2 – 4 percentage points of the cost increase (see also annex 3).

No clear indications were given as to the reasons for any price increase: 75 – 80% did not express themselves on any potential reason suggested: Higher demand for toys; toys are more complex/advanced; toys are generally of better quality; increased transport costs; new requirements of the Toy Safety Directive (namely those in addition to the former Toy Safety Directive); external factors (crisis); lower demand for toys. The option to report any 'other' reason for a price increase remained unanswered by all. - Analogous questions relating to a potential price decrease remained without any answer.

Thus, it seems that the Toy Safety Directive has not lead to a major price increase of toys, but certainly not to a price decrease. The increased costs appear to have been partly internalised by companies.

5.2.4. Benefits of the Toy Safety Directive

The benefits of the Toy Safety Directive in terms of safety could in principle be confirmed by a lower number of toy-related accidents and injuries. They could also be indicated by a higher number of toys restricted from the market and by a reduced trade in toys, at least for a certain period after the introduction of the Directive and until toy manufacturers have adapted to the Directive.

However, as explained further above,[222] these figures are either not existing, incomplete or may be confounded by many other factors. As a result, it appears impossible to draw unambiguous quantitative conclusions on the benefits of the Toy Safety Directive. Nevertheless it can more generally be noted that the overall proportion of child-product related injuries with children younger than 14 years in the IDB ranged from 0.01% to 0.04% of the total. This can be considered to be comparably low.

Already the 2008 IA[223] tried to estimate the (future) benefits of Directive, naming for example the reduction of the number of toy-related accidents and 'significant health benefits in medium and long term'. However the statistics on accidents available then did

[221] Eurostat HICP, prc_hicp_aind, last update: 17-04-2019

[222] See section on Limitations of available data further above and annex 3 for a detailed explanation.

[223] See 2008 IA, section 8.2.

not allow to quantify the benefits. The new chemical requirements were estimated, on the basis of questionnaires to stakeholders such as manufacturers or environmental groups, to provide financial benefits of almost € 13 billion. However the 2008 IA also noted that figures on the basis of questionnaires 'may not be fully reliable because of the inherent stakeholder's interest in the assessment.'

The 2008 IA noted, as direct benefits to industry, a reduced legal uncertainty as to the definitions and roles of economic operators and the definitions of toys, as well as the clarification of the responsibilities of the Member States' surveillance authorities, thereby protecting legitimate manufacturers, suppliers and distributors from counterfeit products and questionable imports. The 2008 IA however also noted that '[t]hese benefits cannot be quantified based on the available data.'

The 2008 IA further noted that Member States' authorities expected significant benefits from the many changes proposed for the Toy Safety Directive, including from the modified definitions of toys and of economic operators. The latter could be 'reducing legal costs if a consumer or the relevant body takes an economic operator to court.'

When asked about possible benefits of the Toy Safety Directive in the 2018 public consultation, companies, business associations and public authorities acknowledged widely (60 – 80%) that the detailed provisions of the Toy Safety Directive ensure legal certainty and a level playing field (annex 8). Notified Bodies and consumer organisations however were less enthusiastic about it (30 – 40%) or preferred to be neutral (30 – 70%).

Moreover, as indicated by companies and business associations/organisations in the context of the public consultation (see annex 2), among the benefits of the Toy Safety Directive is the fact that the CE mark is considered as helpful when selling toys to customers and outside the EU, which can be seen as evidence that the CE mark brings an added value to the companies in terms of reputation.

Also, stakeholders appreciated that the safety assessment is a good tool to ensure the safety of toys (70 – 90%), only consumer organisations were less convinced (70%) (annex 8). Economic operators reported in the 2019 targeted consultation that the safety assessment allows companies to focus on the relevant safety aspects of a toy (60%), and thus helps to reduce (testing) costs (50%) (annex 8).

5.2.5. Balance of benefits and costs

Whereas it does not appear possible to quantify the benefits of the Directive (see above), costs related to the Toy Safety Directive have been quantified to a certain extent (see further above). As a result, however, it is not possible to provide a quantitative balance of benefits and costs. Even qualitatively it does not appear possible, for example, to counterweigh 'reduced legal uncertainty' or 'added value in terms of reputation' against increased monetary costs due to more stringent safety requirements, which in turn provide a benefit due to the higher level of protection for children.

Nevertheless, in the 2018 public consultation, half of the companies and business associations considered that the benefits of the Toy Safety Directive outweigh the costs, sometimes even by far (Table 5.12). A further 20% of the companies considered the costs proportionate to the benefits, and some 30% of the companies and business associations

noted that the costs would (by far) outweigh the costs. – The other stakeholders highlighted even more that the benefits of the Toy Safety Directive outweigh the costs.

Table 5.12. How do the benefits of the Toy Safety Directive compare to its costs? (% of respondents*)

Stakeholders responding**	The benefits /by far/ outweigh the costs	The costs are proportionate to the benefits	The costs /by far/ outweigh the benefits	No opinion / Don't know
Companies (32)	50	20	30	0
Business associations (12)	50	0	30	30
Notified bodies (7)	60	40	0	0
Public authorities (31)	60	20	0	20
Consumer organisations (6)	80	0	0	20

* Rounded to the nearest single significant number, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

Considering the benefits as outweighing the costs may be due to the fact that the protection of children is highly valued in society and that, therefore, 'any cost' is justified. Reputable toy manufacturers may therefore prefer to acknowledge this societal attitude and rather tend declare that the benefits (by far) outweigh the costs.

Importantly, however, the reportedly increased costs resulting from the Toy Safety Directive (in comparison with its predecessor Directive) did not prevent new companies to join the toy sector. Figures from the association of the European toy industry suggest that 500 new companies have entered the sector between 2013 and 2017. This gave a total of 5,600 toy companies in the EU, of which 99% are SMEs.[224] It may appear therefore that the toy sector was attractive enough, in particular for SMEs, so that the number of toy companies increased by some 10% within five years, and this despite the full applicability of the increased number of requirements of the new Toy Safety Directive, including chemical, as of mid-2013, and the related costs.

On the other hand, in the eyes of the association, there are many other external factors to take into consideration, such as the impact of the economic crisis in the period 2008 – 2013. There might have been a return to the 'normal' level as of 2013, and lately e-Commerce and considerable changes in the retail channels (such as the Toys 'r' Us going out of business) have been of influence. It is therefore difficult to make assumptions on a direct impact of the Toy Safety Directive on the number of companies in the sector, especially as there are no data available on the impact of the economic crisis on the toy sector.

5.2.6. Is there scope for simplification?

Obligations of economic operators

The Toy Safety Directive appears to be quite complex due to its many obligations imposed in particular on the manufacturers of toys. Manufacturers not only have to ensure that their toys comply with the (safety) requirements, but also have to document

[224] Toy Industries of Europe. The European toy industry. Flyer designed in July 2017. https://www.toyindustries.eu/wp-content/uploads/2018/01/TIE-EU-Toy-Sector-Facts-and-Figures-FINAL.pdf

this unambiguously and keep the documentation for 10 years. Even after having placed the toy on the market, they have to monitor it and take action if they consider or have reason to believe that the toy is not compliant, even at the price of recalling it from consumers.

Importers have less obligations than manufacturers, and distributors even less, but both have to ensure that only compliant (and thus safe) toys are available on the market.

In practice, economic operators may not know their obligations. Even the most basic document, the EC Declaration of Conformity of the manufacturer, may be difficult to obtain or might be incorrect. This was reported by 15 - 16 of the 27 Member States' 2014 – 2018 national reports, available at the time of writing. According to these reports, also the Technical documentation is difficult to obtain or incorrect, and the safety assessment, which is part of the Technical documentation, is no better, as reported by 5 – 9 of the 27 Member States.

On the other hand the Directive leaves far-reaching freedom to economic operators, and in particular to manufacturers: they can decide when to start the development of a toy, how to design it, how, where, when and by whom to have it tested for safety, where to have it manufactured at what price, and when and where to place it on the market. Except in particular circumstances where the intervention of a third party is required (namely for EC-type examination), there is no intervention of, or fee to be paid to, any third party in the entire process that could delay or block the entry of a toy on the market. Manufacturers are free to decide on their way of action, in cooperation with importers and distributors as appropriate.

Also, there is a good body of tips[225] and guidance[226] available for manufacturers, importers, distributors and any other stakeholders, including on the applicable legislation[227] and including flow-charts, suggested templates for checklists and actual examples in particular in the 'Technical documentation guidance document'. Most of the guidance is available in all EU languages and in Chinese.

Of course all this assistance cannot provide immediate answers to very specific questions on toys (and non-toys) manufactured under specific circumstances, however its existence has been appreciated by stakeholders when they contacted the Commission services to inquire about specific details.

Weighing the obligations and the freedom for economic operators including the available tips and guidance against the need to protect children therefore suggests that the balance is about right, and a simplification entailing fewer obligations would run the risk of losing protection for children.

[225] Steps for manufacturers; Steps for importers; Steps for distributors. https://ec.europa.eu/growth/sectors/toys/placing-on-eu-market_en

[226] Guidance on Toy Safety. https://ec.europa.eu/growth/sectors/toys/safety/guidance_en

[227] Legislation. https://ec.europa.eu/growth/sectors/toys/safety/legislation_en

Third-party approval

For a toy manufacturer the self-certification conformity assessment can be burdensome, among others due to the need to identify the appropriate test methods for his toy. On the other hand, a conformity assessment via an EC-type examination leaves the testing to a third party, the Notified Body.

However, in both cases the Technical documentation has to be put together, which is time-consuming, and it can even cause delays.[228] Getting a third party approval thus appears to add a further delay to the marketing of a toy, and additional costs.

In addition, if all toys were to be subject to an EC-type conformity assessment, this would require a considerable increase in the number of notified bodies, since only around 3% of the toys in the EU market have so far been subject to third-party testing.[229] Linked to this would be considerable more efforts, and costs, to control laboratories' quality.

To note that, in the 2018 public consultation, an association of Notified Bodies suggested that toys for children under 3 years of age be required to pass an EC-type examination as carried out by Notified Bodies.

Placing all limit values for chemicals in a single piece of legislation

Limit values for chemicals in toys can not only be found in the Toy Safety Directive but also in other pieces of EU legislation such as REACH, CLP or the RoHS Directive. Identifying the limit values applicable to a toy can therefore be cumbersome. Placing all limit values in a single piece of legislation could relieve from this burden.

Considering the Toy Safety Directive to be this single piece of legislation – a 'one-stop-shop' – would have several benefits. All economic operators, Member States' market surveillance authorities and any other stakeholder would find all information in the Directive they are acquainted with, the limit values could be specifically targeted to the needs of the Toy Safety Directive since the necessary expert knowledge in particular on the exposure from toys would be readily available, any double testing to fulfil the requirements in different pieces of legislation could be avoided, and there would be no confusion or risk of overlapping since only the limit values in the Toy Safety Directive would have to be taken into account. All this could foreseeably simplify the application of the Directive and thus offer benefits for all.

Ensuring consistency with other pieces of legislation

In the 2018 public consultation stakeholders reported complexities and overlaps of the Toy Safety Directive with other pieces of legislation as regards inconsistent requirements and chemical limit values (see section 5.4 Coherence). None of these perceptions was however substantiated with clear, specific evidence or at least illustrative examples.

The latter appears to confirm the experience of the Commission services that there are no two chemical limit values for toys that would contradict each other (apart from the limit values for nitrosamines and nitrosatable substances (see section on 'Effectiveness')).

[228] Information from the NB-Toys group.

[229] Information from the NB-Toys group.

Stakeholders may however have understood the question 'Are you are aware of any different limit values for chemicals in other EU or national legislation?' in a wider sense, and indeed there are migration limit values for certain metal elements in the Toy Safety Directive, but content limit values for some of those elements in REACH and in the RoHS directive (see section 5.4 Coherence). Also, when two limit values of the same kind apply to the same (toy) material, the stricter limit value applies because the less strict value is then also complied with. Thus, although the applicable limit value can always be identified unambiguously, there can be confusion and a more or less considerable effort to identify the applicable limit value, which lowers the efficiency of the Directive.

5.3. Relevance

5.3.1. Is the Toy Safety Directive's requirement that toys have to be safe still relevant?

In light of the many unsafe toys on the market, as shown by the weekly notifications on the EU Safety gate RAPEX, the safety requirements of the Toy Safety Directive still play a crucial role. These requirements, supported by standards providing the technical specifications and test methods to check compliance with the requirements, give market surveillance authorities the means to restrict dangerous toys from the market before they can affect the health of children. The Toy Safety Directive is, therefore, a relevant policy measure for the safety of toys, in that it requires that all toys placed on the EU market comply with its safety provisions that are specific for the different risks possibly inherent to toys.

The requirement that toys be safe has undoubtedly been confirmed to be relevant by at least a very large majority, if not all, stakeholders (Table 5.13) in the 2018 public consultation.

Table 5.13. The Toy Safety Directive requires toys to be safe. Is this objective (still) relevant? (% of respondents*)

Stakeholders responding**	To a large extent	To a moderate extent	To some extent / To a small extent / Not at all	Don't know
Companies (32)	80	10	0	0
Business associations (12)	100	0	0	0
Notified bodies (7)	90	10	0	0
Public authorities (31)	90	10	0	0
Consumer organisations (6)	100	0	0	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

The many detailed safety requirements in the Toy Safety Directive were considered as helpful by a 70% majority of companies and of business associations (Table 5.14) in the 2018 public consultation. Those details were rated definitely higher by Notified Bodies, public authorities and consumer organisations.

Table 5.14. The Toy Safety Directive provides for many detailed requirements on toys' physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity. Is it helpful that the Toy Safety Directive includes that many details? (% of respondents*)

Stakeholders responding**	To a large extent	To a moderate extent	To some extent / To a small extent / Not at all	Don't know
Companies (32)	70	10	20	0
Business associations (12)	70	10	20	10
Notified bodies (7)	100	0	0	0
Public authorities (31)	80	10	0	0
Consumer organisations (6)	100	0	0	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

The 12 adaptations of the Toy Safety Directive to technical and scientific developments between 2012 and 2018 (see annex 4) have primarily been adding stricter limit values for chemicals in toys. In the eyes of stakeholders they however do not appropriately reflect the developments that have been taking place (Table 5.15). While about half of the companies and business associations concede that the Directive is up-to-date to a large or moderate extent, Notified Bodies, public authorities and consumer organisations rather see the Directive as being moderately up-to-date, or less.

Table 5.15. Do changes to the Toy Safety Directive appropriately reflect all the latest technical, scientific and social developments? (% of respondents*)

Stakeholders responding**	To a large extent	To a moderate extent	To some extent / To a small extent / Not at all	Don't know
Companies (32)	30	20	40	10
Business associations (12)	30	30	40	10
Notified bodies (7)	0	40	60	0
Public authorities (31)	10	40	30	20
Consumer organisations (6)	0	30	70	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

In their comments,

- Companies and business associations noted that changes to the Toy Safety Directive were made through a 'political' approach: Limit values would only be made stricter, but if scientific evidence indicated the contrary, limits would not be released accordingly. Companies mainly referred to the application of recital 22 of the Directive[230] in connection with the strengthening of the limit value for lead, since

[230] Recital 22: 'The specific limit values laid down in Directive 88/378/EEC for certain substances should also be updated to take account of the development of scientific knowledge. Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.'

recital 22 requires setting the limit value for lead (and five other hazardous metal compounds) at half of what science commands, due to lead (and the five other compounds) being 'particularly toxic'. Similar concerns for 'political' limit setting had been raised in the 2015 external study. Points anecdotally referred to in the comments were nano particles, the absence of risks from books, the treatment of personal data and the respect for human rights in toy manufacture.

In reply to these comments it has to be said that a limit value for a chemical is set on the basis of a risk assessment of that chemical, which is a scientific exercise. Deriving then a limit value from the risk assessment is linked to the question how much risk a society is ready to accept. For example, in the limit-setting for carcinogens: is it acceptable that 1 person in 100,000 may get cancer, or should it be 1 in a million? No science can provide an answer to this, it is thus a political decision, a decision in light of the societal background.

Against this background it is difficult to make a limit value less strict, even if science suggests that the risk would not increase beyond what society tolerates. On the other hand, science evolves and may well provide new evidence that a chemical is more toxic than established previously. A prominent example of this is the toxicity of lead which, although well-known for decades, was recognised to harm children's intelligence in even smallest amounts. The limit value for lead in toys therefore had to be made 7-fold stricter (see above).

- Notified Bodies considered that the Toy Safety Directive missed out the recent risks linked to data and privacy protection. In the 2015 external study of the Directive, Notified Bodies were only concerned about the inclusion (or not) of slings and catapult in the Directive.

  As a reply it has to be said that the Toy Safety Directive does indeed not cover privacy, this would require a new Directive. The same goes for toy slings and catapults which, although being toys in light of the Directive, are excluded from its scope.[231]

- Public authorities equally commented most often about the missing coverage of data and privacy protection, but also referred to the inadequacies of the Toy Safety Directive concerning CMRs, nitrosamines, the 'rapidly evolving market' and the slow adaptation process in general. This is different from the 2015 external study where authorities had generally confirmed the relevance of the adaptation mechanisms.

  In reply it can be said that a new Directive would be necessary to take account of the comments on privacy (see above), CMRs and nitrosamines (see further above). The claimed slowing down of the adaptation process since 2015 was probably due to the need to collect sufficient technical and scientific evidence to ensure that the amending directives could resist any potential legal challenge, including before the WTO.

- Consumer organisations called for broadening the scope for changes of the Toy Safety Directive, Article 46 would be too limited. Market changes and new risks

[231] Article 2(2) of the Toy Safety Directive.

could require to change the Directive's scope, to identify toys that needed third party testing, to ban certain toys or set chemical limit values for any kind of toy (not only for toys intended for the under 3 and for toys intended to be placed in the mouth). Similar concerns had been voiced in the 2015 external study.

These comments, which had also been raised by the other stakeholders above, effectively call for a new Toy Safety Directive adopted by the EU co-legislators.

5.3.2. Is the Directive still relevant in view of new type of risks such as cybersecurity?

Consumers are increasingly using connected devices in their daily lives. While the number of connected products is rising, many of these products are manufactured without even basic security features in their system. This lack of security increases the risk that consumers become victims of malicious cyberattacks.

Internet-connected toys were not relevant for the Toy Safety Directive when adopted, since such toys did not exist at that time. There are therefore no specific rules in the Directive to address the risks that internet-connected toys can present. In the meantime, more and more toys which can connect to the internet have come to the market. 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.

In the present evaluation the issue of security of internet-connected toys came out as a relevant concern. Already in their reply to the Roadmap of the present evaluation (see annex 2, section III) 4 stakeholders[232] expressed their concerns about internet-connected toys and related security and data privacy threats. They requested that the scope of the Toy Safety Directive be extended to include new safety requirements on information security which cannot be addressed by the Directive in its current version.[233] This is because the safety requirements covered by the Toy Safety Directive are limited to health and safety (see the particular safety requirements in Annex II: physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene, radioactivity[234]) and do not cover information security. The Toy Safety Directive therefore cannot address the security threats that new technologies pose. As the Toy Safety Directive does not have specific requirements for internet-connected toys, they would be covered horizontally by the General Product Safety Directive, as long as they might have an impact on the safety of consumers. For example, one notification in the Safety Gate RAPEX clearly refers to the vulnerability of a smart watch which could lead to localisation of children by intruders.

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[232] 2 consumer organisations, a federation and a Notified Body.

[233] Feedback on the Roadmap is available at: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3667279_en

[234] See section 2.1.2 above.

According to respondents, the concept of 'safety' in the Toy Safety Directive is too narrow and fails to protect children from the security flaws of connected devices thereby jeopardising their safety. A 2016 report by the Norwegian Consumer Council[235] exposed security flaws in a number of Bluetooth-connected toys that left their users' data vulnerable to cyberattacks. Two campaigns, run by the national consumer organisation in 2016 (#ToyFail[236]) and 2017 (#WatchOut[237]), have echoed the inadequate security mechanisms of popular consumer connected products intended for children and sold across the EU.

A recent investigation from another national consumer organisation revealed that four out of seven connected toys tested could easily be hacked and enable anybody to use the toy to communicate with a child.[238] Another campaign run by the consumer organisations from Belgium, Germany and Spain found similar security flaws and revealed that anyone could connect to the Bluetooth network of the toys without being required to provide a password or any other type of authentication.

On these grounds, the consumer organisations requested that the General Product Safety Directive as well as product specific safety legislation including the Toy Safety Directive be updated to ensure that they are in line with the new 'security for safety' concept of the general legal framework.[239] These concerns were confirmed in respondents' contributions to the 2018 public consultation.[240]

On the other hand, it is also to be noted that the described risks of internet-connected toys are due to criminal misuse of connected toys by third parties.

Further to consumer organisations, also politicians (members of the European Parliament[241]) have been vocal in calling for an update of the safety concept in the EU regulatory framework, in order to cover these risks.

On 12 March 2019, the European Parliament adopted the EU Cybersecurity Regulation.[242] This Regulation will establish a voluntary cybersecurity certification

[235] See https://www.forbrukerradet.no/siste-nytt/connected-toys-violate-consumer-laws/

[236] #ToyFail: https://fil.forbrukerradet.no/wp-content/uploads/2016/12/toyfail-report-desember2016.pdf

[237] #WatchOut:https://fil.forbrukerradet.no/wp-content/uploads/2017/10/watchout-rapport-october-2017.pdf

[238] http://press.which.co.uk/whichpressreleases/which-issues-child-safety-warning-on-connected-toys/

[239] See BEUC position paper 'CYBERSECURITY FOR CONNECTED PRODUCTS' at http://www.anec.eu/images/Publications/position-papers/Digital/ANEC-DIGITAL-2018-G-001final.pdf

[240] See the position papers available at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3667279/public-consultation_en

[241] Ref. : http://www.europarl.europa.eu/doceo/document/E-8-2019-001470-ASW_EN.html

[242] 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 (Cybersecurity Act) (Text with EEA relevance). OJ L 151, 7.6.2019, p. 15.

framework for information and communication technology (ICT) products, services and processes in the European Union. The regulation recognises that increased digitalisation and connectivity can jeopardise cybersecurity, and that in this respect children represent particularly vulnerable consumers.

There have been calls on the European Union to adopt legislation which guarantees proper protection against the misappropriation and exploitation of data.

Connected toys usually involve processing of personal data. The General Data Protection Regulation (GDPR)[243], to be applied as of May 2018, regulates such processing, setting out, among others, rules on transparency, information security and parental consent. The GDPR includes a household exemption in Article 2(2), which can exempt certain on-device processing[244]. While the GDPR focuses on organisations processing personal data ('controllers'), its recital 78 also encourages producers of products who are not themselves controllers to take into account the right to data protection when developing and designing such products, with reference to the principles of data protection by design and by default[245], so that their products enable processing that is in line with the principles of the GDPR.

Since the Toy Safety Directive does not at all touch upon cybersecurity issues, those issues could be addressed horizontally because they are not only relevant for toys but also other Internet of Things (IoT) devices for many daily-use products. Covering certain aspects of security and privacy risks separately for toys could lead to a fragmentation of privacy and cyber security rules and thus undermine the internal market.

As all internet-connected wireless devices fall under the Radio Equipment Directive (RED)[246], the Commission has recently adopted a decision to explore whether a delegated act under that Directive can increase the security of internet-connected products whilst ensuring a level playing field for businesses. This initiative on 'Internet-connected radio equipment and wearable radio equipment' includes connected toys and seems to be supported by the toy industry[247].

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[243] 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 (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0679-20160504

[244] See by analogy for connected vehicles: EDPB Guidelines 1/2020 on processing personal data in the context of connected vehicles and mobility related applications (version for public consultation), paragraphs 70 to 75, available at: https://edpb.europa.eu/sites/edpb/files/consultation/edpb_guidelines_202001_connectedvehicles.pdf

[245] EDPB Guidelines 4/2019 on Article 25 Data Protection by Design and by Default, paragraph 1, available at: https://edpb.europa.eu/sites/edpb/files/consultation/edpb_guidelines_201904_dataprotection_by_design_and_by_default.pdf

[246] 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

[247] See TIE position at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-6426936_en

The initiative aims to assess whether a delegated act under the RED can further enhance protection by requesting manufacturers to demonstrate, as a market access condition, that their products can (1) protect the personal data and privacy (in line with the principles of GDPR), (2) protect from fraud and (3) do not harm the network to which they are connected. The Impact Assessment study has been published on the related Commission website.[248]

Delegated acts under the RED[249] could require manufacturers to demonstrate that personal data and privacy are protected before an internet-connected wireless device can be placed on the market. This would entail that, if Member States identify a radio-connected product presenting a serious risk related to personal data, privacy or fraud, a notification should be submitted through the EU Safety gate RAPEX. In contrast to this, Member States can currently only rely on national acts, if they exist, to withdraw products from the market that negatively impact data protection and privacy.

If adopted, a delegated act under the RED[250] would entail that, if Member States identify a radio-connected product presenting a serious risk related to personal data, privacy or fraud, a notification should be submitted through the EU Safety gate RAPEX. In contrast to this, Member States can currently only rely on national acts, if they exist, to withdraw products from the market that negatively impact data protection and privacy.

In conclusion, the above initiatives are expected to strengthen the security by design of internet-connected products, including toys.

5.3.3. Is the requirement on the free movement of goods in the Toy Safety Directive still relevant?

The key objective of the Toy Safety Directive to ensure the free movement of toys is directly related to the size and prominence of the toy sector, which justify the need for a common legislation easing the smooth functioning of the internal market. The considerable number of toys crossing the borders require legislative certainty on the applicable rules for placing toys on the internal market and their free movement therein. The harmonisation of national requirements is therefore crucial. The Directive indeed requires that all toys placed on the EU market comply with the same safety requirements thus eliminating possible barriers that would stem from different regulatory systems in the Member States.

[248] https://ec.europa.eu/docsroom/documents/40763

[249] Article 3(3) provides the basis for further delegated regulation governing additional aspects, empowering the Commission to adopt delegated acts in order to specify which categories or classes of radio equipment are concerned by each of the requirements set out in its points (a) to (i). The requirements referred to in points (a) to (i) relate to interoperability, emergency services, software, fraud, accessibility, privacy, personal data and misuse.

[250] Article 3(3) provides the basis for further delegated regulation governing additional aspects, empowering the Commission to adopt delegated acts in order to specify which categories or classes of radio equipment are concerned by each of the requirements set out in its points (a) to (i). The requirements referred to in points (a) to (i) relate to interoperability, emergency services, software, fraud, accessibility, privacy, personal data and misuse.

The free movement of toys in the EU market has been confirmed as highly relevant by (almost) all stakeholders, with some lesser enthusiasm from public authorities (Table 5.16) in the 2018 public consultation.

Table 5.16. The Toy Safety Directive allows safe toys to be marketed throughout the EU. Is this objective (still) relevant? (% of respondents*)

Stakeholders responding**	To a large extent	To a moderate extent	To some extent / To a small extent / Not at all	Don't know
Companies (32)	90	10	0	0
Business associations (12)	100	0	0	0
Notified bodies (7)	90	0	0	10
Public authorities (31)	70	20	0	10
Consumer organisations (6)	100	0	0	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

5.3.4. Is the current monitoring and evaluation system fit for purpose?

As explained further above, available data cannot be used to clearly identify effects of the Toy Safety Directive, since those data are often incomplete, not representative or there are too many confounding factors. This concerns data on toy-related injuries, on marketing restrictions for toys, on toy trade, on costs related to toy production, and on the feedback collected through stakeholder consultations. Any trend in such data could only vaguely be linked, if at all, to the requirements of the Toy Safety Directive, with some exception perhaps for the cost data reported by the toy industry. For example, the data from Orbitz which were used for the purpose of the present evaluation are representative but they are limited to the costs of materials, therefore the database does not allow to get the level of granularity expected for the evaluation, i. e., which provisions are driving the costs. The targeted consultation of economic operators will need to remain the main source of data for the assessment of the costs of the Directive.

Isolating the effects of the Toy Safety Directive from the many confounding factors thus appears to be very difficult. Perhaps techniques of multifactorial analyses could provide some further insight, but mathematical-statistical tools usually reflect correlations and cannot demonstrate cause-effect relationships. Effects of the Directive may however be masked by unforeseeable decisions of economic operators.

As concerns the IDB, although it is currently the largest and best available source of information on accidents and injuries in Europe, this database has however never been used for research purposes in general, nor for the evaluation of product safety or European health related programmes in particular. One possible explanation could be that the collection of data at the EU Member States' level, in particular the selection of representative reference hospitals, needs substantial improvements.

Two levels of datasets are available:

(1) IDB-MDS (minimum data set) that is used to compute European Core Health Indicators (ECHI), specifically ECHI indicator 29b "Home, leisure, school injuries: registered based incidence";

(2) IDB-FDS (full data set) that collects more detailed information in particular regarding the product category leading to the injury (EuroSafe 2013).

The MDS version has proven to be useful to create European Core Indicators (ECHI). The FDS collects valuable and detailed information, in particular on product category related injuries. The harmonised classification of product and injuries makes comparison of cases possible across recording hospitals and Member States. However, the sample feeding the FDS version would need to be improved substantially in order to be valuable in quantitative studies at the European level, in particular in the consistency of the sample over time and the representativeness of selected hospitals. To correct estimates and improve the sample, a number of methods can be implemented, as it is done already in the MDS version (extrapolation methods and corrected weighted estimates) or taking insights for instance from the system used in the US with the NEISS standardised data abstraction (EuroSafe 2016)

The FDS shows the limits of the current European system in the collection of harmonised data: enforcement of data collection and sustainable source of funding. More than 30 years of data have been collected so far but these can and have been unfortunately only be used in a very limited way, in qualitative study or case specific studies based on one hospital and one year.

Safety gate RAPEX

The impact of the Toy Safety Directive on the number of toys removed from the market in EU countries has been assessed in the JRC study based on information collected by Safety gate RAPEX, from which three product categories were used as control groups, and three geographic areas were considered. The usefulness of the Safety gate RAPEX data is that they reflect the activities of the market surveillance authorities on the dangerous toys that they have identified on the market during their targeted activities. However, to improve the usefulness of Safety gate RAPEX further, it would be interesting to have in addition the number of compliant toys that market surveillance authorities have inspected. This could give a more complete picture of specific categories of compliant toys and could help orientating market surveillance activities, where needed, away from (largely) compliant toy categories to those that are (largely) missing any record of compliance.

Nevertheless, it appears possible to identify effects of the Directive in the short-term and for single toys, once a new requirement triggers changes in the design, in the raw materials or in the production process of a toy. Manufacturers would probably be best placed to demonstrate those effects, but may however not provide any related data, in particular in quantitative terms, due to the sensitiveness of such data for their business.

On the other hand, effects of the Directive can relatively easily be seen in any activity of market surveillance and customs, in particular when restricting the marketing of specific toys. The related data are being reported publicly, and they reflect the effects of the Directive, although only in the non-representative way in which market surveillance authorities (and customs) are acting.

Future data collection could present better harmonised data on toys. The Member States' 5-yearly reports on the application of the Toy Safety Directive have shown inconsistent reporting of market surveillance's activities across the different Member States. The Toy Safety Directive only provides for a general reporting obligation for Member States, but

does not set any specific requirements for such reporting, thus leaving room for manoeuvre to Member States as concerns the data collection at national level. While each individual report highlights interesting aspects of the data presented, it could be useful to identify the indicators and the related data needs for future monitoring and evaluation, so that the Member States would know in advance what kind of data they will be asked to provide for the next evaluation period. This could ensure that indeed comparable data are collected, for example concerning the number of non-compliant toys vis-à-vis the total number of inspections carried out and the total numbers of toys traded in each Member State.

In addition, Member States could be requested to report on their measures relating to specific (categories of) toys, on novel toys 'flooding' the market, on the blockage of toys at the EU borders, and similar. This could provide a realistic picture on the ad-hoc effects of the Directive, and perhaps suggest where further improvements are needed.

5.4. Coherence

5.4.1. Is the Toy Safety Directive coherent with other EU or Member State legislation?

In the 2018 public consultation, stakeholders mostly reported about perceived incoherencies in the area of chemicals, in particular on restrictions of hazardous chemicals and the related limit values. Companies, business associations, Notified Bodies and consumer organisations often referred to other chemicals legislation such as REACH or the CLP Regulation. Also the Biocidal Products Regulation[251] was named. Public authorities further referred to the Food Imitating Products Directive[252] and a possible overlap with the Toy Safety Directive. They also saw different requirements for affixing the CE mark under the Toy Safety Directive, the Radio Equipment Directive[253] and the RoHS Directive.[254] Consumer organisations noted an inconsistent approach of the Toy Safety Directive and the Directive on General Product Safety regarding childcare articles, deploring that protection from chemicals in childcare articles was less than from toys, although exposure of children to such chemicals would be similar.

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[251] 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, p. 1. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20140425&qid=1571659897414&from=EN

[252] Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers. OJ L 192, 11.7.1987, p. 49. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31987L0357&qid=1571659964745&from=EN

[253] Directive 1999/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. OJ L 91, 7.4.1999, p. 10. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0005&qid=1571660072469&from=EN

[254] 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. OJ L 174, 1.7.2011, p. 88. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20190722&qid=1571660168647&from=EN

However, in all cases of perceived inconsistencies above, little or no details were given to substantiate them, nor examples to illustrate them. It was therefore not possible to verify what actually caused the concerns.

For the particular case of childcare articles, it is well understandable that the high level of protection acknowledged for chemicals under the Toy Safety Directive should equally apply to childcare articles and children in their first months and years. Consideration however has to be given to the exposure from each product group:

- Whereas exposure to chemicals in toys is always linked to play, exposure from childcare articles is linked to a quite different range of activities, namely 'sleep, relaxation, hygiene, the feeding of children or sucking on the part of children' which childcare articles are supposed to facilitate according to the definition of 'childcare articles' for the prohibition of phthalates (in toys and childcare articles);[255]
- Also the age span of children is different: Under 14 years for toys, but perhaps up to 6 years for childcare articles.

Each product group thus requires its own expertise to ensure tailor-made safety for children; merging both under the same umbrella for the sake of 'consistency' would bear the risk of failure.

To conclude: From managing the Toy Safety Directive the only apparent inconsistency with other EU or Member State legislation appeared to be Germany's stricter limit values for nitrosamines and nitrosatable substances.

5.4.2. Is the Toy Safety Directive coherent with the risk assessment and risk management approaches under other pieces of EU legislation?

Concerning the risk assessments provided to the Commission by different agencies and scientific committees under different pieces of EU legislation, 'there are areas of potential overlap (e.g. toys, detergents or other consumer goods, nanomaterials). This means that the same substance can be assessed by ECHA or by one of the EU scientific committees, depending on which legislation applies, and possibly lead to diverging opinions.'[256] The Commission 'has already started to work on streamlining the hazard/risk assessment by ECHA and EFSA to better ensure the convergence of conclusions. There are additional opportunities for simplifying the current set-up and streamlining the risk assessment processes among all relevant EU assessment bodies. This could make the functioning of the chemicals legislation more efficient (e.g. avoiding duplication of efforts) and more predictable (e.g. reducing the risk of potentially diverging outcomes of hazard/risk assessments at EU level).'[257] On the positive side, however, the 'good and effective cooperation between the SCCS and the SCHEER is ensured via the establishment of the Inter-committee

[255] Entries 51 and 52 of Annex XVII of REACH.

[256] Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses COM(2019) 264 final, SWD(2019) 199 final, p. 8. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0264&from=EN

[257] Report from the Commission … , p. 8. See footnote above.

Coordination Group (ICCG) which deals with (amongst others) matters relating to harmonisation of risk assessment and diverging scientific opinions.'[258]

In risk management there are inconsistencies reported regarding the protection of vulnerable groups of the population such as children.[259] Civil society groups and NGOs highlighted a 'lack of an overarching approach to the protection of vulnerable groups' which 'could lead to different levels of protection between different pieces of legislation for the same vulnerable group (e.g. children)'. The analysis of risk management for vulnerable groups[260] showed 'that not all pieces of legislation within the scope of this FC [Fitness Check] take into account risks to vulnerable groups. Where such risks are taken into consideration, the definition of vulnerable populations covered varies as there is no horizontally applicable definition of 'vulnerable group'. This means that risks for such groups are addressed on case-by-case basis through product/risk/sector specific legislation taking into consideration circumstances, products or environments of chemical exposure that could lead to different level of protection across the legislation.' On the other hand, 'the assessment … did not come to a conclusion on the extent of the issue and if, in practice, risks to vulnerable populations are not sufficiently well addressed and managed because of these legislative gaps and inconsistencies.'[261]

5.4.3. Are there different limit values for chemicals in other EU or national legislation?

Limit values for chemical substances in toys are not only provided by the Toy Safety Directive but also by other pieces of EU legislation. For example, the limit value for the CMR DEHP [262] under the Toy Safety Directive is the 'relevant concentration' in the CLP Regulation, according to Annex II, Part III, point 4(a) of the Directive. That 'relevant concentration' is the generic concentration limit for reprotoxic substances in the CLP Regulation and is 0,3%.[263] On the other hand, REACH limits DEHP in toys (and childcare articles) to 0,1%.[264]

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[258] Commission Staff Working Document. Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. Accompanying the document Report from the Commission … (see footnote 220), p. 77. https://eur-lex.europa.eu/resource.html?uri=cellar:e7eb0a70-9757-11e9-9369-01aa75ed71a1.0001.02/DOC_1&format=PDF

[259] Report from the Commission …, p. 9. See footnote above.

[260] Commission Staff Working Document …, p. 90. See footnote above.

[261] Commission Staff Working Document …, p. 92. See footnote above.

[262] Di-(2-ethylhexyl) phthalate (CAS No 117-81-7). Classified as reprotoxic category 1B in Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1.

[263] Table 3.7.2 of the CLP Regulation.

[264] Annex XVII, entry 51 of REACH.

Indeed these are different limit values for DEHP, and it may be cumbersome in practice to have to identify the strictest limit value before testing a toy. Nevertheless, to help finding the pieces of legislation applying to toys, a list of applicable EU legislation is available on the relevant Commission website.[265]

Also the RoHS Directive applies to toys. From the point of view of environmental protection, electrical and electronic equipment should not contain more than 0,1% lead in homogeneous materials.[266] This provision has been used in particular in 2019 in a range of EU Safety gate RAPEX notifications[267] concerning toys including electric or electronic parts where the lead exceeded the limit value in the solders.

Since solders are normally enclosed inside a toy, such levels of lead are not covered by the limit values for lead in the Toy Safety Directive,[268] as those do not apply 'to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin'.

Thus, different limit values may come from different protection purposes: health protection from the Toy Safety Directive, environmental protection from the RoHS Directive. Expert knowledge is thus required to deal with the many aspects of EU legislation.

Although the existence of complementary limit values for chemicals in different pieces of EU legislation, as illustrated above, is unfortunate for non-experts, a further kind of different limit values is of some more concern. An example is the limit value for cadmium in the Toy Safety Directive and in REACH.

The Toy Safety Directive requires that no more than 17 mg/kg cadmium may migrate out of the paint on a toy,[269] whereas REACH requires a paint to contain less than 0,1% (1000 mg/kg) cadmium.[270] Since migration and content limits cannot be converted (by calculation) into each other, the paint on a toy has to be tested twice. This appears to be an unnecessary burden, since the Toy Safety Directive is already specifically designed to provide for a safe cadmium limit, and the REACH cadmium limit therefore cannot be 'safer'. – To note that a migration limit can be as easily tested as a content limit, as long as a reliable test method is available, such as the test method for cadmium (and 18 further 'elements') in toy safety standard EN 71-3.

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265 http://ec.europa.eu/growth/sectors/toys/safety/legislation_en

266 Article 4(1) and Annex II of the RoHS Directive.

267 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=en. Search for 'solder' as a 'Free text'.

268 Limit values for lead in three kinds of toy materials; in Annex II, Part III, point 13 of the Toy Safety Directive.

269 Annex II, Part III, Point 13 of the Toy Safety Directive. Column 'mg/kg in scraped-off toy material' in the table.

270 Annex XVII, entry 23 of REACH.

Similarly, toy jewellery such as bracelets, necklaces or rings is subject to the related lead migration limit value (23 mg/kg) in the Toy Safety Directive[271] and to the content limit value (0,05% = 500 mg/kg) in REACH.[272] As explained above, toy jewellery has to be tested twice although the lead limit provided in the Toy Safety Directive is considered to provide safety to children already.

Furthermore, the REACH restriction for CMRs in textiles[273] overlaps with the Toy Safety Directive[274] regarding the limits for the following metal elements and their compounds: arsenic, cadmium, chromium VI and lead. Whereas the REACH content limit is 1 mg/kg in all cases, the Directive's migration limits for these four elements are 70,000 mg/kg, 17 mg/kg, 0.2 mg/kg respectively 0.053 mg/kg as of 18 November 2019, and 23 mg/kg, respectively. Since both sets of limits require an acidic extraction,[275, 276] a comparison is approximately possible, and the stricter limits apply. Nevertheless, since the tests are not identical, they would both have to be carried out if legal certainty were to be achieved.

Avoiding the above concerns could be achieved by exempting toys from restrictions in other pieces of legislation when chemicals are already regulated by the Toy Safety Directive. An example of this is the limit value for lead in articles supplied to the general public in REACH,[277] which is 0.05%, but which does not apply to toys.[278] For this limit the concerned Commission services considered already in the drafting phase that lead in toys was sufficiently addressed under the Toy Safety Directive and that the REACH limit should not apply to toys.

On the other hand, where two tests have to be carried out, it may be sufficient for a manufacturer to 'double-test' his toy a few times to gain experience which limit value is more difficult to comply with by his toy. He could then test the toys from series production only against that limit value and would be to a large extent sure that the toys would also comply with the other limit value.

An incoherence that, as mentioned further above, also limits the Toy Safety Directive's effectiveness are the limit values for nitrosamines and nitrosatable substances, on which German legislation is stricter than the Toy Safety Directive. The Commission did

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271 Annex II, Part III, Point 13 of the Toy Safety Directive. Column 'mg/kg in scraped-off toy material' in the table.

272 Annex XVII, entry 63, No 1 of REACH.

273 Annex XVII, entry 72 of REACH. Commission Regulation (EU) 2018/1513. OJ L 256, 12.10.2018., p. 1.

274 Annex II, Part III, point 13 of the Toy Safety Directive. Column for 'scraped-off toy material'.

275 Explanatory guide on the restriction on CMRs 1A and 1B in textiles and clothing. 3. List of available analytical methods for substances covered by this restriction. https://ec.europa.eu/docsroom/documents/32006.

276 EN 71-3:2019.

277 Annex XVII, entry 63, No 7 of REACH.

278 Annex XVII, entry 63, No 8(k)(iii) of REACH.

acknowledge that the stricter limits are justified on grounds of major need of protection of human health when allowing Germany to keep its lower national limits.[279] Also, at the Commission's request, the lower limits have been included in the related toy safety standard.[280] Lowering the limits in the Directive would require an ordinary legislative procedure since, according to the Toy Safety Directive, the Commission is not empowered to change the limits in a Comitology procedure.

This incoherence was the most noted one with regard to chemical limit values in the 2018 public consultation. To a lesser extent were the other incoherencies described above equally referred to, although not in that detail. The quantitative evaluation of the responses showed that large parts of all stakeholders, with the exception of public authorities, reported to be aware of inconsistencies (table 5.17).

Table 5.17. Are you are aware of any different limit values for chemicals in other EU or national legislation? (% of respondents*)

Stakeholders responding**	Yes	No	Don't know	No opinion
Companies (32)	60	10	10	20
Business associations (12)	80	0	20	0
Notified bodies (7)	60	0	0	40
Public authorities (31)	10	30	20	40
Consumer organisations (6)	70	30	0	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

To remedy the noted inconsistencies, prior consultation when establishing new legislation was repeatedly recommended by stakeholders in the 2018 public consultation, as well as the exemption of toys from other legislation, in particular if the limit in the Toy Safety Directive was considered to provide safety indeed.

Already in the 2015 external study, inconsistencies with regard to chemical limit values were reported.[281] Finding the applicable legislation outside the Toy Safety Directive was considered to be cumbersome, however the legal framework should be maintained in order to ensure the safety of the vulnerable population group that children are.

In the 2015 external study[282] stakeholders suggested a horizontal framework or the alignment of limit values for toys to those of food or cosmetics. They also indicated that chemicals in materials should be regulated, regardless of whether the materials were used in toys or elsewhere.

[279] Recital 78 of Commission Decision 2012/160/EU.

[280] EN 71-12:2017 Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances.

[281] 2015 external study, p. 96 ff. See footnote further above.

[282] 2015 external study, p. 98 f. See footnote further above.

5.5. EU added value

The Toy Safety Directive is a 'maximum harmonisation directive', adopted on the basis of Article 95 of the Treaty establishing the European Community[283] to establish an internal market for toys, both with regard to the safety of toys and their placing on the market. National legislation therefore cannot impose provisions that would go beyond the safety requirements for toys or affect their placing on the market. Also the 1988 Toy Safety Directive was a 'maximum harmonisation directive'.

The added value of the Toy Safety Directive, in comparison to individual Member State legislation, thus relates to the

- same high level of protection of children's health across the EU: consumers can trust that the toys they purchase have to comply with the same high safety requirements in any EU country;
- economic benefits coming from a large harmonised market with about 72 million children under 14 years of age.[284] Manufacturers have to follow only a single set of requirements (a 'one-stop shop') when making toys for the entire EU, and importers and distributors equally just need to follow a single set of rules when marketing toys in the EU.

Without the Toy Safety Directive, Member States would most likely establish diverging national rules on the safety of toys, to the detriment of internal market:

- During the expert discussions to limit phenol in toys, two Member States insisted to have only a single limit value instead of the two that were eventually established: (1) a limit value for phenol in polymeric materials, (2) a limit value for phenol as a preservative in aqueous toy materials;[285]
- Guidance document No 18 on puffer balls and similar toys[286] took several years to be adopted by the AdCo. Repeatedly, Member States expressed diverging views until a compromise was found that appeared acceptable to all;
- The discussions at AdCo meetings and the almost daily email exchanges within AdCo members on the classification of products as toys (or not) or as toys for children under 36 months (or older) help to find common views across all Member States.

These examples show that the Toy Safety Directive forces Member States to take account of the other Member States' views when establishing rules under the Directive or when implementing it. Without the Directive, Member States would not hesitate to go their own way, leading to divergent levels of safety and to separate national markets. The Directive thus clearly provides an EU added value through its harmonising effect.

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[283] Treaty establishing the European Community (Consolidated version 2002), in OJ C 325, 24.12.2002, p. 33–184, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12002E%2FTXT

[284] Eurostat data of 2011. https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=cens_11ag_r3&lang=en

[285] See the related amendment of the Toy Safety Directive in annex 4.

[286] https://ec.europa.eu/docsroom/documents/37141

The only issue hindering the complete harmonisation is the derogation for Germany allowing it to maintain its national limit values for nitrosamines and nitrosatable substances; these limit values are stricter than those in the Toy Safety Directive (see further above). However, the toy industry has consistently confirmed that this was not an issue for it. It appears therefore that in practice the derogation is not a hindrance to the free movement of toys throughout the EU.

When asked about the added value of the Toy Safety Directive in the 2018 public consultation, all stakeholders expressed overwhelming support (100% in almost all cases; see annex 11, table 1).

Inquiring in some more detail into the Toy Safety Directive's added value for the different stakeholder groups, the majority of companies agreed (or agreed even entirely) with the creation of a large market for toys, the simplification of trade and the harmonisation of testing methodologies and standards (80%; see annex 11, table 2). They were however much less convinced that the costs for the development and manufacture of toys would be lowered by the Directive (30%).

Business associations' views were similar to companies', however their agreements were less pronounced (60 – 70%; see annex 11, table 3).

Notified Bodies thought that the Toy Safety Directive has indeed helped to harmonise testing and standards (100%), but were less convinced that it has increased opportunities for conformity assessment in the EU (60%; see Annex 11, table 4).

Public authorities strongly believed that the Toy Safety Directive helps harmonising testing methodologies and standards (90%), and they highly appreciated its added value for their work with other Member States (90%; see annex 11, table 5).

Consumer organisations were quite neutral on the Toy Safety Directive's added value for harmonising tests and standards (30%), in contrast to all other stakeholders above (see annex 11, table 6). They were also rather neutral regarding an added value for market surveillance (30%), as opposed to public authorities above. However they were entirely enthusiastic about the re-use of test reports from other consumer organisations in the EU (100%).

Thus, all stakeholders were enthusiastic about the EU added value of the Toy Safety Directive in general (see annex 11, table 1), they linked this to matters of their own interest:

- companies and business associations to the large market and the simplification of trade (and to quite a majority also to the harmonisation of testing methodologies and standards);
- Notified Bodies completely to the harmonisation of testing and standards (and to quite an extent also to the opportunities for conformity assessment throughout the EU);
- public authorities very largely to the harmonisation of testing and standards and to their working together with authorities from other Member States, and
- consumer organisations to the re-use of test reports from their counter parts in other EU countries.

Already in the 2015 external study, stakeholders recognised the added value of the Toy Safety Directive in facilitating trade and reducing trading costs in the internal market.[287] Stakeholders also generally agreed that the Directive contributes to streamlining testing and standards.[288] Although SMEs denounced the very high costs caused by the Directive, in particular due to the safety requirements, national rules were not considered to be more beneficial.[289]

6. CONCLUSIONS

6.1. 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.

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

[287] 2015 external study, p. 99. See footnote further above.

[288] 2015 external study, p. 100. See footnote further above.

[289] 2015 external study, p. 100. See footnote further above.

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. [290]

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'.

[290] See footnote on 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 harmonisation legislation, which regulate in a more specific manner particular aspects of market surveillance and enforcement.

6.2. 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 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.

6.3. 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.

6.4. 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.

6.5. 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 1 : Procedural information

1. LEAD DG, D*e*CIDE PLANNING/CWP REFERENCES

Lead DG: Directorate-General for Growth - Internal Market, Industry, Entrepreneurship and SMEs (DG GROW); Unit D3: Biotechnology and Food Supply Chain.

Agenda planning/work programme reference: PLAN/2018/3078

2. ORGANISATION AND TIMING

Organisation and timing: the inter-service Steering Group consisted of SG, DG JUST, DG ENV, DG TAXUD and DG SANTE. After the kick-off meeting on 18 July 2018, it met on 16 May 2019, 3 July 2019, 3 October 2019 and 15 October 2019.

3. EXCEPTIONS TO THE BETTER REGULATION GUIDELINES

Not applicable.

4. CONSULTATION OF THE RSB (IF APPLICABLE)

The upstream meeting with the Regulatory Scrutiny Board (RSB) took place on 18 October 2018 and the final meeting with the RSB after the submission of the draft Staff Working Document (SWD) on 20 November 2019.

Evaluation of the Toy Safety Directive: Overview on how the comments and suggestions of the RSB on the draft Staff Working Document have been addressed in the version submitted in March 2020

Summary of the findings	How the comments have been addressed
(1) The report does not sufficiently support its conclusions. It does not explain well which evidence points to shortcomings in the Directive, or how benefits outweigh the costs.	A number of new sections were added and the existing sections revised in order to better support the conclusions and the shortcomings of the Directive. Sections 'Benefits of the Toy Safety Directive' (5.2.4) and 'Balance of benefits and costs' (5.2.5) have been revised. The conclusions on efficiency have been nuanced accordingly.
(2) The report notes a lack of data to measure the impact on children's health, but does not draw lessons for future data collection, monitoring and evaluation arrangements.	Extensive considerations were added in the new section 'Is the current monitoring and evaluation system fit for purpose?' (5.3.4) to better identify the limitations of the IDB injury database in the assessment of the impact of the Directive on children's health and injuries and the limitations of the Safety gate RAPEX system to assess the impact of the Toy Safety Directive on the number of toys removed from the market. This section also provides ideas on how the IDB and the Safety gate Rapex could be improved.
(3) The evaluation does not make clear why its focus is on protecting children from chemical risks in particular, and does not sufficiently explain the link to	The focus on the protection from chemicals is now explained in detail in the section 'Why focus on chemical safety?' (5.1.1.1). The link to the internal market has been addressed in

the internal market.	'Effectiveness related to the free movement of toys in the EU' (5.1.2) where an explanation on why the two objectives (safety and internal market) are linked as well as an analysis of the internal market has been provided, including data on the intra-EU trade. The table on the intervention logic in the section 'The intervention logic' (2.1.3) has been revised to highlight that the differentiation between the two strategic objectives (safety and internal market) cannot be seen to be strict, since some elements are relevant for both. Moreover, it now includes also external factors (internet-connected toys, on-line sales, the 2008 economic crisis).
What to improve	**How the suggestions have been addressed**
(1) The report should substantiate better its conclusions or make clear that some are tentative. The evaluation identifies a number of deficiencies of the Directive based only on the opinions of some Member States (e.g. regarding the age limit of 36 months for chemical exposure, the allowed concentrations of CMR substances, and the limits for nitrosamines and nitrosatable substances). The report should explain the motivation behind these opinions and present evidence to support these findings. This could be for instance new scientific knowledge showing that the provisions of the Directive are no longer appropriate.	The conclusions are now more modulated in line with the weight of the evidence presented. The deficiencies identified are now motivated as follows: – age limit of 36 months for chemical exposure Section 5.1.1.2 Is the Directive effective in protecting children from the risk of chemicals?, sub-section *Chemicals in general i*ncludes 'In the Commission services' view …' a technical-scientific substantiation why the 36 months limit is inadequate. – allowed concentrations of CMR substances Section 5.1.1.2 Is the Directive effective in protecting children from the risk of chemicals?, sub-section *CMR substances in general i*ncludes the explanation that the allowed concentrations aim to properly identify and communicate the hazards of chemical mixtures, but do not take account of possible exposures which is necessary to assess the risk; and a comparison table why the allowed concentrations are too high for child protection purposes. – limits for nitrosamines and nitrosatable substances Section 5.1.1.2 Is the Directive effective in protecting children from the risk of chemicals?, sub-section *Specific CMRs: Nitrosamines and nitrosatable substances* explains that the limit for nitrosamines was based on a Scientific Committee opinion on nitrosamines in balloons (but not all toys), and that CEN 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.
(2) The report should justify better the conclusion that the benefits outweigh the costs. There is evidence that the legislation is costly for enterprises, in particular SMEs. The analysis should also discuss the benefits of the Directive for industry, considering also effects on reputation.	Section 5.2.5 'Balance of benefits and costs' reports that 'half of the companies and business associations in the 2018 public consultation considered that the benefits of the Toy Safety Directive outweigh the costs, sometimes even by far.' A new paragraph has been inserted in this section to identify as a plausible justification to this statement the companies' inner interests to protect their reputation. A paragraph has been inserted in the same section explaining that it is not possible to provide a quantitative nor qualitative balance of benefits and costs. The conclusions have therefore been nuanced. Additional information has been added in section 'Market evolution' (2.1.1) which refers to innovation and to a low concentration in the toy market as well as to the fact that toy producers face cost and price competition to a significant extent. This section also indicates that the toy sector was attractive enough, in particular for SMEs.

It could also analyse whether the high costs had an impact on the sector, for instance in terms of innovation and concentration.	Section 'Balance of benefits and costs' (5.2.5) was also revised. It reports now that almost 10% of new companies have joined the toy sector during the five years from 2013 – 2017, despite the costs linked to the application of the Toy Safety Directive, reported to be higher than under the predecessor Directive. A paragraph has been added in section 'Benefits of the toy safety directive' (5.2.4): as indicated by companies and business associations/organisations in the context of the public consultation (see Annex 2), among the benefits of the Toy Safety Directive is the fact that the CE mark is considered as helpful when selling toys to customers and outside the EU, which can be seen as evidence that the CE marking brings an added value to the companies in terms of reputation.
(3) The report should draw conclusions for future data collection and monitoring and evaluation arrangements. The data used do not allow an assessment of the impact of the Directive on children's health and injuries. Stakeholders and several earlier reports had already highlighted this. The report should also assess the quality and usefulness of the Member States' reports. The evaluation could make more use of the available data on surveillance and enforcement, including the rapid alert system for products that pose a risk to health.	A new section 'Is the current monitoring and evaluation system fit for purpose?' (5.3.4) was added. It provides some ideas on why the current monitoring does not work. This new section has also assessed the data quality of the Member States' 5-yearly reports, showing that data reporting is insufficient. Section 'Is the Directive effective with regard to surveillance?' (5.1.3) explains the sometimes limited usefulness of Member States' reports, but also uses them to calculate market surveillance's effectiveness when checking dangerous toys and to highlight what hampers the effectiveness of the Directive in the practice of market surveillance. Limitations of the Safety gate RAPEX data to detect an impact of the Toy Safety Directive have now been described in the revised section 'Data on marketing restrictions for toys' (4.3.2): No impact detectable as of mid-2011 (application of the Directive's new requirements except the chemical requirements) and as of mid-2013 (application of the Directive's new requirements on chemicals).
(4) The evaluation should better justify its focus on protecting children from chemical risks. It should explain new developments and demands in this area. It should also consider that there are links between the objective to protect children's health and the functioning of the internal market for toys. It could develop the analysis of market surveillance and assess the standardisation system.	New section 'Why focus on chemical safety?' (5.1.1.1) added to the Effectiveness assessment. Link between the maximum harmonisation of safety requirements and the free movement in the internal market explained in 'Effectiveness related to the free movement of toys in the EU' (5.1.2) where an explanation on why the two objectives (safety and internal market) are linked has been provided. New Regulation on Market Surveillance and Product Compliance and its link to market surveillance of toys addressed in – 'The intervention logic' (2.1.3), sub-section 'Baseline and points of comparison'; – 'Is the Directive effective with regard to surveillance?'(5.1.3) – 'Costs related to different provisions of the Toy Safety Directive' (5.2.1.3). Standardisation system:

	– Effectiveness of toy safety standards addressed in 'Are standards effectively supporting the safety of toys?' (5.1.1.4) – Costs of toy safety standards addressed in 'Costs related to different provisions of the Toy Safety Directive' (5.2.1.3).
(5) The report could discuss to what extent using the 2008 impact assessment as a benchmark for the analysis is adequate. The report should assess whether the changes introduced to the 2009 Commission proposal during the legislative process affect the Directive's relevance and effectiveness.	The SWD explains in 'The intervention logic' (2.1.3), sub-section 'Baseline and points of comparison', the baseline and clarifies the difficulties related to the identification of points of comparison for some new requirements of the Toy Safety Directive. The SWD now includes changes to the Commission proposal for the 2009 Toy Safety Directive in 'The intervention logic' (2.1.3), sub-section 'Baseline and points of comparison', as regards several provisions on chemicals. Also the sub-section '*CMR substances in general*' refers to new elements inserted in the proposals during the law-making process, as well as sub-section '*Specific CMRs: Nitrosamines and nitrosatable substances*'. The new section 'Has the law-making process affected the effectiveness of the Toy Safety Directive?' (5.1.5) refers in addition to provisions on warnings and instructions and safety information added during the law-making process.
(6) The report should aim for a convincing narrative with a non-expert audience in mind.	Non-expert language used as much as possible, with concrete examples for illustrative purposes.

On 27 April 2020 the RSB delivered a positive opinion on the resubmitted evaluation staff working document (SWD) which included recommendations on how the SWD can still be further improved and invited the evaluation team to consider these recommendations in the final version of the SWD.

Evaluation of the Toy Safety Directive: Overview on how the recommendations of the RSB on the draft Staff Working Document have been addressed in the revised version (June 2020)

Summary of the findings	How the comments have been addressed
The conclusions are not comprehensive and do not fully reflect the analysis. They do not sufficiently draw out policy lessons for the future. The report does not present conclusions on the effectiveness in protecting children from risks other than chemicals, on enhancing the internal market for toys, or related to the standardisation system. The conclusions do not reflect the findings related to data collection, monitoring and evaluation arrangements.	The conclusions have been extended so as to cover all the main points raised in the analysis. The specific findings raised by the RSB on the effectiveness in protecting children from risks other than chemicals, on enhancing the internal market for toys, on the standardisation system and on data collection, monitoring and evaluation arrangements have been integrated in the conclusions of the revised SWD. Policy lessons for the future where have been drawn out where relevant (for example, regarding the protection from chemicals in toys where urgent action is deemed essential, see 6.1).
The report does not present a clear conclusion on the impact of the Directive on trade	Section 'Effectiveness related to the free movement of toys in the EU' (5.1.2) includes conclusions on the

	Directive's effects on trade.
What to improve	**How the suggestions have been addressed**
(1) The report should integrate the findings of its improved analysis in the conclusions, in particular on the effectiveness in protecting children from risks other than chemicals, on the internal market for toys, and on the standardisation system. The conclusions should also reflect the findings related to data collection, monitoring and evaluation arrangements.	Specific findings on the effectiveness in protecting children from risks other than chemicals, on enhancing the internal market for toys, on the standardisation system and on data collection, monitoring and evaluation arrangements have been integrated in the conclusions of the revised SWD (see 6.1 and 6.3).
(2) The report should be cautious in using figures on new companies to justify the conclusions on efficiency. The report uses figures from a flyer of the toy industry to argue that the Directive has not prevented companies from entering the toy market. Figures from such non-authoritative sources should be interpreted with caution, unless they can be further substantiated.	A new paragraph has been introduced in the analysis (see 2.1.1) as well as in the conclusions (see 6.2) referring to the fact that an increase of economic activity on toys could also be seen in the steep increase of intra-EU toy exports from 2012 – 2016, hinting to a certain increase of competitiveness of EU economic operators. This finding is based on figures coming from an authoritative source such as Eurostat (see figure E2), which supports the data provided by the toy industry. Data on number of manufacturers of toys and games from Eurostat was added to further substantiate the findings. Additional analysis on firm profits were added in the efficiency section.
(3) The report should present clear conclusions on the impact of the Directive on trade. The report presents an analysis suggesting that the Directive may have reduced imports of toys, although the results should be interpreted with caution. On the other hand, the report also suggests that the Directive has not hindered intra-EU export of toys covered by the Directive. It could expand how this has helped the competitiveness of the EU industry. The report should discuss these findings and reflect them in the conclusions.	A new paragraph has been inserted in section 4.3.3 indicating that during the slight decrease of toy imports into the EU between 2010 and 2013, possibly related to the application of the Toy Safety Directive, intra-EU toy exports increased by some 20% (figure E.2). This might suggest a potentially higher competitiveness of EU toy manufacturers during the first years of application of the Directive, presumably through their better access to first-hand information and their subsequent quicker adaptation to the requirements of the new Directive.
(4) The evaluation could further analyse the stakeholders' views about perceived incoherencies in the area of chemicals, as expressed in the 2018 public consultation. The report now concludes that the Directive is coherent, because stakeholders did not substantiate their claims.	A paragraph has been added in both in the analysis and in the conclusions (see 5.2.6 and 6.4) to explain that there are no two chemical limit values for toys that would contradict each other (apart from the limit values for nitrosamines and nitrosatable substances) and that stakeholders may however have understood the question in a wider sense.
(5) Finally, the conclusions should more clearly draw out the main lessons learnt that require policy-makers' attention.	Where relevant, the main lessons learnt that require policy-makers' attention have been drawn out in the conclusions, for example regarding the protection from chemicals in toys where urgent action is deemed essential (see 6.1).

5. EVIDENCE, SOURCES AND QUALITY

The evaluation was based on a variety of sources, ranging from a public consultation targeting different stakeholders (EU citizens, consumer organizations, business associations, companies/business organizations, national authorities, Notified

Bodies/others), previous studies and impact assessment, an external study as well as literature, open on-line sources and publicly available reports, including national reports by Member States. The main source of information were the stakeholder consultations.

The two main studies used for the purpose of the present evaluation are the following:

- Evaluation of the benefits and the costs generated by the Toy Safety Directive: a supply side analysis (JRC study) by the Joint Research Centre, Competence Centre on Microeconomic Impact Evaluation (October 2019);
- Evaluation of directive 2009/48/EC on the safety of toys – Final Report (2015 study) by Technopolis (December 2015).

General market information was collected from the European industry associations' publications and from Eurostat. More detailed cost related information was collected via a specific survey of economic operators.

The robustness of the consultations:

- During the preparatory phase, the evaluation team used existing studies/impact assessment, reports by Member States and meeting documents of the Expert Group on Toy Safety to prepare the next steps in the evaluation. The work resulted in questionnaires for the targeted survey and the public consultation.

- The evaluation team (1.5 persons) was assisted by a steering group (7 people) composed of representatives of different Commission directorates-generals who participated in the 5 meetings organised by the evaluation team and monitored the development of the Roadmap, the consultation strategy, the questionnaires for the public consultation and were regularly consulted on the different versions of the staff working document.

- The evaluation team received the scientific support from the Competence Centre on Microeconomic Evaluation (CC-ME) of Unit JRC.I.1 that produced a study on the quantification of costs and benefits of the Toy Safety Directive. The data were primarily taken from the Bureau Van Dijk Orbis database.

- The public consultation was widely publicised not only via institutional channels (such as via the Expert Group on Toy safety) but also via indirect channels (such as promotional campaign on social media) to unlock the potential of stakeholders who initially had not engaged in the evaluation process.

- Contributions by industry appear to be coherent and representative for the sector, whereas the information collected via the questionnaires is not representative of the majority of them. The open consultation resulted in 112 replies and confirmed the information already obtained from economic operators and national authorities.

- By triangulating data from the targeted survey, the JRC study and the open public consultation, it has been possible to identify divergences between the data collected through the different tools.

– Compliance costs appear to be limited: however, information related to market size and compliance costs need to be interpreted with care and should be seen as indications of an order of magnitude rather than as precise estimates.

Annex 2: Stakeholder consultation

Synopsis report on the stakeholder consultations for the evaluation of the Toy Safety Directive

I. Introduction

The stakeholder consultations for the evaluation of the Toy Safety Directive 2009/48/EC began in 2014 with the work of an external contractor and continued until March 2019[291] under an internal evaluation by the Commission services. The evaluation exercise was to assess the performance of the Toy Safety Directive in relation to its objectives of a) ensuring a high level of safety of toys with a view to ensuring the health and safety of children, and b) of guaranteeing the functioning of the internal market for toys.

As highlighted in the Roadmap,[292] the consultation involved collecting input from a wide range of stakeholders: general public including consumers; authorities in 28 Member States and in the EEA-EFTA countries; industry including SMEs: manufacturers, importers, distributors; consumer associations: ANEC (The European consumer voice in standardisation), BEUC (The European Consumer Organisation). Notified Bodies: NB-Toys Group; European Standardisation organisations: CEN, CENELEC.

Both public and targeted consultations were undertaken:

- A Roadmap describing the context, purpose and scope of the evaluation as well as the stakeholders involved and the data collection and methodology to be used, was published in July 2018 and was open for feedback during 4 weeks;
- A public consultation was launched in September 2018 on the Commission's central consultation web page 'Have your say'[293] for 12 weeks in 23 EU languages. It was promoted by widely informing Member States and other stakeholders concerned with toy safety.
- A targeted consultation with economic operators to collect detailed data on costs and benefits related to the Directive was launched in early February 2019 and was open during 6 weeks.
- Within the external study started in 2014, direct interviews with economic operators, consumer representatives, test laboratories' representatives and the relevant European Standardisation Organizations (ESOs) were conducted.

This Synopsis Report summarises and analyses the contributions received in the consultations mentioned above. These analyses were used to assess the effectiveness,

[291] The cut-off date was 29 March 2019. Stakeholder contributions received by the Commission after that date could not be taken into account in preparing this document.

[292] See https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3667279_en .

[293] https://ec.europa.eu/info/law/better-regulation/have-your-say

efficiency, coherence with other legislation (whether EU or Member States' national legislation), relevance and EU added value of the Toy Safety Directive.

In the consultation process, stakeholders put forward a number of proposals to modify and extend the scope of the Toy Safety Directive, to include products such as childcare articles. These were outside of the scope of the current evaluation/consultation and might be taken into consideration in the future. All other messages, however, have been summarised in the relevant sections below.

II. Stakeholder consultation in the external 2015 evaluation

An external study of the Toy Safety Directive, requested by the Commission, was carried out by an external contractor in 2014 and 2015. It was to assess the Toy Safety Directive's relevance in addressing current needs, its effectiveness and efficiency in meeting its objectives, its coherence with the EU legislative framework relevant for toys and its EU added value.

A total of 47 face-to-face and skype interviews were carried out in 2015 by the external contractor with relevant stakeholders of which: 14 industry associations; 20 manufacturers (both large and SMEs); 5 distributors; 3 consumers' associations; 2 Notified Bodies; 2 standardisation organisations; 1 expert on toy safety

The evaluation has shown that the Toy Safety Directive is relevant and effective for the safety and the economic sector of toys: it sets EU wide requirements for all economic operators concerned with toys and provides specific provisions addressing at least all major risks related to toys. Moreover, the Toy Safety Directive does not seem to hinder the import of toys into the EU market. Only few contributions suggested that costly safety requirements would hinder toy innovation.

While economic operators and the majority of Member States are generally satisfied with the Toy Safety Directive's performance, consumer associations and a few Member States are more sceptical about the Toy Safety Directive's capacity to properly deal with all aspects of toy safety. In particular, they deem limit values for chemicals as either inadequate or missing.

The 'grey area' between toys and 'not-toys', the existence of different testing methodologies and the lack of adequate resources at the disposal of national Competent Authorities emerged as the main issues hindering a consistent implementation of the Toy Safety Directive by the Member States. Whilst the costs related to chemical requirements are deemed proportionate by stakeholders who consider them as justified for achieving children's safety, major inefficiencies stem from shortcomings in the Toy Safety Directive enforcement, which induce implementation bottlenecks and useless delays.

Policy recommendations of the 2015 external study concern soft regulatory measures to maximise the Toy Safety Directive's performance. They include: an effective communication system between all stakeholders concerned with the Toy Safety Directive, including an '*ad hoc* queries system' empowering stakeholders who face a specific issue to ask how other actors have managed it in the past or in other contexts; a common market surveillance framework, including minimum standards on market controls; a common procedural framework for conformity assessment, including minimum standards to be referred to when assessing the conformity of toys by means of the EC-type examination; measures aiming to improve the Toy Safety Directive's

provisions, such as the assessment of both the need for stricter chemical limits and the feasibility of using new technologies such as QR codes for warnings; measures aiming at improving the Toy Safety Directive's working mechanisms, including the balanced involvement of all stakeholder categories concerned with the Toy Safety Directive and the systematic monitoring of injuries and accidents due to toys; incentives to economic operators to better comply with the Toy Safety Directive, such as subsidies for research activities aiming to stimulate innovation that may be currently hindered by the high costs needed for performing both safety and conformity assessments of toys.

Finally, the evaluation suggests to proceed with the international alignment of toy safety beyond Europe. This would ease both the stakeholders' understanding of the requirements they are subject to and the trade of toys, since safety parameters would be equal irrespective of the place where toys are produced.

III. Consultation on the Roadmap (July-August 2018)

The Roadmap for the commission internal evaluation was published in July 2018 and was open for feedback on the Commission's central consultation web page 'Have your say' for 4 weeks. A total of 9 responses were received (from 2 consumers' associations, 3 industry associations, 2 Notified Bodies, 1 citizen and 1 Member State).

- 3 stakeholders called for compulsory third party testing for toys rather than relying on post-market surveillance, especially in areas of higher risk associated with toys for the most vulnerable children under 36 months of age. To this purpose they suggested that the evaluation also look at the conformity assessment procedure since the high non-compliance levels are directly linked to the existing provisions on conformity assessment;

- 3 stakeholders advocated a strengthening of chemical requirements for toys, in particular CMRs and endocrine disruptors, as well as a broadening of the Comitology in order to set limits also for toys for children above 36 months of age (other than those intended to be placed in the mouth);

- 2 stakeholders highlighted the need of better market surveillance on toys to step up the number of controls before toys are placed on the market, improve traceability and accountability along the supply chain - including toys that are sold online - and systematically collect information about accidents with toys through a Pan-European Accident and Injury Database;

- 4 stakeholders were concerned that the current legal framework and its definition for a 'safe' toy does not unequivocally cover Internet-connected toys and related security threats: they requested that the scope of the Toy Safety Directive be extended to include new safety requirements on information security;

- Further proposals put forward by one stakeholder include the need to refer to the current Cosmetics Regulation (instead of the old Cosmetics Directive), a clarification of Annex B 'Classification of substances and mixtures', an alignment of the Toy Safety Directive to the new standard EN 71-1:2014+A1:2018: all of these would need a revision of the Toy Safety Directive via the Ordinary Legislative Procedure (OLP);

- Further requests from stakeholders relate to the introduction of limits to impulse noise levels in toys and of specific requirements for visibility and legibility of warnings on toys (e.g. a minimum letter size) in order to enable Member States to enforce these requirements in a uniform way.

IV. Open public consultation (September – December 2018)

1. Origin of the replies

The 116 replies to the Open Public Consultation were mainly provided by companies/business organisations and public authorities (28% and 27%, respectively), followed by EU citizens (22%). Fewer replies came from business associations (10%), Notified Bodies (7%) and consumer organisations (5%).

By country of origin, the largest number of replies came from Spain (with 29 contributors), Germany (17), Belgium (10), Italy (10) and the Netherlands (6).

2. Feedback from the contributors (except individual consumers)

Effectiveness

The majority of **consumer organisations** considered that to some extent, the Toy Safety Directive certainly brought improvements to toy safety in the EU, but they all agreed that the Toy Safety Directive definitely has helped to ensure the free movement of toys throughout the EU by harmonising rules and procedures for placing toys on the market. Most of them were aware of problems implementing or enforcing the Toy Safety Directive in the Member States. Regarding the possible solutions to overcome the problems, consumer organisations considered as most helpful to ensure better collaboration between market surveillance authorities, including customs, in different Member States. To make the Toy Safety Directive more effective all consumer organisations considered a list of chemicals permitted in toys (‘positive list’) as the highest priority. The second highest priority was to improve communication and collaboration amongst stakeholders and with the European Commission. Almost all consumer organisations were of the opinion that an EU Regulation on toy safety would be more effective than the current EU Directive to ensure a high level of protection of children and the marketing of toys throughout the EU.

The majority of **business associations** considered that the Toy Safety Directive has helped to improve the safety of toys placed on the market to a large or moderate extent. Half of the business associations agreed that the Toy Safety Directive has helped to ensure the free movement of toys in the EU, however, interpretational differences and national deviations are still to be solved. A large majority reported problems with the implementation and enforcement of the Toy Safety Directive in the Member States, the most significant problem being market surveillance authorities acting differently in different Member States. To overcome these problems they indicated that it would be most helpful to establish rules to better control internet shops and to ensure better collaboration between authorities in different EU countries. To make the Toy Safety Directive more effective they suggested an improvement of the guidance documents on the Toy Safety Directive as well as better communication and collaboration amongst stakeholders and with the European Commission.

Two thirds of the responding **companies/business organisations** considered that the Toy Safety Directive has helped to improve the placing on the market of toys and their free movement throughout the EU to a large or moderate extent. Less than half of them acknowledged the existence of problems in the implementation and enforcement of the Toy Safety Directive, the most relevant problems being that market surveillance is not always targeting the 'bad guys' and that Internet toy shops are not effectively controlled. The proposed solutions to those problems were in line with the problems' own nature: market surveillance should focus more on the 'bad guys', better surveillance rules for internet shops should be established and better collaboration between market surveillance authorities in different EU countries should be ensured. Priorities to enhance the Toy Safety Directive's effectiveness were identified in the following improvement of guidance documents on the Toy Safety Directive and communication and collaboration amongst stakeholders and with the European Commission.

Public authorities, by a large majority, considered the Toy Safety Directive to have helped improving the safety of toys placed on the market and ensuring the free movement of toys throughout the EU. However, two-thirds of them signalled problems of implementation or enforcement of the Toy Safety Directive. The two most outstanding problems mentioned were the understaffing of the authorities, including customs, and the fact that under the Toy Safety Directive Internet toy shops cannot be effectively controlled. Predominant solutions suggested by respondents were the following establishing rules to better control internet shops and providing more staff for market surveillance authorities, including customs. To boost the effectiveness of the Toy Safety Directive, public authorities clearly preferred two actions, consisting in improving the guidance documents on the Toy Safety Directive and the communication and collaboration amongst stakeholders and with the European Commission.

The majority of **Notified Bodies** considered that to some extent, the Toy Safety Directive certainly brought improvements to toy safety in the EU, and to a moderate extent that the Toy Safety Directive has definitely helped to ensure the free movement of toys throughout the EU by harmonising rules and procedures for placing toys on the market. Most of them encountered problems in the implementation of the Toy Safety Directive arising from the conformity assessment of toys. They identified two significant problems: 1) manufacturers apply for an EC-type examination when their toys do not comply with a referenced harmonised standard; 2) there are issues arising from the guidance documents for the harmonised application of the Toy Safety Directive. Among the solutions to overcome those problems, they suggested to issue guidance documents at EU level for Notified Bodies and a better exchange of information between Notified Bodies about conformity assessments carried out.

Efficiency

Concerning the possible **benefits** of the Toy Safety Directive, **consumer organisations** agree that the warnings are now more visible than those under the preceding Directive. They also consider the safety assessment to be a good tool to ensure the safety of toys, that standards and testing methodologies have improved since the date of application of the Toy Safety Directive, and also that the detailed provisions in the Toy Safety Directive guarantee a level playing field as well as legal certainty. As concerns possible **costs** of the Toy Safety Directive, consumer organisations considered that purchasing the necessary standards and adapting toys to amendments of the Toy Safety Directive is very costly. They also stated that standards with test methods become available too late after

the Toy Safety Directive is amended. Nonetheless, 5 out of 6 consumer organisations declared that the benefits of the Directive outweigh the costs.

The most costly issues identified were the following: getting information on a toy's supply chain, checking compliance with the Toy Safety Directive requirements and enforcing the Toy Safety Directive in online sales. The majority of consumer organisations considered that the Toy Safety Directive's requirements are adequate to ensure the safety of toys and their free movement throughout the EU.

Business associations considered the following to be the highest **benefits** of the Toy Safety Directive: the detailed provisions in the Toy Safety Directive guarantee a level playing field and ensure legal certainty, the safety assessment is a good tool to ensure the safety of toys and the CE mark is helpful when selling toys to consumers.

With regard to possible **costs** of the Toy Safety Directive, business associations reported that manufacturers had to invest in technical and human resources to adapt to the new requirements of the Toy Safety Directive, and that the technical documentation causes significant costs. In addition, they highlighted the costs for adapting to the amendments of the Toy Safety Directive. Among the most costly issues, business associations identified the following: taking account of all safety requirements and generating the technical documentation and the EC-type examination certificate.

The majority of **company/business organisations** agreed predominantly with the following **benefits** of the Toy Safety Directive: the safety assessment is a good tool to ensure the safety of toys, the CE mark is helpful when selling toys to consumers and the detailed provisions in the Toy Safety Directive ensure legal certainty. On the possible **costs** of the Toy Safety Directive, the majority of company/business organisations agreed to the largest extent that the technical documentation causes significant costs and that it is costly to adapt to amendments of the Toy Safety Directive, that the costs of manufacturing toys have increased compared to those under the preceding Directive and that manufacturers had to invest in technical and human resources to adapt to the new requirements of the Toy Safety Directive. Contributors identified as most costly issues the following ones: getting supply chain information; generating the technical documentation; generating an EC-type examination certificate; taking account of all safety requirements.

Public authorities valued the following statements highest with regard to the **benefits** of the Toy Safety Directive: the safety assessment is a good tool to ensure the safety of toys, the CE mark on toy helps authorities in their market surveillance activities and the detailed provisions in the Toy Safety Directive ensure legal certainty. Standards and testing methodologies have improved compared to those under the preceding Directive.

With regard to possible **costs** of the Toy Safety Directive, responding public authorities expressed that purchasing the necessary standards is expensive for market surveillance. In addition, they stressed that it is also costly to adapt to amendments of the Toy Safety Directive.

Among the most costly issues, public authorities identified the following: enforcing the Toy Safety Directive in online sales, getting the safety assessment and the technical documentation from the economic operator, missing standard test methods. Finally, a clear majority of public authorities considered, to a large or a moderate extent, that the

Toy Safety Directive's requirements ensure both the safety and the free movement of toys throughout the EU.

The majority of the responding **Notified Bodies** agreed mainly with the following statements concerning possible **benefits** of the Toy Safety Directive: warnings are now better visible than those under the preceding Directive, the safety assessment is a good tool to ensure the safety of toys, standards and testing methodologies have improved compared to those under the preceding Directive and the safety requirements of the Toy Safety Directive are aligned with the latest technical and scientific developments.

The majority of the Notified Bodies agreed with the following statements concerning possible **costs** of the Toy Safety Directive: testing costs have increased compared to the preceding Directive, standards with test methods become available too late after the Toy Safety Directive is amended and Notified Bodies had to invest in technical and human resources to adapt to the new requirements of the Toy Safety Directive. Notified Bodies identified the most costly issues in this order: developing a new test, adapting to new requirements of the Toy Safety Directive and to a new harmonised standard.

Relevance

All responding **consumer organisations** considered the Toy Safety Directive's requirement that toys be safe to be relevant to a large extent and recognised the high relevance of the Toy Safety Directive to include detailed requirements on toys. Most of them indicated that the changes to the Toy Safety Directive do not at all appropriately reflect all the latest technical, scientific and social developments and that the Toy Safety Directive has no simple and easy possibility for changes.

All responding **business associations** considered that the Toy Safety Directive's requirement for toys to be safe is relevant to a large extent but only a majority acknowledged the high relevance of the Toy Safety Directive to include detailed requirements on toys. A majority of associations believed that the changes to the Toy Safety Directive appropriately reflect all the latest technical, scientific and social developments.

A majority of **company/Business organisations** confirmed the high relevance of the requirement of toys to be safe and underlined the high relevance that the Toy Safety Directive include detailed requirements for toys. However, only some of them believe to a large extent that the changes to the Toy Safety Directive appropriately reflect all the latest technical, scientific and social developments.

The overwhelming majority of **public authorities** considered that the Toy Safety Directive's requirement of toys to be safe is relevant to a large extent and a large majority underlined the high relevance of the Toy Safety Directive to provide detailed requirements on toys. However, not all public authorities believed that the changes to the Toy Safety Directive reflect all the latest technical, scientific and social developments.

Almost all **Notified Bodies** considered that the Toy Safety Directive's requirement of toys to be safe is relevant to a large extent. They commented that the safety objective should be the priority in setting all the other requirements. However, they also thought that Third Part testing would be beneficial for toy safety, as the US example would show. All of them supported the high relevance of the Toy Safety Directive to include detailed requirements on the safety of toys, but only some of them believed that the changes to the

Toy Safety Directive reflect all the latest technical, scientific and social developments. They commented that as the design of toys is continuously changing (in particular concerning digitalisation) and different products increase exponentially, it should be made easier to update certain parts of the Toy Safety Directive.

Coherence

Most of the responding **Consumer organisations** stated that they are aware of contradictions/overlaps/inconsistencies/missing links between the Toy Safety Directive and other legislation in the EU or in the Member States. For example, the majority of them reported being aware of different limit values for chemicals in other EU or national legislation.

A large majority of **business associations** stated being aware of contradictions/overlaps/inconsistencies/missing links and expressed their awareness of different limit values for chemicals in other EU or national legislation. To bring the Toy Safety Directive more in line with other EU or national legislation, respondents suggested the adoption of a EU Regulation instead of a Directive

Only a slight majority of **company/business organisations** stated that they are aware of contradictions/overlaps/inconsistencies/missing links between the Toy Safety Directive and other legislation in the EU or in the Member States. A majority of them expressed awareness of different limit values for chemicals in other EU or national legislation.

Less than one third of the responding **public authorities** stated that they are aware of contradictions/overlaps/inconsistencies/missing links between the Toy Safety Directive and other legislation in the EU or in the Member States. Only a few of them expressed their awareness of different limit values for chemicals in other EU or national legislation.

Over half of the **Notified Bodies** expressed their awareness of contradictions/overlaps/inconsistencies/missing links between the Toy Safety Directive and other legislation in the EU or in the Member States and reported different limit values for chemicals in other EU or national legislation, such as on bisphenol A (BPA), plasticisers and nitrosamines.

EU added value

All **consumer organisations** agreed that it is better for toy safety and the marketing of toys in the EU to have the Toy Safety Directive than having individual Member State laws, but they were rather neutral on the harmonisation effects of the Toy Safety Directive on testing methodologies and standards and the facilitation of market surveillance across Member States.

Also all responding **business associations** preferred the Toy Safety Directive over individual Member State legislation with regard to toy safety and the marketing of toys in the EU. They considered a EU Directive to give legal certainty for intra-EU trade, and individual Member State legislation impractical. The majority of them agreed that the Toy Safety Directive creates a large market for the same toy, simplifies the trade of toys in the EU and helps harmonising testing methodologies and standards.

Almost all **company/business organisations** considered the Toy Safety Directive to be better for toy safety and the marketing of toys in the EU than having individual Member

State legislation. However, not all of them agreed that the Toy Safety Directive creates a large market for the same toy, simplifies the trade of toys in the EU and helps harmonising testing methodologies and standards. They also commented that the Toy Safety Directive has been taken as a model for many countries for their own standards and that it is a world-class legislation adopted or imitated by several third countries; that it facilitates trade with non-EU countries since the high level of toy safety is well-known in those countries.

Almost all **public authorities** declared that it is better for toy safety and the marketing of toys in the EU to have the Toy Safety Directive, which is applicable throughout the EU, than having individual Member State legislation. Concerning the EU added value of the Toy Safety Directive, the clear majority of public authorities agreed that the Toy Safety Directive helps to harmonise testing methodologies and standards and that exchanges between market surveillance authorities from other Member States are useful for their own work, as well as joint projects with them.

Notified Bodies unanimously declared that it is better for toy safety and the marketing of toys in the EU to have the Toy Safety Directive, than having individual Member State legislation. The majority of them agreed that the largest added value of the Toy Safety Directive is to help harmonising testing methodologies and standards. They commented that the Toy Safety Directive is not about opportunities but about legal compliance and protection and improving the safety of citizens, and that EC-type examination could be an added value when enforced by the authorities for high risk products or new products.

3. Feedback from Consumers

Consumers were asked to answer questions particularly adapted to their situation, which is different from that of the other stakeholders consulted.

A clear majority of **consumer** respondents considered that the toys sold in the EU are safe to a large or a moderate extent. Consumers generally expressed concern about the safety of toys imported in the EU, including when purchased online. Only half of the respondents recognised that the Toy Safety Directive has helped to reduce the number of toy-related injuries, at least to some extent.

A clear majority reported reading all the information on a toy packaging carefully, the '3 years age warning symbol' was correctly recognised by all consumers as being required for toys not intended for children under 3 that might however be dangerous for those children.

A large majority reported that they correctly recognised the meaning of the symbol 'CE' on toy packaging. The majority of consumers expressed not having encountered any problems with unsafe toys. Small parts from toys were reported to cause problems.

Half of the consumers indicated that they contacted the supplier or retail shop in case of an unsafe toy, and only few of them contacted a consumer association. A large majority had never encountered a recall of a toy.

Most respondents declared buying toys online, considering that these toys sold online are safe to a large, moderate or some extent. Some reported buying toys only from known brands and dealers.

A slight majority of consumers considered that the Toy Safety Directive ensures that children across the EU have an equal level of protection.

V. Targeted stakeholder consultation (February-March 2019)

The survey targeted toy manufacturers, importers and distributors and was run on the EUSurvey Platform. Responses arrived between 14 February 2019 and 29 March 2019. The participation in the survey was voluntary, therefore its results are an indication and are not representative in statistical sense. The questionnaires, once finalised, were sent to TIE and uploaded in CIRCA asking TIE and the members of the Expert Group to disseminate them.

The Commission received 32 replies: 26 from toy manufacturers (81%), 5 from toy importers (16%) and 1 from a toy distributor. Five additional replies did not provide answers to any of the questions and thus were not taken into account. Most replies came from Spain and the Netherlands (22% or 7 replies each). All respondents in the importers' and distributors' group and 60% in the manufacturers' group were SMEs. All respondents stated that their company was established before 2011 – meaning that they had experience with the current Toy Safety Directive.

In response to the question 'Have you experienced any significant change in the price of toys in general since the Toy Safety Directive became fully applicable in July 2013?' half of respondents reported price increases while the other half saw no significant price changes[294]. The requirements of Toy Safety Directive were chosen as the most significant reason for price increases, followed by increased complexity of toys, higher quality, impact of external factors (such as crisis), and higher transport cost. The Toy Safety Directive requirements were chosen as the most significant reason by all the analysed groups: manufacturers, importers/distributers, large companies and SMEs

Manufacturers agreed that constant changes to the Toy Safety Directive requirements are a cause of continuous new costs. They also agreed that their costs increase with stricter requirements and the number of different toys they produced. There was general agreement that SMEs have difficulties dealing with the costs imposed by the Toy Safety Directive. More specifically all respondents agreed that the lack of standards or the fact that standards are not referenced on time are causing additional costs, due to the fact that EC-type examination becomes necessary. Almost all stated that restrictions on the use of certain chemicals induce additional costs. Nearly all stated that distributors in the EU request test reports even if they are not necessary, however it seems that in most cases test from laboratories outside EU are accepted.

On the other hand, concerning the benefits of Toy Safety Directive, almost all agreed that performing a safety assessment of a toy allows them to focus on the relevant safety aspects of the toy. And 70% agreed that safety assessments help them to reduce costs.

Almost all manufacturers (91%) stated that their production costs had increased since July 2013, while the remaining 9% said the costs had not changed.[295] The new

[294] 52% of respondents (15 answers) reported price increase and 48% (14 answers) price decrease.

[295] 21 answers and 2 answers, respectively.

requirements of the Toy Safety Directive were quoted as the most significant reason for production cost increases.

One off costs of adapting to the new Toy Safety Directive requirements (such as e.g. hiring new staff or investment in technical resources) were reported on average as about 2% of annual turnover. Technical resources, such as software to measure chemical substances or an IT system, were among the most costly investments that companies had to carry out in order to comply with Toy Safety Directive

VI. National reports on the application of the Toy Safety Directive.

Reporting on the application of the Toy Safety Directive is an obligation under Article 48 of the Toy Safety Directive. The first five-yearly reports (2009-2014) were submitted by all Member States in 2014. The second reporting period for the years 2014-2018 ran between 28 May 2019 – when the questionnaires were sent to the Member States – until the deadline of 20 July 2019. However, some contributions were received after the deadline.

The questionnaire included questions concerning the national legislation transposing the Toy Safety Directive as well as its amendments (notably, the difficulties encountered when transposing the Directive into national legislation), the institutional and administrative arrangements at national level, the evaluation of the national situation concerning the safety of toys and the effectiveness of the Directive (definition of toy, safety requirements, warnings, EC declaration of conformity, safety assessment, CE marking, conformity assessment, technical documentation, procedure for dealing with toys presenting a risk and EU safeguard procedure, the exchange of information between member States and the Committee Procedure). Questions on market surveillance activities were also covered by the questionnaires for Member States, notably on enforcement, co-ordination, co-operation and exchange of information within the Member State, statistics on the market surveillance activities carried out for the period 2014 – 2018, RAPEX data and cooperation with Third Countries.

The Member States' reports will feed into the summary that the Commission is to draw up and publish according to the above mentioned Article 48 of the Toy Safety Directive.

Annex 3: Methods and analytical models

1. Process/Methodology

1.1. Desk research

The desk research relied on existing documents at the international, EU and national level provided by the European Commission and identified by means of due diligence work and internet search. These documents included relevant literature on toy safety and the sector, the policy context and the legal framework of reference.

1.1.1. Literature on toy industry and safety issues

Sources

As regards the toy industry, the main source of information has been the ECSIP Report (2013), as it specifically focuses on the toy industry.

The source of data used for the market analysis in the 2015 Final Report on the Evaluation of Directive 2009/48/EC on the Safety of Toys is the Amadeus – Bureau Van Dijk database. Specifically, the analysis in the context of that evaluation was based on the following sample groups: 162 companies classified as 'Manufacture of games and toys' (NACE 32.4); 25,845 manufacturing companies located in the 28 Member States (with the exclusion of toy-manufacturing companies) and 785 manufacturing companies located outside the EU.

Evidence on toy safety issues was collected starting from RAPEX notifications filtered by 'risk category'. The filtering process allowed for aggregation and ranking of the main risk categories. The research has then been oriented towards the existing relevant literature on the main risk categories as resulting from the RAPEX notification analysis.

As for the emerging issues related to toys, the initial input on their relevance was found in the 2008 Impact Assessment and in the ECSIP Report, eventually finding confirmation in the literature review. The literature ranged from articles, scientific papers and reports, studies - press releases, data and alerts for dangerous products (e.g. RAPEX weekly reports[296]) elaborated by relevant organisations at EU level - such as PROSAFE, EuroSafe, Toy Industries of Europe (TIE) among others.

Use

The relevant literature fed the initial framing of the current safety risks, of the toy free movement and of the emerging issues related to toys.

Amadeus has been used to conduct the market analysis, as presented in section 6.3.1.3 of the 2015 evaluation report of the Toy Safety Directive. The aim of the market analysis

296 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=en

was to triangulate the stakeholders' perceptions on the costs entailed by the Directive with statistical data in order to find out any correlation between the increase of costs and the entry into force of the Toy Safety Directive. In other words, the objective was to understand whether costs have increased because of the Directive or due to other external variables. The comparison of costs entailed by the Toy Safety Directive with the reasonability of these costs as perceived by stakeholders enhanced the overall evaluation of the Directive's efficiency.

1.1.2. Policy framework

Sources

Insights on the policy context have been gathered through relevant information concerning infringement procedures and the ongoing work of the European Commission and of Member States on toy safety, NB-Toys protocols and recommendations, the requests for standardisation and the amendments to the Toy Safety Directive.

Another information source to understand the current policy context consisted in the national reports drafted by national competent authorities, which constitute an obligation under the Toy Safety Directive

Use

Infringement procedures and court cases have been used to understand the level of harmonisation achieved across Member States. This has also helped to understand the stances of many economic operators on possible limitations to the free movement of toys. The ongoing work of the European Commission on toy safety and related documents has been crucial to identify the Directive's adaptation mechanisms and to understand the extent to which they relate to the evolving context. As a source for the desk research, the 2014 national reports are used in the analysis of toy free movement. Moreover, the national reports provide findings on the Directive's implementation and enforcement as presented in section 3, expressing the perspective of public authorities dealing with the Directive. The national reports submitted in 2019 have also been used for the purpose of the current evaluation.

1.1.3. Legal framework

Sources

The legal framework included the legislation relevant for toys, as provided in DG GROW website and listed in the box below.

Box 3 - EU legislation relevant for the toy industry

- Directive 94/62/EC on packaging and packaging waste;
- Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (EMC);
- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC;
- Directive 2006/95/EC on the harmonisation of the laws of MS relating to electrical equipment designed for use within certain voltage limits;
- Directive 2008/98/EC on waste and repealing certain Directives;
- Directive 2011/65/EU, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS);
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) (recast);
- Directive 2014/30/EU on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast);
- 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 (R&TTE);
- Regulation (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC;
- Regulation (EC) No 1935/2004 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 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 1907/2006;
- Regulation No 1223/2009 on cosmetic products;
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Use

The legal framework was of crucial importance to analyse possible overlapping and/or duplications between the Toy Safety Directive and other EU or Member State legislative acts. More in general, the analysis of the legal framework helped understand the overall EU approach to the safety and the sector of toys.

1.2. Stakeholder consultations

Sources

The stakeholders' consultations relied both on a public consultation and on a targeted survey of relevant economic operators, aimed at collecting data on the costs entailed by the Toy Safety Directive.

Moreover, within the framework of the 2015 external study, direct interviews with economic operators, consumer representatives, test laboratories' representatives and the relevant European Standardisation Organizations (ESOs) were conducted.

A Synopsis Report summarising the results of different consultations activities is included in Annex 2.

Further information on key stakeholders to be involved has been collected in the desk research.

In the open public consultation, questionnaires have been tailored to different stakeholders' roles and stakes. This has further facilitated the triangulation of data and information with the aim of ensuring as much transparency and reliability as possible to the evaluation.

Use

Based on the in-depth literature review, the relevant issues for the evaluation process have been identified. The questionnaires served the purpose of confirming, investigating and better understanding the main topics that emerged from the desk research. Firstly, the replies to the stakeholders' consultations provided the stakeholders' perspective on the Toy Safety Directive, including suggestions, difficulties and requests on the main issues considered during the evaluation process. Furthermore, they allowed for triangulation of information among different categories of actors.

To conclude, it is worth underlining that the relatively low number of responses received has not represented a significant research constraint. While some divergences emerged among the opinions expressed by different stakeholder categories, a high homogeneity has been observed within each category. Stakeholders belonging to the same category largely agreed on the main topics addressed in the questionnaires and no major contradiction has been raised. Therefore, a larger number of respondents would only have been of limited added value.

2. Limitations – robustness of findings

As specified in section 1.2, the evidence collected in this report is based on the application of the Toy Safety Directive since mid-2011, when the Directive's provisions entered into application[297]. The evidence is even more recent for chemicals provisions that were to be applied only as of mid-2013. However, many of the elements assessed under the current evaluation, such as the principle of free movement of toys in the internal market, were already present in the previous Directive. Therefore, many observable outputs and outcomes cannot be attributed exclusively to the application of the new Toy Safety Directive because a direct link could be established with provisions already in force when the new Toy Safety Directive started to apply.

2.1. Lack of statistics on toy-related injuries

The IDB is currently the largest and best available source of information on accidents and injuries in Europe.

[297] With reference to the market analysis mainly grounded on ECSIP (2013), data are previous to 2011.

The IDB contains data on accidents and injuries from selected emergency departments (ED) of hospitals in EU Member States from 1996. Patients are surveyed to gather information on the cause of the injury and accident (activity when the injury occurred, area, unintentional, intentional injuries, etc.) and their socio-demographic characteristics (age, gender, country, etc.).

The IDB is hosted by the European Commission (EC), and was set up by DG SANTE under the injury prevention programme, in order to provide central access to the data collected by the MS under the European home and leisure accident surveillance system (EHLASS) programme. (EuroSafe 2016).

The IDB started in 1996 for the first countries participating and is currently the largest and more detailed database on injuries in Europe covering all types of injuries.

Collection of data is managed at the Member State level. In particular, Member States participate on a voluntary basis and are free to select the hospitals (ED units) from which the data is collected but need to ensure the representativeness of the event recorded.

2.1.1 Evaluation strategy

To measure the causal impact of the Toy Safety Directive on the reduction of toy-related accidents, one would need a detailed database tracing the toy from its country of origin (manufacture) and entrance into the internal market until its use by the child and observe the potential occurrence of injury or accident due to this specific toy.

One also needs to take into account that the impact of the Toy Safety Directive on toy related injury might be measurable from one to several years after the introduction of the Toy Safety Directive i.e. the time elapsed between the introduction of the safe toy on the market, the use of the child, and the expected occurrence of an accident.

2.1.3 Information needed and collected in the IDB

The evaluation of the effectiveness of the Toy Safety Directive on toy-related injuries could, in principle, benefit from the data collected by the IDB-FDS because any injury event is linked to the external circumstances that led to the injury and to the involved products.

Data collected on toy-related or child-product related injuries need to be representative and comparable over time and across countries. The available information should allow to observe and quantify the Toy Safety Directive impact (if existent) in at least over a 5 year-window around the introduction date of the Toy Safety Directive in 2011. In other words, one would need a longitudinal dataset of injury-records by MS and for each year from at least 2005 to 2016.

2.1.4 Limitations of the IDB in the evaluation of Toy Safety Directive

The IDB-FDS collects harmonised and detailed information about the product category involved in the injury. However, the product (brand, identifier) is not identified in a systematic and homogeneous way. This information is only available for some limited cases through additional details recorded in narratives (free text fields). As a consequence, the distinction between safe and unsafe toys leading to injuries is not possible.

A bigger concern is the quality, the consistency and the representativeness of the sample over time and across country of the IDB-FDS. Data collected are very heterogeneous: the number of hospitals participating varies across time and countries, and are from different types (children hospitals, general hospitals etc.). In consequence, not all types of injuries are recorded across time. In addition, data for some countries is only recorded for a couple of years; some Member States dropped out of the EU-IDB despite continuing to collect similar data for national use.

However, the records of unintentional injuries, home and leisure injuries or injuries affecting children only are of better quality and availability than the other types of injuries. Therefore, for the purpose of the Toy Safety Directive evaluation focusing on toy- and children-related injuries, the IDB data is potentially appropriate.

The information on hospitals (hospital identifier) started to be recorded in 2009 at the earliest; in most cases it is only available since 2012. The evaluation of the Toy Safety Directive would require information on hospitals in the years before and after the introduction of the Toy Safety Directive (hospital identifier, type of hospital).

The quality of the data and the amount of records is also increasing over time; however, even in recent years, the number of hospitals participating in the IDB is small and national FDS samples are often not representative at the national level (EuroSafe 2017a, EuroSafe 2017b). This is a big impediment to the use of this data for evaluation purposes.

2.1.5 Results of the detailed investigation[298]

Given the limitations of the IDB described in the preceding section, one alternative strategy could be to select those countries with the best level of information. This would limit the data to two or three countries out of 26. For these countries, counterfactual impact evaluation methods (such as a difference-in-difference strategy) could be attempted to measure the impact of the Toy Safety Directive on toy-related injuries a reasonable degree of confidence.

In the remaining of this subsection, the results of a more detailed feasibility investigation are presented and aim at replying to the following questions: (1) are there a number of Member States with a representative sample of injury records? (2), and is the time period covered for those Member States long enough? (5 years window around the introduction of the Toy Safety Directive)

Sample selection

In the analysis, only records related to unintentional injuries, due to child products and for individuals under 14 years old were selected. This sample represents 4.11% of the recorded injuries involving children under 14 years of age.

Total number of observations	7,717,897
Drop intentional injuries	7,562,195
Keep location of injuries: home, school, recreational areas	3,620,658
Keep injuries with activity when injured is: education, sports and exercise during leisure time, leisure or play	1,484,293

[298] For confidentiality reason, the name of the Member States has been anonymised.

Injuries of individuals under 14 years old	904,221
Keep injuries related to child products	37,152 (4.11%)

Table 1 further below displays the time period for which data is available by country and whether information on the hospital identifier is recorded. Countries for which information was available only before (Country 2, Country 3, Country 7, Country 8, Country 9, Country 10, Country 12, Country 13, and Country 19) or only after the implementation of the Toy Safety Directive in 2011 (Country 4, Country 11, Country 14, Country 18, Country 20, Country 22, Country 5, Country 15, and Country 16) were excluded from the sample. When information on hospital identifier was missing, the information gathered in (EuroSafe, 2017a) was used to check whether the hospitals present in the database remained constant over the time period.

The above criteria selected data from four countries: Country 1, Country 6, the Country 17, and Country 21.

Descriptive statistics on selected countries

Similar to the strategy followed in (Dumangane et al, 2019; Guthmuller & Elia, 2018) the number of injury events before and after the introduction of the Toy Safety Directive in 2011 due to different child product categories were compared, namely:

(1) toys as defined in the Directive;
(2) public playground equipment;
(3) child equipment (or baby and child article) and
(4) other type of specified child products (as defined in the IDB, EuroSafe (2013) code 06.98).

Figure 1 reports the proportion of events by child-product categories among the total number of events involving children younger than 14 years of age for each year.

For Country 1, the Country 17, and Country 6, the time series starts in 2008/2009, whereas for Country 21 it starts in 2002. The number of child product related injuries seems to remain constant in the longest time series available (Country 21). The data exhibits no peaks/or decreases around the year 2011 and/or 2013, or thereafter until 2017. The proportion of injuries follows a decreasing trend over the entire period. This pattern is similar in Country 1 and in the Country 17.

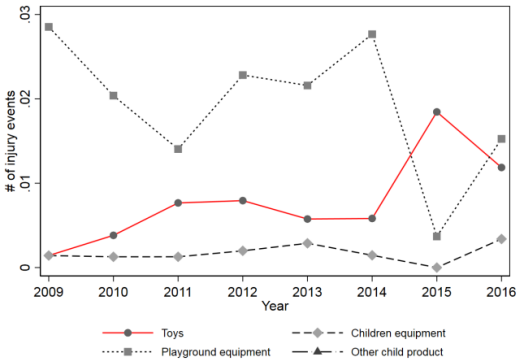
In the Country 17, there seems to be a decrease in injury events involving public playground in 2013-2014. However, this decrease is not present in Country 1 and in Country 21. The shorter time period covered by the data in Country 6 does not allow drawing any conclusion related to child-product related injuries. If the number of child-product recorded injury event differs (Country 1 with approx. 15 events on average per year, the Country 17, Country 6, and Country 21 approx. 100 in average per year, see Figure A in Appendix), the proportion of child-product related injury event ranges between 0.01% and 0.04% amongst the total of injury events involving children younger than 14 years of age.

In total, and with regard to the two objectives of this investigation, the overall data quality (heterogeneity in the type of injury event collected by each Member State) and the insufficient number of time periods of data collected in most of the Member States in

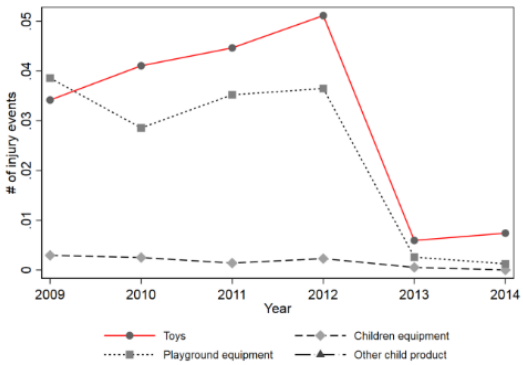
the IDB does not permit a robust quantification of the impact of the Toy Safety Directive on toy-related injuries.

Table 1: Countries and timeline of data collection

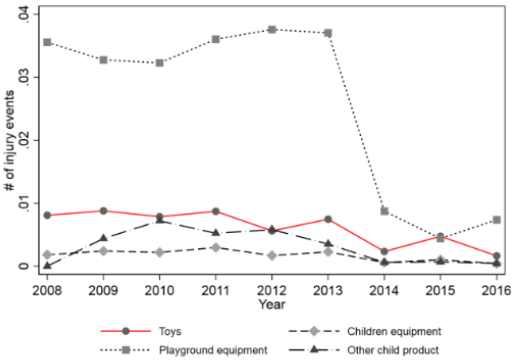
Country	Time period of data availability	Information on hospital identifier
Country 1	**1996 – 2016**	**2009 – 2016**
Country 2	1996 – 1999	No information
Country 3	2006 – 2009	2009 and 2013
Country 4	2009 – 2013	No information
Country 5	2006 – 2016	2009 – 2016
Country 6	**1996 – 2014**	**2009 – 2014**
Country 7	1996 – 2001	No information
Country 8	1996 – 1998	No information
Country 9	1996 – 2007	No information
Country 10	1996 – 2001	No information
Country 11	2013	No information
Country 12	1996 – 2002	No information
Country 13	1996 -1998, 2002, 05, 14	2014
Country 14	2013- 2016	2013 – 2016
Country 15	2005 – 2016	2010 – 2016
Country 16	2006 – 2015	2009 – 2015
Country 17	**1996 – 2016**	**2009 – 2012**
Country 18	2013	2013
Country 19	1996 – 1998 (2006)	No information
Country 20	2012- 2013	No information
Country 21	**1996 – 2017**	**2009 – 2017**
Country 22	2003 – 2016	2009 – 2016



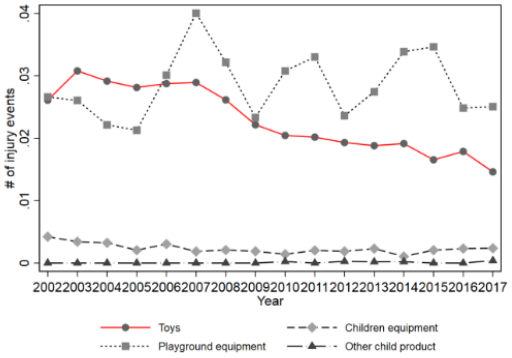
Country 1



Country 6



Country 17



Country 21

Figure 1: Proportion of injuries event related to infant and child product by subtypes

Note: Toy (code 06.02), Playground equipment (code 06.03), children equipment (bay baby and child article, code 06.01), other specified infant and child product (code 06.98)

2.2. Lack of statistics on costs caused by the Toy Safety Directive

The 2015 evaluation of costs and burdens caused by the 2009 Toy Safety Directive is mainly qualitative. A more quantitative approach was indeed not feasible in the context of that evaluation, mainly because of the lack of data on costs induced by the Directive. The lack of statistics could have been compensated by a large survey to collect data, but this was not in the scope of the evaluation. As a result, the available information made it difficult to obtain exhaustive and comprehensive information on costs supported by firms to comply with the Directive's requirements. Furthermore, this kind of information was not provided in the national reports, thus preventing the quantification of costs borne by Member States. Finally, there are a number of factors (e.g. new technical or scientific developments, changes in the price of raw materials) that can influence production costs. As a consequence, economic operators were not always able to distinguish cost increases directly caused by the Directive from those induced by exogenous factors.

The 2015 study missed a serious quantification of cost/benefits (data was based on 50 interviews) and this is particularly important given the fact that the IA supporting the Toy Safety Directive provided quite a lot of data, for example,:

- Cost and benefits related to chemical requirements;
- Costs and benefits related technical file requirements;
- Costs related to labelling (three scenarios: low, medium, high estimates for each company size: small, medium, multinational);
- Costs related to choking risk requirements(three scenarios: low, medium, high estimates for different company size: small and multinational);
- Costs related to affixing CE- marking;
- Costs related to conformity assessment procedures;
- 3 case studies (small, medium and multinational company) concerning costs of proposed modifications.

The cost quantifications in the 2008 IA were based on two support studies, the first one being Europe Economics 2007 (chemical requirements costs), where the calculations are based on stakeholder consultation (experts and survey). The other study (RPA. 2004) provided 3 case studies (copied to IA) and an estimate of costs related to non- chemical requirements (calculations are based on three hypothetical case studies and stakeholder survey)

The 2015 external study had therefore to be supplemented by a quantitative analysis. A study was therefore commissioned to the Commission's Joint Research Center (JRC) on the cost-benefits quantification in the framework of the evaluation of Toys Directive in order to:

- check the existing literature
- verify the costs and benefit methodology used in IA (ad replicate of feasible);
- check to what extent the estimated impacts have been materialised.

Further information could also be found in other sectorial evaluations produced by GROW/ENV, such as the Fitness check on chemicals legislation (excluding REACH)[299]

[299] http://ec.europa.eu/growth/sectors/chemicals/ec-support_en

– which also includes a case-study on toys – and the ECHA Forum joint market surveillance action.[300]

In order to fill in this data gap, a targeted survey for economic operators was undertaken which provided 32 responses (26 from toy manufacturers, 5 from toy importers and 1 from a toy distributor). See following section 3 below for further details.

3. Analysis of impact of the Toy Safety Directive on costs and prices

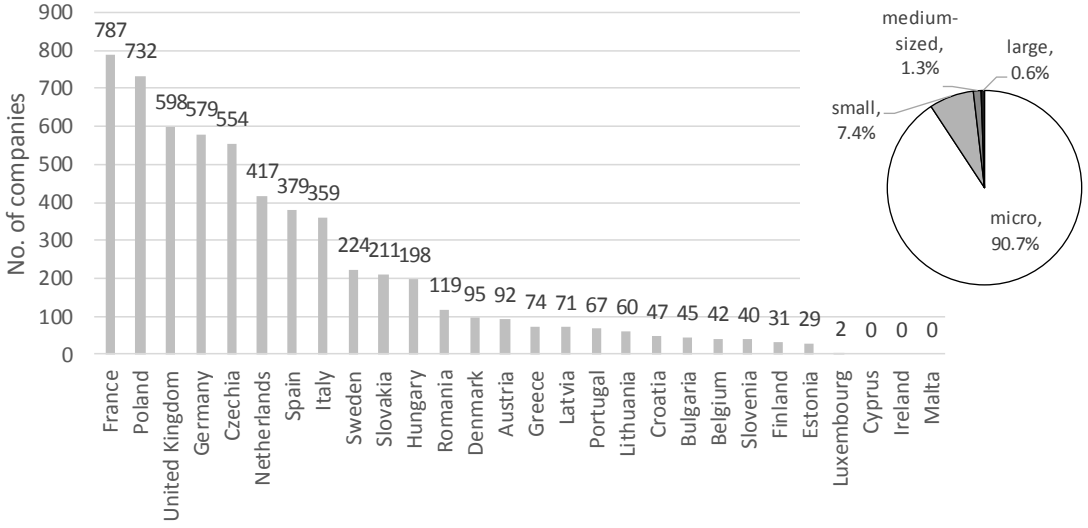
Analysis are based on the results of targeted survey (see also annex 2) and data from Eurostat. It must be noted that results of the targeted survey are not representative in statistical sense and are based on a very small number of replies. Therefore, although the evaluation team tried to extrapolate these numbers, the results must be treated as a ball park estimate, an indication of the magnitude of cost rather than an actual statistical figure.

3.1. Demographics of manufacturers

According to Eurostat, in 2011 in the EU there were around 5,000 companies in the NACE code C324 'Manufacture of games and toys' this number increased to around 6,000 in 2017.[301]

In that NACE code in 2016 there were only 33 large companies (0.6%) in the EU, the rest were SMEs (90.7% micro companies, 7.4% small and 1.3% medium-sized). The majority of companies were located in France, Poland, UK and Germany. The highest number of large companies was located in Germany. (Fig. 2)/

Fig. 2. Number of manufacturers of games and toys by country and size in 2016



Note: Data for NACE C324 'Manufacture of games and toys'. Large companies employ more than 250 employees, medium-sized between 50 and 249, small between 10 and 49 and micro below 10.
Source: Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2],[sbs_sc_ind_r2]

[300] https://echa.europa.eu/-/inspectors-find-phthalates-in-toys-and-asbestos-in-second-hand-products

[301] Eurostat Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) [sbs_na_ind_r2], Last update: 21-03-2019

3.2. Description of respondents to the targeted survey

The Commission received 32 replies:[302] 26 from toy manufacturers (81%), 5 from toy importers (16%) and 1 from a toy distributor. Most replies came from Spain and the Netherlands (22% or 7 replies from each). All respondents in importers and distributers group and 60% in manufacturers group were SMEs (Fig. X.1). All respondents stated that their company was established before 2011 – meaning that they had experience with the current Toy Safety Directive.

In case of manufacturers large companies who replied produced on average 240 toy types (median of 100) requiring a safety assessment, and on average around 33 million toys a year. SMEs produced on average 78 toy types[303] (median of 30), with an average annual production of 3.6m. The combined EU turnover for 2017 of those toy manufacturers who replied amounted to € 11.3billion.[304] The majority of that turnover was generated from toy sales in the EU (average 70%, median 90%) with SMEs selling more in the EU than the large firms did. Three manufacturers were producing toys only in the EU, others produced in many EU and non-EU countries (e.g., 80% had manufacturing in China and 20% in Vietnam). All firms were selling their toys in more than one EU country, 60% in the entire EU, 80% in the US, more than 40% in Brazil, China, Gulf States, India, Mexico, Russia, South Africa and Turkey.

Among the six toy importers, all were SMEs. The number of toy types requiring safety assessments ranged from 12 to 1,000, they import on average 3.3m toys. The combined EU turnover of those who provided it amounted to € 30m. All were importing from China, other countries of origin included Hong Kong, Vietnam, Malaysia, USA, Mexico and Brazil. One importer was selling only in its country, the rest were covering two to six EU countries.

The one toy distributor was a micro firm, with four toy types requiring safety assessment. It was selling mainly via the internet into two EU countries.

3.3. One-off costs of adapting to the requirements of the Toy Safety Directive

Between 2010 and 2013, according to the Eurostat there were around 5,000 firms producing toys in the EU, with between 10 and 30 large firms[305] and the rest SMEs. Large companies were responsible for around two thirds of the turnover of the toy industry.

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302 Five additional replies did not provide answers to any of the questions and thus were not taken into account.

303 This average excludes one outlier who reported production of 4m toy types.

304 Dominated by three large multinational companies who accounted for €10.6 billion

305 Between 2010 and 2016 the number of large companies reported by Eurostat is between 10 and 30. The number reported for 2011 till 2013 is around 10, however for 2010 and 2015-2016 it is 30. While there may be different reasons for that fluctuation (e.g. it is possible that around 20 firms were on the threshold and thus flipping between large and SMEs category, or smaller firms could merge, or big multinationals could enter the market) for the calculations throughout this period we assumed that there were around 30 large firms.

As reported in section 5.2, one-off costs of large companies amounted to between 1% (median) and 1.7% (average) of annual turnover, while for SMEs it was between 2.4% (average) and 3% (median).

Using Eurostat data on turnover and number of companies, we can calculate that average annual cost of implementing Toy Safety Directive was between € 2.1 and 3.5m per large firm and between € 16,000 – 20,000 per SME.

In terms of the whole toy manufacturing industry the one-off cost amounted to between € 140m and 200m. (table 2).

Table 2. One-off cost of implementing Toy Safety Directive for toy manufacturers

	All sizes	Large	SME
Cost per company (€)	32,300 – 36,100	2.1 – 3.5 million	16,300 – 20,600
Cost per toy industry (€ million)	141 – 203	59 – 100	82 – 103

Note: 2018 prices, average number of firms and turnover between 2010 and 2013 used, average number of large firms 29. Ranges based on median and average percentage of cost as reported in the targeted survey.
Source: Own analysis based on targeted survey and Eurostat [sbs_sc_ind_r2], [prc_hicp_aind]

3.4. Impact on prices

According to Eurostat between 2013 and 2018 all prices rose by 5% while prices of 'games, toys and hobbies' declined by 2%.[306] However a more detailed price inflation index for 'toys and celebration articles' shows price increase from 2015 to 2018 of 4%.[307]

This is broadly in line with the 2.9% toy price increase since 2013 reported by respondents to the targeted survey.

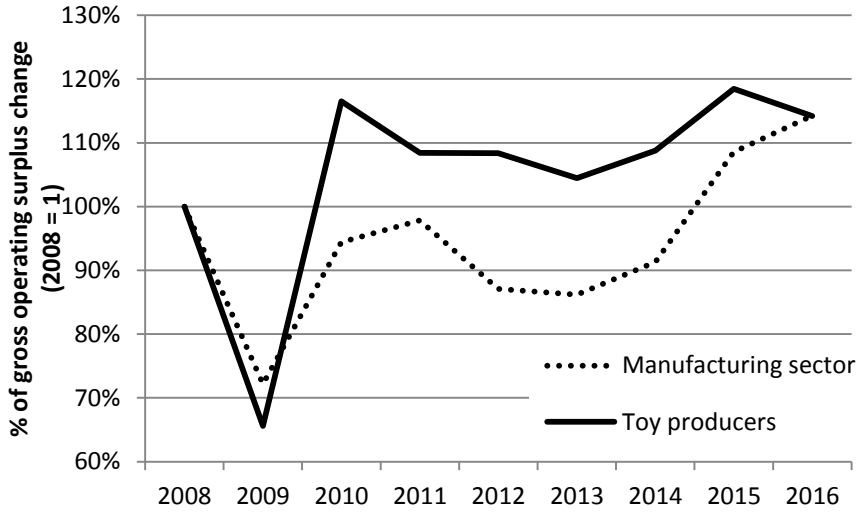
	All replies*	Manu-facturers	Importers and distributors	Large	SMEs
Price increased	52%	43%	83%	57%	50%
Price remained unchanged	48%	57%	17%	43%	50%
Price decreased					
Weighted average of those who said it increased	5.6%	5.8%	5.4%	6.8%	5.3%
Weighted average for all	2.9%	2.5%	4.5%	3.9%	2.7%
No. of replies	29	23	6	7	22

Source: Own analysis based on targeted survey

It is interesting to note that the reported cost increase was higher and amounted to 6.8%. This suggests that not all cost were transmitted to consumers, and companies internalised from 2pp to 4pp of the increased cost. This can at least partially be supported by an analysis of firm profits which dropped between 2010 and 2011 while the whole industry was growing, also reduction between 2012 and 2013 was deeper than for the whole industry[308] (Fig. Y.2).

[306] Eurostat HICP, prc_hicp_aind, last update: 17-04-2019.
[307] Eurostat HICP, prc_hicp_aind, last update: 17-04-2019, data for 2013-2015 not available.
[308] Please note that there may be many other factors explaining that difference.

Fig. 3. Development of profit per firm since 2008 for toy producers and manufacturing sector



Note: Gross operating surplus[309] per firm in NACE C324 'Manufacture of games and toys' and NACE C 'Manufacturing', 2018 prices. Source: Eurostat, [sbs_na_ind_r2], [prc_hicp_aind]

[309] Gross operating surplus or profits is defined, in the context of structural business statistics, as value added minus personnel costs. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Gross_operating_surplus_-_SBS

Annex 4: 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:

- 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)
- November 2019: Revision of the migration limits for aluminium (Commission Directive (EU) 2019/1922)
- May 2018: Revision of the specific limit value for chromium VI (Commission Directive (EU) 2018/725)
- 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)
- 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)
- March 2017: Revision of the migration limits for lead (Council Directive (EU) 2017/738)
- 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)
- 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)
- 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)
- June 2014: Additional permitted use of the CMR substance nickel (Commission Directive 2014/84/EU)
- 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)
- 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)
- July 2013: Revision of the migration limits for barium (Commission Regulation (EU) No 681/2013)
- March 2012: Revision of the migration limits for cadmium (Commission Directive 2012/7/EU)

Annex 5: Main provisions of the Toy Safety Directive

a. Safety requirements

The essential safety requirements for toys are outlined in article 10(1) of the Toy Safety Directive. They include general safety requirements (in paragraph 2) and particular safety requirements (in Annex II).

As for the general safety requirements, the Directive envisages firstly that toys have to be safe both for users - namely for the children playing with the toy - and for third parties such as parents, supervisors, other children or even complete outsiders. Secondly, toys are required to be safe when used as intended by the manufacturer but also when used in other foreseeable ways, bearing in mind children's behaviour. Thirdly, when designing and manufacturing a toy, the ability of children - and, where appropriate, of their supervisors - to use it shall be taken into account, in order to properly ensure a safe use of the toy.

The particular safety requirements concern physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity (see section 2.1.2 above).

b. Safety assessment

Article 18 states that 'Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.' Safety assessments are often carried out before submitting the toy to the conformity assessment, but may be completed at a later stage as well; in any case, at the latest before placing the toy on the market.

c. Conformity assessment

According to article 19, the conformity assessment aims at demonstrating whether specified requirements relating to a toy have been fulfilled. When there are harmonised standards covering all the safety requirements relevant for the toy, and when the reference of the harmonised standards has been published in the Official Journal of the EU, the manufacturer can carry out the conformity assessment himself. Otherwise, and any time the manufacturer deems it necessary, an external conformity assessment body or Notified Body must be involved. When carried out by the Notified Body, the conformity assessment is called EC-type examination and it is accompanied by an EC-type examination certificate delivered by the Notified Body – as far as the examination demonstrates conformity of the toy with all relevant requirements (see section 2.1.2 above).

d. EC declaration of conformity and CE marking

The provisions of the Toy Safety Directive require manufacturers to sign a Declaration of Conformity (DoC), which is the manufacturer's declaration that the toy satisfies all the essential safety requirements.

As proof it must contain the statements 'This declaration of conformity is issued under the sole responsibility of the manufacturer' and 'The object of the declaration is in conformity with the relevant Community harmonisation legislation.' The EC declaration of conformity, whose structure and content are outlined in Annex III to the Directive, shall be translated into the language(s) required by the Member State where the toy is placed or made available on the market.

In addition to the EC declaration of conformity, all toys made available on the EU market shall bear the CE marking (article 16(1)), which is to be affixed only by the manufacturer

or by his authorised representative. According to article 17(1) of the Directive the CE marking must be affixed 'visibly, legibly and indelibly to the toy, to an affixed label, or to the packaging.' Member States shall rely on it to presume that the toy is in conformity with the relevant safety requirements (article 16(3)).
Article 4(3) of the Directive requires manufacturers to keep the EC declaration of conformity for a period of 10 years after the toy has been placed on the market. Article 6(8) requires importers to keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities for a period of 10 years after the toy has been placed on the market.

e. Warnings

Article 11(1) lays down the general rules for warnings applying to all toys. Warnings have to be used only where appropriate for a safe use and have to specify proper use limitations. Part B of Annex V provides specific warnings for certain categories of toys.[310] In particular, toys that are not suitable for children under 36 months of age shall bear a warning such as 'Not suitable for children under 36 months', or 'Not suitable for children under three years', or a warning in the form of a pictogram. The pictogram or warning text must be accompanied by the description of the hazard and the potential harm that makes the product unsuitable.
As for the location of the warnings, article 11(2) states that 'the manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy'.

f. Traceability

Traceability, which is 'the ability to trace the history of the product', enables the effective control of the production process and supply chain. Traceability is ensured through requiring manufacturers and (for imported products) importers to indicate directly on the toy, on its packaging or in a document accompanying the toy, their name, registered trade name or registered trade mark and the address at which they can be contacted (article 4(6) and 6(3)).
Furthermore, manufacturers are obliged to provide the toy with a type, batch, serial or model number or other elements allowing its identification, thus further ensuring product traceability.

g. Technical documentation

The provisions of the Toy Safety Directive require manufacturers to put together a technical documentation file. In particular, Article 4(3) requires manufacturers to keep

[310] Particular toy categories are:
1. Toys not intended for use by children under 36 months;
2. Activity toys;
3. Functional toys;
4. Chemical toys;
5. Skates, roller skates, online skates, skateboards, scooters and toy bicycles for children;
6. Aquatic toys;
7. Toys in food;
8. Imitations of protective masks and helmets;
9. Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps;
10. Packaging for fragrances in olfactory board games, cosmetic kits and gustative games.

the technical documentation for a period of 10 years after the toy has been placed on the market.[311]

h. Identification of economic operators in the supply chain

Economic operators shall, on request, identify any economic operator who has supplied them with a toy and/or to whom they have supplied a toy (article 9). They have to be able to keep this information at the disposal of national surveillance authorities for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and for a period of 10 years after they have been supplied with the toy, in the case of other economic operators.

i. Amendments

Article 46 empowers the Commission to amend the Directive's provisions concerning

- the list of products that are not considered as toys within the meaning of the Directive (Annex I);
- the list of allergenic fragrances and the migration limit values of elements used in toys (Points 11 and 13 of Part III of Annex II);
- the warnings (Annex V);
- the permitted use of CMR substances (Appendix A) as well as
- the specific limit values for chemicals in toys intended for use by children under 36 months of age or intended to be placed in the mouth (Appendix C).

In addition, Article 47 establishes the Directive's Committee and its procedure, and rules how amendments shall be carried out.

j. Penalties

Concerning penalties, article 51 establishes that 'Member States shall lay down rules on penalties for economic operators - that may include criminal sanctions - applicable to infringements of the national provisions adopted pursuant to the Directive, and shall take all measures necessary to ensure that they are implemented.' Penalties are required to be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement.

[311] The content of the technical documentation is detailed in Annex IV, where the following documentation is required to be included:

- A detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
- The safety assessment(s);
- Description of the conformity assessment procedure;
- A copy of the EC declaration of conformity;
- The addresses of the places of manufacture and storage;
- Copies of documents that the manufacturer has submitted to a Notified Body, if involved;
- Test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure; and
- A copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 19(3).

Annex 6: How a toy safety standard supports the Toy Safety Directive

The Toy Safety Directive sets the safety requirements that toys have to fulfil in order that children can play safely with those toys. 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.'[312] 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',[313] 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. [314] The standard thus sets the detailed specifications for testing a toy against the Directive's requirements.

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.[315] 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.

[312] Annex II, Part I, point 4 (d) of the Toy Safety Directive 2009/48/EC.

[313] Standard EN 71-1:2014+A1:2018, clause 5.1 a).

[314] Standard EN 71-1:2014+A1:2018, clause 5.1 b).

[315] Latest as Commission Implementing Decision (EU) 2019/1728 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council. OJ L 263, 16.10.2019, p. 32.

Annex 7: 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 71-2:2011+A1:2014 Safety of toys – Part 2: Flammability
3.	EN 71-3:2019 Safety of toys – Part 3: Migration of certain elements
4.	EN 71-4:2013 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+A2:2018 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 71-12:2013 Safety of toys – Part 12: N-Nitrosamines and N-nitrosatable substances
9.	EN 71-13:2014 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.	Electrical safety requirements EN 62115:2005/A11:2012/AC:2013 EN 62115:2005/A11:2012 EN 62115:2005/A12:2015 EN 62115:2005/A2:2011/AC:2011 EN 62115:2005/A2:2011 IEC 62115:2003/A2:2010 (Modified)

Annex 8: Problems identified in the 2008 IA and addressed in the 2009 Toy Safety Directive

2008 IA: Problems identified			**Response in the 2009 Toy Safety Directive**
Scope and concepts	*The toy definition lacked clarity.*	The 'use in play' and 'play value' concepts are not clear.	Article 2: scope of the Toy Safety Directive (the definition of toy refers to 'products designed or intended, whether or not exclusively, for use in play') Annex I: list of products not considered as toys within the meaning of the Toy Safety Directive
	The 1988 Toy Safety Directive does not comply with the European Commission's standards for Smart Regulation and good legislative practices	Need to avoid ambiguities and complicated sentences, to provide individual articles with proper titles and to group them under section-headings	The 2009 Directive has been drafted according to this point.
	Clarification on the relationship between the Toy Safety Directive and the GPSD	The GPSD applies to toys in cases not always clearly defined.	Article 52(2): GPSD does not apply to toys: Recital 4: toys also subject to GPSD which applies in a complementary manner to specific sectorial legislation
Safety require-ments	*Outdated safety requirements*	Physical and mechanical requirements	Annex II, Part I: physical and mechanical properties
		Electrical properties	Annex II, Part IV: electrical properties
	Lack of safety requirements for recently identified hazards	Safety requirements for chemicals should be revised	Annex II, Part III: chemical properties
		Lack of safety requirements for noise	Annex II, Part I, point 10: safety requirements for noise
		Lack of safety requirements for lasers	Annex II, Part IV, point 8: safety requirements for lasers
		Lack of safety requirements for electrically powered ride-on toys and for activity toys	Annex II, Part IV: electrical properties Annex II, Part I, point 7: requirement for maximum design speed of electrically driven ride-on toys
		Lack of specific safety requirements for toys in food	Annex II, Part I, point 4(f): requirements for toys contained within food or co-mingled with food Annex V, Part B, point 7: warning for toys contained within food or co-mingled with food

	Lack of clarity in the general safety requirement	The statement '*Normal behaviour of children'* created interpretation problems.	Article 10(2): general safety requirement (referring to the behaviour of children)
	Lack of complete warning requirements	User limitations should be included	Annex V, Part A: general warnings (referring to user limitations)
		Adult supervision should be ensured	Annex V, Part A: general warnings (referring to adult supervision)
Enforce-ment	*Market surveillance*	Requirement for manufacturers to perform hazard/risk analysis is not mandatory	Article 18: requirement for manufacturers to perform hazard/risk analysis
		Lack of any specific requirement for manufacturers to keep hazard/risk analysis in the technical file	Article 21 and Annex IV: requirement for manufacturers to keep hazard/risk analysis in the technical file
	Lack of appropriate institutional framework for Member States and the European Commission	Need to enhance the effectiveness and timeliness of implementing the Directive	Chapter VII: Committee procedures providing for the Regulatory Procedure with Scrutiny (RPS) to amend non-essential elements of the Toy Safety Directive for the purpose of adapting them to technical and scientific developments
	Non-satisfactory toy-related information and traceability	Lack of clarity of the rules concerning the CE marking	Article 16: general principles of the CE marking Article 17: rules and conditions for affixing the CE marking

Annex 9: Occurrence of nitrosamines and nitrosatable substances in toys – Market surveillance data

The Commission's EU Safety gate data show 33 notifications from Member States from 2012 to 2019,[316] mostly balloons, but also one finger paint, with nitrosamines exceeding the limit in 25 cases, nitrosatable substances in 16 cases, and the combined occurrence of nitrosamines and nitrosatable substances in 8 cases.

Additional data on nitrosamines in toys provided by Member States showed that:

- A campaign in Denmark in 2014 found no nitrosamines in finger paint sets (up to 6 colours per set), with the exception of one yellow paint that largely exceeded the limit;
- Tests on balloons in Germany from 2013 to 2017 showed that of 230 balloons tested for nitrosamines, 11 exceeded the limit, 161 others released nitrosamines below the limit. The 634 balloons tested for nitrosatable substances exceeded the limit in 46 cases, and they released nitrosatable substances in 395 cases. – In 2015 no nitrosamines were detected in 8 finger paints;
- Tests for nitrosamines and nitrosatable substances in France from 2011 to 2017 showed that 2 out of 5 balloons exceeded the limits for nitrosamines and nitrosatable substances. Further 11 toys, such as soft plastic toys or finger paints, did not release nitrosamines or nitrosatable substances;
- A Dutch report from 2018 showed that of 58 balloons tested, 16 released nitrosamines and nitrosatable substances above the Directive's limits. A further 30 balloons released nitrosamines or nitrosatable substances, however below the limit;
- In Austria, 4 balloon samples in 2016 and 5 in 2017 did not exceed the limits for nitrosamines and nitrosatable substances. In the same way, 3 balloon samples in 2015 in Sweden did not exceed the limits. In Bulgaria, no nitrosamines or nitrosatable substances were found in 10 balloon samples in 2015;
- Data from Norway from 2014, 2016 and 2018 reported 45 balloons tested: 13 released nitrosamines above the limit, 3 further were below the limit. Of other toys, such as finger paints or rubber ducks, one finger paint showed nitrosamines above the limit. Nitrosatable substances exceeded the limit in 22 balloons, 1 finger paint and 1 penguin rubber toy; in addition, 14 balloons released nitrosatable substances, but less than the limit.

The above illustrates that nitrosamines and nitrosatable substances continue to exceed the current limits in the Toy Safety Directive, in particular in balloons, much less so in finger paints or other toys. Nitrosatable substances are more often found in toys than the nitrosamines themselves.

[316] Up to 27.5.2019.

Annex 10: Possible benefits of the Toy Safety Directive

Selected results from the 2018 public consultation

Table 1. The detailed provisions in the Toy Safety Directive ensure legal certainty (% of respondents*)

Stakeholders responding**	Agree entirely/ Agree	Neither agree nor disagree	Disagree/ Entirely disagree	No opinion
Companies (32)	80	10	10	0
Business associations (12)	60	20	30	0
Notified bodies (7)	30	60	10	0
Public authorities (31)	80	10	0	10
Consumer organisations (6)	30	70	0	0

* Rounded to the nearest 10%, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

Table 2. The detailed provisions in the Toy Safety Directive guarantee a level playing field. (% of respondents*)

Stakeholders responding**	Agree entirely/ Agree	Neither agree nor disagree	Disagree/ Entirely disagree	No opinion
Companies (32)	80	10	10	10
Business associations (12)	80	0	30	0
Notified bodies (7)	40	30	30	0
Public authorities (31)	70	20	0	10
Consumer organisations (6)	30	70	0	0

* Rounded to the nearest 10%, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

Table 3. The safety assessment is a good tool to ensure the safety of toys (% of respondents*)

Stakeholders responding**	Agree entirely/ Agree	Neither agree nor disagree	Disagree/ Entirely disagree	No opinion
Companies (32)	90	0	0	0
Business associations (12)	80	10	0	20
Notified bodies (7)	70	10	10	0
Public authorities (31)	80	10	10	10
Consumer organisations (6)	30	70	0	0

* Rounded to the nearest 10%, to avoid the impression of over-precision

** Number of respondents in brackets

Source: Own analysis based on public consultation

Table 4. Considerations of economic operators on the safety assessment (% of the 37 respondents*)

Statements	Agree entirely/ Agree	Neither agree nor disagree	Disagree/ Entirely disagree	No opinion / No answer
The safety assessment of a toy allows my company to focus on the relevant safety aspects of the toy	60	10	10	30
The safety assessment of a toy to be manufactured helps to reduce costs.	50	0	20	30

* Rounded to the nearest 10%, to avoid the impression of over-precision.

Source: Own analysis based on public consultation

Annex 11: EU added value

Selected results from the 2018 public consultation

Table 1. Is it better for toy safety and the marketing of toys in the EU to have the Toy Safety Directive which is applicable throughout the EU, or to have individual Member State legislation? (% of respondents*)

Stakeholders responding**	Agree (entirely)	Neither agree nor disagree	(Entirely) disagree	No opinion
Companies (32)	100	0	0	0
Business associations (12)	100	0	0	0
Notified bodies (7)	100	0	0	0
Public authorities (31)	90	0	0	0
Consumer organisations (6)	100	0	0	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision. Figures may therefore not add up to 100%.
** Number of respondents in brackets
Source: Own analysis based on public consultation

Table 2. To what extent do you agree with the following statements concerning the EU added value of the Toy Safety Directive? (% of respondents*)

Companies responding (32)**	Agree (entirely)	Neither agree nor disagree	(Entirely) disagree	No opinion
The Toy Safety Directive creates a large market for the same toy.	80	10	10	10
The Toy Safety Directive simplifies the trade of toys in the EU.	80	10	10	10
The Toy Safety Directive significantly lowers product development costs.	30	30	30	10
The Toy Safety Directive significantly lowers manufacturing costs.	30	30	40	10
The Toy Safety Directive helps harmonise testing methodologies and standards.	70	20	0	10

* Rounded to the nearest single significant number, to avoid the impression of over-precision. Figures may therefore not add up to 100%.
** Number of respondents in brackets
Source: Own analysis based on public consultation

Table 3. To what extent do you agree with the following statements concerning the EU added value of the Toy Safety Directive? (% of respondents*)

Business associations responding (12)**	Agree (entirely)	Neither agree nor disagree	(Entirely) disagree	No opinion
The Toy Safety Directive creates a large market for the same toy.	60	20	20	10
The Toy Safety Directive simplifies the trade of toys in the EU.	70	0	30	10
The Toy Safety Directive significantly lowers product development costs.	30	10	30	30
The Toy Safety Directive significantly lowers manufacturing costs.	30	10	30	30
The Toy Safety Directive helps harmonise testing methodologies and standards.	50	30	10	20

* Rounded to the nearest single significant number, to avoid the impression of over-precision. Figures may therefore not add up to 100%.
** Number of respondents in brackets
Source: Own analysis based on public consultation

Table 4. To what extent do you agree with the following statements concerning the EU added value of the Toy Safety Directive? (% of respondents*)

Notified bodies (7)**	Agree (entirely)	Neither agree nor disagree	(Entirely) disagree	No opinion
The Toy Safety Directive helps harmonise testing methodologies and standards.	100	0	0	0
The Toy Safety Directive helps increase opportunities for conformity assessment throughout the EU.	60	0	40	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision. Figures may therefore not add up to 100%.
** Number of respondents in brackets
Source: Own analysis based on public consultation

Table 5. To what extent do you agree with the following statements concerning the EU added value of the Toy Safety Directive? (% of respondents*)

Public authorities responding (31)**	Agree (entirely)	Neither agree nor disagree	(Entirely) disagree	No opinion
The Toy Safety Directive helps harmonise testing methodologies and standards.	90	10	0	0
The Toy Safety Directive facilitates market surveillance across Member States.	90	10	0	10
Joint projects with market surveillance colleagues from other Member States provide important insights.	90	10	0	0
Meeting market surveillance colleagues from other Member States is useful for my own work.	90	0	0	10

* Rounded to the nearest single significant number, to avoid the impression of over-precision. Figures may therefore not add up to 100%.
** Number of respondents in brackets
Source: Own analysis based on public consultation

Table 6. To what extent do you agree with the following statements concerning the EU added value of the Toy Safety Directive? (% of respondents*)

Consumer organisations responding (6)**	Agree (entirely)	Neither agree nor disagree	(Entirely) disagree	No opinion
The Toy Safety Directive helps harmonise testing methodologies and standards.	30	70	0	0
The Toy Safety Directive facilitates market surveillance across Member States.	30	70	0	0
The Toy Safety Directive is applicable throughout the EU, so test reports from consumer organisations in other EU countries can be interesting for our own organisation.	100	0	0	0

* Rounded to the nearest single significant number, to avoid the impression of over-precision. Figures may therefore not add up to 100%.
** Number of respondents in brackets
Source: Own analysis based on public consultation