Evaluation of Directive 2009/48/EC on the Safety of Toys

Final Report

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European Commission

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Directorate D - Consumer, Environmental and Health Technologies
Unit D3 - Biotechnology and Food Supply Chain

Contact: GROW-TOYS@ec.europa.eu
B-1049 Brussels

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List of abbreviations

AC	Alternating Current
ADCO	Administrative Cooperation
BSCI	Business Social Compliance Initiative
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
DG	Directorate General
DG SANCO	Directorate General for Health and Consumers
DG TAXUD	Directorate General Taxation and Customs Union
DIY	Do It Yourself
DoC	Declaration of Conformity
EC	European Commission
EFSA	European Food Safety Authority
EMC	Electromagnetic Compatibility
EN	European Standard
ESO(s)	European Standardisation Organisation(s)
ETSI	European Telecommunications Standards Institute
EU	European Union
FFR	First Findings and Recommendations
GPSD	General Product Safety Directive
IA	Impact Assessment
IEC	International Electrotechnical Commission
IPR	Intellectual Property Right(s)
ISO	International Organization for Standardization
MS	Member State(s)
MSA	Market Surveillance Authority(ies)
NB	Notified Body(ies)
NGO(s)	Non-Governmental Organisation(s)
OJEU	Official Journal of the EU
R&D	Research and Development
R&TTE	Radio and Telecommunications Terminal Equipment
RACER	Relevant, Accepted, Credible, Easy, Robust
RAPEX	EU Rapid Exchange System for dangerous non-food products

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	Netherlands' National Institute for Public Health and the Environment
RoHS	Restriction of Hazardous Substances
SAICM	Strategic Approach to International Chemicals Management
SCCS	Scientific Committee on Consumer Safety
SCHER	Scientific Committee on Health and Environmental Risks
SME(s)	Small- and Medium-sized Enterprise(s)
SR	Specific Recommendation
TC	Technical Committee
TCEP	Tris(2-chloroethyl)phosphate
TCPP	Tris(2-chloro-1-methylethyl) phosphate
TDCP	Tris[2-chloro-1-(chloromethyl)ethyl] phosphate
TIE	Toy Industries of Europe
ToR	Terms of Reference
TSD	Toy Safety Directive
UK	United Kingdom
US(A)	United States (of America)
W.A.T.C.H.	World Against Toys Causing Harm
WHO	World Health Organization
WTO	World Trade Organization

ABSTRACT (EN)

Directive 2009/48/EC on the safety of toys aims at ensuring a high level of safety for children while safeguarding the free movement of toys in the EU.

This study assesses the relevance of the Directive in addressing current needs, effectiveness and efficiency of its provisions, its coherence with the EU legislative framework and the European added value. The evaluation results will be used by the European Commission to assess the need for amending the 2009 Directive and/or putting in place new/enhanced tools for its implementation.

The study confirms the Directive to be an effective tool for toy safety and for the trade in the Internal Market, thanks to the introduction of strict safety standards and harmonised procedures across Member States. As for the compliance and administrative costs entailed by the Directive, they turned out to be proportionate in order to achieve the Directive's objectives. Moreover, no major overlapping or duplication related to other EU legislative instruments emerged, but rather room for improvement, particularly concerning the enforcement activities.

Overall, while economic operators are generally satisfied with the current Directive, consumer associations call for stricter safety requirements, in particular in the area of chemicals. Still, the study suggests that, at this stage, both enforcement shortcomings and possible revisions asked for by consumer representatives can be addressed without a general overhaul of the Directive.

ABSTRACT (FR)

La Directive 2009/48/CE relative à la sécurité des jouets vise à garantir un niveau élevé de sécurité des jouets pour enfants, tout en assurant la libre circulation des jouets dans la Communauté Européenne.

Cette étude évalue la pertinence de la Directive par rapport aux besoins actuels, l'efficacité et l'efficience de ses dispositions, sa cohérence par rapport au cadre législatif de l'UE et la valeur ajoutée de l'intervention européenne. Les résultats de l'évaluation serviront de base à la Commission européenne afin d'évaluer la nécessité de modifier la Directive et/ou la mise en place de nouveaux/meilleurs outils pour sa mise en œuvre.

L'étude conclut que la TSD assure efficacement la sécurité des enfants, tout en garantissant le bon fonctionnement du marché intérieur grâce à l'introduction de standards de sécurité et de procédures harmonisées dans tous les États Membres. Les coûts de conformité et administratifs entrainés par la Directive demeurent quant à eux généralement raisonnables et proportionnels à ses objectifs. La Directive s'intègre par ailleurs en cohérence avec le cadre législatif actuel de l'UE et elle ne cause pas de duplications de coûts. Enfin, des défauts majeurs ont été identifiés dans les activités d'exécution, qui appellent à de possibles améliorations.

De fait, les opérateurs économiques sont généralement satisfaits de la législation actuelle, tandis que les consommateurs exigent des normes de sécurité plus strictes, surtout pour ce qui concerne les valeurs chimiques. Toutefois, les défaillances observées dans l'application toute comme les révisions sollicitées par les consommateurs peuvent être corrigées sans une révision drastique de la Directive.

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1 INTRODUCTION

1.1. Purpose of the evaluation

The objective of the study is to conduct an external evaluation of Directive 2009/48/EC[1] (TSD) on the safety of toys in order to assess the performance of the Directive in meeting the objectives of ensuring a high level of safety for children while safeguarding an efficient internal market.

The evaluation results will be used by the European Commission (EC) to assess the need for amending the 2009 Directive and/or putting in place new tools or enhancing existing tools for its implementation. Therefore, this evaluation aims at providing the European Commission with evidence-based recommendations on possible improvements of the current EU legislative framework for toys.

The evaluation is focused on the **relevance** of the Directive in addressing current needs, the **effectiveness** and **efficiency** in achieving its objectives, the **coherence** with the EU legislative framework relevant for toys and the overall **European added value**.

1.2. Scope of the evaluation

According to the Terms of Reference (ToR), the scope of the evaluation is defined as follows:

- **Legislation**: the 2009 Directive, its implementation in the EU and impacts;
- **Timeframe**: five years since 2009, when the Directive entered into force , bearing in mind that it only started applying on 20 July 2011, except for chemical provisions that started applying on 20 July 2013;
- **Territory**: the 28 EU Member States (MS), where the protection of children's health and safety and the functioning of the internal market is to be achieved, and the world, since the Directive's obligations for manufacturers apply to both EU and non-EU manufacturers;
- **Stakeholders**: consumer associations, toy manufacturers – in particular SMEs - and industry associations (including industries whose products may not be immediately perceived as toys, but are toys for the purposes of the 2009 Directive, e.g. books or stationery with a play value for children), toy importers, distributors, national Market Surveillance Authorities (MSA), national Customs Authorities, Member State authorities in charge of the implementation of the 2009 Directive, Notified Bodies (NB) and European Standardisation Organisations.

[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.

1.3. Guide to the reader

1.3.1. Structure of the report and guidance to read it

This report is structured in eight main chapters. The current **Chapter one** introduces the study, including its purpose (1.1) and scope (1.2); furthermore, a guide is provided to the reader (1.3) so as to facilitate the report's readability, by explaining the contents of the different sections, how information and findings are reported and the meaning of crucial definitions in the context of the Directive's evaluation.

Chapter two outlines the background of Directive 2009/48/EC, in order to frame the relevant EU legislative context and the steps that led to the current TSD (2.1). After detailing the EU policy and legislative frameworks of reference, the Directive is introduced together with its objectives and intervention logic (2.2).

Chapter three sketches the evaluation questions at the heart of this study, framing them in relation to the evaluation criteria that guided the assignment.

Chapter four presents the methodological approach to conduct the evaluation (4.1) and the major limitations encountered when gathering and analysing data (4.2).

Findings are presented in **Chapter five**. They include the analysis of the main known and emerging issues concerning the safety and the sector of toys (5.1) and the salient points of the Directive's implementation and enforcement (5.2). The evaluation findings are based on the in-depth analysis of both the relevant literature and the national reports.[2] In order to enhance the fluency and consistency across the different sections, findings are progressively numbered as they are presented in the report. The table below briefly presents the key findings, the corresponding sections in the report and the sources they result from.

[2] Article 48 of the 2009 Directive requires Member States to send the European Commission a report on the application of the Directive by 20 July 2014 (and every five years thereafter). The report shall contain an evaluation of the situation concerning the safety of toys and of the effectiveness of the Directive, as well as a presentation of market surveillance activities at national level. All reports follow a standard template provided by the EC to the Member State authorities. The template includes 49 questions covering 4 broad sections:

The institutional and administrative arrangements at national level, with contacts and characteristics of competent authorities and Market Surveillance Authorities;

The national legislations transposing the TSD and its amendments and difficulties encountered in the transposition;

The evaluation of TSD with detailed questions on efficiency, effectiveness, appropriateness and clarity of its provisions;

Market surveillance, with a focus on enforcement, related statistics and RAPEX.

It should be noted that one national report is missing, while the others do not always cover all the issues included in the template.

Table 1 – Findings and information sources

Findings	Section	Sources
From 1 to 11	5.1.1 - Current safety risks	Literature review and RAPEX
From 12 to 18	5.1.2 - Free movement of toys	Infringements cases, literature review and national reports
From 19 to 21	5.1.3 - Emerging issues related to toys	Literature review and national reports
From 22 to 48	5.2 - Management of the Directive at national level	National reports

The evaluation questions are answered in **Chapter six,** based on the analysis of both data gathered through desk research and information provided by relevant stakeholders during the interviews. The answers to the evaluation questions are supported by cross-references to the key findings. The aim is to clearly present the evidence on which the evaluation is based, ensuring full correspondence between the research findings and the evaluation answers.

The evaluation conclusions are drafted in **Chapter seven**, according to each evaluation criterion. Final conclusions express the authors' suggestions and are followed by specific recommendations related to particular problems that the study highlights.

Besides the specific recommendations mirroring the main issues as detailed in the conclusions, the general recommendations are presented in **Chapter eight** and concern broader issues that are common to several actors - and related needs - at the same time.

1.3.2. Definition of crucial concepts as provided by the Directive

"**Risk**" means the probable rate of occurrence of a hazard causing harm, and the degree of severity of the harm.

"**Hazard**" means a potential source of harm.

"**Economic operator**" means the manufacturer, the authorised representative, the importer and the distributor.

"**Manufacturer**" means any natural or legal person who manufactures a toy, or has a toy designed or manufactured and markets that toy under his name or trademark.

"**Authorised representative**" means any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

"**Importer**" means any natural or legal person established within the Community who places a toy from a third country on the Community market.

"**Distributor**" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a toy available on the market.

"**Recall**" means any measure aimed at achieving the return of a toy that has already been made available to the end user.

"**Withdrawal**" means any measure aimed at preventing a toy in the supply chain from being made available on the market.

2 BACKGROUND TO THE TOY SAFETY DIRECTIVE

2.1. Baseline

2.1.1. The EU legislative context

With reference to the EU legislation for goods – including toys - it is possible to identify four main phases, which have progressively transformed the EU legislative framework up to date:

- The "Old Approach", which detailed all the necessary technical and administrative requirements in the legislative acts;
- The "New Approach" developed in 1985,[3] which detailed only the "essential requirements" leaving the technical details to European harmonised standards (EN);
- The "Global Approach" adopted in July 2008,[4] laying down a horizontal framework of common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation;
- The "New Legislative Framework" adopted in July 2008,[5] which defined all the necessary elements for effective conformity assessment, accreditation and market surveillance, including the control of products imported into the European Union.

Built on the "New Approach", two new concepts reached the top of the EU legislative agenda: the definition of essential requirements and the process of conformity assessment.

Essential 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.[6] As a consequence, there may be several safety requirements associated to the same product.

Conformity assessment is the verification of product compliance with the applicable essential requirements. It is to be carried out by the manufacturer or by a third party – a Notified Body that has been previously recognised 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.

Manufacturers can refer to **harmonised standards**[7] to demonstrate that products comply with relevant EU legislation. The application of harmonised standards is voluntary. However,

[3] Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards.

[4] 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.

[5] 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; 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.

[6] DG ENTR (2014). The "Blue Guide" on the implementation of EU product rules, p. 32.

[7] A harmonised standard is a standard adopted by one of the European standardisation bodies (CEN, CENELEC or ETSI) on the basis of a request made by the Commission (a so-called "mandate").

as long as a product conforms to the applicable harmonised standards that are referenced in the Official Journal of the EU (OJEU), it benefits from the presumption of conformity. When not applying harmonised standards, the manufacturer must externalise the conformity assessment to a Notified Body, this process being known as "EC-type examination". The safety assessment to be carried out by the manufacturer is mandatory, regardless of which of the two possible conformity assessment procedures is applied.

The establishment of common procedures to assess **product conformity** was at the basis of the so-called "Global Approach", defining a European framework of reference for product marketing. In this context, Directive 2001/95/EC on general product safety (GPSD)[8] is intended to ensure a high level of safety throughout the EU for consumer products that are not covered by any sector-specific EU legislation, including by establishing a sequence of common procedures for Market Surveillance Authorities.

The GPSD established the EU Rapid Information Exchange System for dangerous products (RAPEX).[9] **RAPEX** aims at enhancing the exchange of information between Member States and the European Commission on measures taken to prevent or restrict the marketing or the use of products posing a risk to the health and safety of consumers or to the public interest.

The increasing complexity of the EU legislative framework, both in terms of procedures and actors involved, called for the reinforcement of the product conformity process and of its consistency across Europe. Furthermore, it raised the need for clarifying roles and responsibilities along the product supply chain.

The **"New Legislative Framework"** directly responds to these needs. It further details the procedures required to ensure product compliance with essential requirements and specifies requirements for different economic operators and competent authorities.

2.1.2. The 1988 Toy Safety Directive and the 2008 Impact Assessment

In the context of the EU internal market, the 1988 Toy Safety Directive[10] was adopted in order to harmonise the different safety levels across Member States. This was crucial as the lack of consistency across the EU not only caused market deficiencies, but also hampered an effective protection of children against risks that may arise from toys.

The 1988 Directive was revised in 2009 based on an Impact Assessment (IA)[11] that identified three main areas for improvement. Firstly, **safety requirements** were outdated and not fully responding to newly identified hazards. Warning requirements also needed to be refined. Secondly, Member States highlighted the need for improving both the **enforcement consistency and effectiveness** of market surveillance and of the

[8] 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&qid=1461229957327&from=EN

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

[10] 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.

[11] Impact Assessment (SEC(2008)38) for the revision of the 1988 Directive. http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_0038_en.pdf

institutional framework concerning the implementation of the Directive and of toy-related information and traceability. Finally, the **scope and concepts** of the Directive turned out to lack clarity. In particular, the Directive needed to be aligned to the EC priority of making legislation clearer and more accessible. The 1988 TSD was indeed difficult to understand since it contained ambiguities, long and complicated sentences and internal and external cross-references. In addition, the 1988 TSD needed a clarification on its relation with the GPSD.

Following the Impact Assessment and the Commission proposal for a new TSD that it accompanied, a new Directive was adopted on 18 June 2009. The following table outlines the problems identified in the 2008 Impact Assessment and where they have been addressed in the 2009 TSD.

Table 2 - Problems identified in the 2008 IA and addressed in the 2009 TSD

2008 IA: Problems identified			**Response in the 2009 TSD**
Safety requirements	*Outdated safety requirements*	Electrical properties	Annex II, part IV
		Physical and mechanical requirements	Annex II, part I
	Lack of safety requirements for recently identified hazards	Safety requirements for chemicals should be revised	Annex II, part III
		Lack of safety requirements for noise	Annex II, part I
		Lack of safety requirements for lasers	Annex II, part IV
		Lack of safety requirements for electrically powered ride-on toys and for activity toys	Annex II, part IV and part I
		Lack of specific safety requirements for toys in food	Annex II, part I Annex V, part B
	Lack of clarity in the general safety requirement	The statement "*Normal behaviour of children*" created interpretation problems	Art. 10(2)
	Lack of complete warning requirements	User limitations should be included	Annex V, part A
		Adult supervision should be ensured	Annex V
Enforcement	*Market surveillance*	Requirement for manufacturers to perform hazard/risk analysis is not mandatory	Art. 18
		Lack of any specific requirement for manufacturers to keep hazard/risk analysis in the technical file	Art. 21 and Annex IV
	Lack of appropriate institutional framework for MS and the EC	Need to enhance the effectiveness and timeliness in implementing the Directive	Chapter VII
	Non-satisfactory toy-related information and traceability	Lack of clarity on the rules concerning the CE marking	Art. 16 and 17

2008 IA: Problems identified			Response in the 2009 TSD
Scope and concepts	*The toy definition lacked clarity*	The "use in play" and "play value" concepts are not clear	Annex I and Art. 2
	The 1988 TSD does not comply with the EC 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 TSD and the GPSD	The GPSD applies to toys in cases not always clearly defined	Art. 52(2) and recital 4

2.2. Description of the Toy Safety Directive and its objectives

2.2.1. Intervention logic of the Directive and its provisions

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 toy cross-border movement.

In order to enhance EU citizens' (and particularly children's) safety, the TSD lays down safety requirements and regulates the conditions for trade and production of toys within - and across - Member States. It had to be transposed into national legislations by 20 January 2011 and applied in the national territories from 20 July 2011, with the exception of the chemical requirements, which started to be applied from 20 July 2013.

To properly represent the Directive's intervention logic, the study identified two strategic objectives and four specific objectives. While the strategic objectives embrace long-term processes, the specific objectives break down the strategic ones into workable tasks. The strategic objectives correspond to the areas of major concern that emerged from the 2008 Impact Assessment. In order to achieve its objectives, the TSD set up "key provisions", addressing the different issues and vulnerabilities that can emerge along the life cycle of a toy - from production to assemblage, trade and use. The Directive's provisions are the input – including tools and mechanisms – expected to trigger short, medium and long term impacts (see the Figure below).

Figure 1 – TSD intervention logic

STRATEGIC OBJECTIVES	SPECIFIC OBJECTIVES	INPUT INTO THE TSD	OUTPUTS (SHORT TERM)	OUTCOMES (MEDIUM TERM)	IMPACTS (LONG TERM)
1. Ensure children's safety **2. To guarantee the smooth functioning of the toy internal market**	1. Strengthening, completing, clarifying and modernising the safety requirements 2. Preventing the placing of non-compliant toys on the market 3. Ensuring harmonisation across MS 4. Enhancing processes to support safety enforcement	1. Safety requirements 2. Warnings 3. EC declaration of conformity 4. CE marking 5. Safety assessment 6. Conformity assessment 7. Traceability 8. Technical documentation 9. Amendments 10. Penalties	1. Harmonised application of the TSD 2. Harmonised standards for presumption of conformity 3. NB for toys 4. Enforcement and market surveillance in all MS 5. Market access only for safe toys 6. Clearer scope of the TSD and reduction of the «grey area» 7. Higher control on toy origins and safety assurance 8. Corrective measures working as deterrent mechanisms against non-compliant toys	1. Reduced number of non-compliant toys 2. TSD aligned with scientific/technological/social developments 3. Reduced barriers to the internal market 4. Mutually recognised procedures for dealing with the lack of harmonised standards	**1. Higher level of safety for children in the EU** **2. Smooth EU internal market for toys**

The main TSD stakeholder categories include **economic operators** - manufacturers, importers and distributors - that have to comply with specific obligations in order to be allowed to place toys on the EU market; **consumer associations** that represent toy final users and are thus directly concerned with safety issues ; **Notified Bodies** that are in charge of the EC-type examination and are coordinated by the so-called Notified Bodies Group (NB-Toys) - see section 2.2.2.2; and **Member State Authorities** that have to check the compliance of toys with the legal requirements.

In what follows, a brief description of the Directive's provisions is presented, in order to clarify who (actor) is in charge of what (requirement) as established by the TSD.

a. Safety requirements

The essential safety requirements for toys are outlined in article 10(1) of the TSD. 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.

Chemicals represent one of the main concerns addressed by the 2009 TSD. The limits for certain chemicals (mainly heavy elements) - that were expressed in bioavailability[12] in the 1988 Directive – have been transformed in migration limits[13] in the 2009 TSD and the related standard EN 71-3 – Migration of certain elements. Moreover, 11 further elements (mainly metals) have been added to the 8 already established in the 1988 TSD.

[12] In the context of the 1988 TSD, bioavailability is defined as the amount of chemicals that actually comes out of a product and can - but may not necessarily - be absorbed by the human body. As regards toys, according to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), bioavailability is 'the amounts of each element in the toy that could be absorbed into the systemic circulation of a child' (EC (2004). Opinion of the CSTEE on 'Assessment of the bioavailability of certain elements in toys').

[13] "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*).

Box 1 – From bioavailability to migration limits in the 2009 TSD

The 2004 opinion of the Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE), [14] in the framework of a revision of the 1988 TSD, stated that the definition of bioavailability (i.e. *the soluble extract having toxicological significance*)[15] was not in line with the general understanding of the term, which is the amount of each element in the toy that could be absorbed into the systemic circulation of a child.

In 2008, this approach was further strengthened in a report drafted by the Netherlands' National Institute for Public Health and the Environment (RIVM).[16] The report, though recognising that bioavailability is considered to be the most correct definition to be used in the context of toy safety, observed that it can be determined experimentally by means of migration tests (or by physiologically based tests). Furthermore, RIVM suggested expressing migration limits in mg/kg toy material. This would indeed link the allowable migration of a substance directly to a toxicologically derived limit value, e.g. the tolerable daily intake. This approach was further sustained by the Scientific Committee on Health and Environmental Risks (SCHER) in 2010.[17]

The 2009 Directive draws a distinction among three types of materials used in toys - dry, brittle, powder-like or pliable; liquid or sticky; and scraped-off – each subject to different migration limits.

Other chemicals regulated by the 2009 Directive include specific allergenic fragrances, and Carcinogenic, Mutagenic, or toxic for Reproduction (CMR) substances.

Finally, the 2009 Directive responds to the need for differentiating provisions according to the **age of the children** and the **intended use** of the toy.[18]

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.[19]

[14] CSTEE (2004), Assessment of the bioavailability of certain elements in toys. http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out235_en.pdf

[15] Directive 88/378/EE of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, Annex II, Part II, 3(2).

[16] RIVM (2008). Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements. Report 320003001. http://www.rivm.nl/dsresource?objectid=rivmp:272028&type=org&disposition=inline&ns_nc=1

[17] SCHER (2010). Evaluation of the Migration Limits for Chemical Elements in Toys. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_126.pdf

[18] Recital 24 of the TSD indeed states that 'in order to ensure adequate protection in the case of toys involving a high degree of exposure, it should be possible to adopt implementing measures establishing specific limit values for chemicals used in toys intended for use by children under 36 months and in other toys intended to be put in the mouth taking into account the requirements of Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food'.

[19] TIE (2009). The 2009 Toy Safety Directive Provisions on Conformity and Safety Assessment, *Factsheet*.

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 number of the harmonised standards has been published in the Official Journal of the EU, the manufacturer shall carry out the conformity assessment himself. Otherwise, and any time the manufacturer deems it necessary, an external conformity assessment body - known as "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.

d. EC declaration of conformity and CE marking

All toys placed on the EU market must be accompanied by the EC declaration of conformity (DoC), whereby the manufacturer declares on his own responsibility the full compliance of the toy with all relevant 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 DoC, 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 can be affixed only by the manufacturer or by his authorised representative. According to article 17(1), 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) requires manufacturers to keep the technical documentation and 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.[20] In particular,

[20] 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;

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", [21] 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, among manufacturers' obligations there is the duty to provide the toy with a type, batch, serial or model number or other elements allowing its identification, further ensuring product traceability.

g. Technical documentation

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;

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.

[21] DG ENTR (2014). The "Blue Guide" on the implementation of EU product rules.

- 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).

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 (art. 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 with the ability 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 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 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.

2.2.2. The adaptation of the Directive to the evolving context

Toys – like all products – are continuously evolving due both to new cultural/commercial trends - and related market demand - and to technical progress. Moreover, safety requirements represent an evolving concept, which needs to be updated according to scientific progress and new health issues. Thus a Directive on the safety of toys should foresee mechanisms able to adapt to the changes occurring in the surrounding context.

There are three main adaptation mechanisms in the frame of the TSD, two related to the New Legislative Framework and one specifically foreseen by the Directive:

- The **standardisation mandates** issued by the Commission in order to request European Standardisation Organisations (ESOs) to develop a new harmonised standard or to update an existing one.
- The **protocols and recommendations** issued by the NB-Toys. Protocols aim at specifying particular requirements, while recommendations respond to the need of providing Notified Bodies with recognised procedures when dealing with essential requirements not covered by any harmonised standard.
- **Article 46**, which – as mentioned above - empowers the Commission to amend relevant parts of the Directive.

2.2.2.1. Standards for toys and requests for standardisation

As detailed in section 2.2.1c, when the conformity assessment is carried out by the manufacturer, toys have to comply with harmonised standards referenced in the OJEU in order to benefit from the presumption of conformity. Harmonised standards for toys referenced in the Official Journal include many standards of the EN 71 standard series on the safety of toys and the CENELEC EN 62115 standard on the safety of electric toys.

Under the 2009 TSD, the Commission has issued three standardisation mandates up to date. The first mandate was issued in 2009, to adapt the existing EU standards on toy safety to the 2009 TSD, and to develop additional standards for the new requirements established by the 2009 TSD. The second and third mandates were issued in 2011, one to address the newly identified risk of "loss of support" in certain inflatable aquatic ride-on toys, and the other for the risk of "possible eye and skin injuries" that may be caused by "items that are propelled into free flight by a child releasing an elastic band".

2.2.2.2. The NB-Toys and related protocols and recommendations

EU Directives based on the New Legislative Framework have coordination groups composed of representatives of Notified Bodies. As each Notified Body can apply the technical standards it considers suitable when carrying out an EC-type examination, the coordination groups are in charge of delivering recommendations and protocols aimed at ensuring consistency in testing procedures and a unified approach to common implementation issues encountered by the Notified Bodies while performing their activities. While the EC is normally represented at the meetings of the coordination groups, the ESOs are only represented when issues concerning harmonised standards arise.

NB-Toys is the coordination group of Notified Bodies under the Toy Safety Directive. To date, NB-Toys has issued four recommendations[22] and four protocols.[23]

[22] NB-Toys/2014/69, Recommendation No. 1. Format EC-type examination certificate Rev 3. NB-Toys/2010/031, Recommendation No. 2. NoBo identification number affixed to the toy or on its packaging. NB-Toys/2011/32, Recommendation No. 3 Rev 1. Can EC-type examination be carried out in case of failure of a safety limit? NB-Toys/2011/33, Recommendation No. 4 Rev 1. Transitional period.

[23] NB-Toys/2014/070, EC Type approval protocol No. 1. Categories of toys which have been submitted to EC-type examination Rev 4. NB-Toys/2014/071, EC-type approval protocol No. 2. Microbiological safety of toys containing aqueous media Rev 2. NB-Toys/2014/072, EC Type approval protocol No. 3. Physical and mechanical properties for rotor blades used in remote controlled flying toys intended for children over 8 years old (e.g. helicopters) Rev 4. NB-Toys/2011/085, EC-Type approval protocol No. 4. Washability of toys.

2.2.2.3. The amendments to the Directive

By virtue of article 46, the TSD has been amended five times between 2012 and 2014:

- In March 2012, **Directive 2012/7/EU** reduced the limits for **cadmium** in toys. This decision was mainly based on the European Food Safety Authority (EFSA) scientific opinion;[24]
- In July 2013, taking into account the opinion of the Scientific Committee on Health and Environmental Risks (SCHER)[25] on the tolerable daily intake of barium, **Regulation (EU) No 681/2013** reduced the limits for **barium**;
- In June 2014, taking into account the opinion of the SCHER on TCEP,[26] **Directive 2014/79/EU** laid down values for flame-retardant **TCEP** and its alternatives **TCPP**[27] and **TDCP**[28] in toys for children under 36 months of age and other toys intended to be placed in the mouth;
- In June 2014, **Directive 2014/81/EU** laid down limit values for **bisphenol A** in toys for children under 36 months and other toys intended to be placed in the mouth, following a scientific opinion of EFSA;[29]
- In June 2014, **Directive 2014/84/EU** granted **nickel** an additional use - exempt from the CMR requirements of the TSD - in toy components that are intended to conduct an electric current, following a scientific opinion by the SCHER.[30]

[24] EFSA (2009). Cadmium in food. Scientific Opinion of the Panel on Contaminants in the Food Chain. Question No EFSA-Q-2007-138. Adopted on 30 January 2009. http://www.efsa.europa.eu/en/scdocs/doc/980.pdf

[25] SCHER (2012). Assessment of the Tolerable Daily Intake of Barium. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_161.pdf

[26] Tris(2-chloroethyl)phosphate. SCHER (2012). Opinion on tris(2-chloroethyl)phosphate (TCEP) in Toys. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_158.pdf

[27] Tris(2-chloro-1-methylethyl) phosphate.

[28] Tris[2-chloro-1-(chloromethyl)ethyl] phosphate.

[29] EFSA (2013). Draft Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. http://www.efsa.europa.eu/en/consultationsclosed/call/130725

[30] SCHER (2012). Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 744 0-02-0) in Toys. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_163.pdf

3 EVALUATION QUESTIONS AND EVALUATION CRITERIA

Thirteen evaluation questions, framed within five evaluation criteria, have been taken from the ToR in order to properly assess the Directive.

Box 2 - Evaluation questions

Relevance

EQ1: To what extent do the objectives of the 2009 Directive (still) correspond to current needs/issues?

EQ2: To what extent do the adaptation mechanisms of the 2009 Directive follow technological, scientific and social developments?

Effectiveness

EQ3: To what extent has the 2009 Directive contributed to the enhancing of the level of safety of toys while maintaining the smooth functioning of the internal market for toys?

EQ4: What are the barriers to effective application and enforcement, in particular through surveillance of toys on the market, if any? How could any such barriers be overcome?

EQ5: Are there any aspects/means/actors that render the 2009 Directive more or less effective, and – if there are – what lessons can be drawn from this?

EQ6: What, if anything (including non-legislative action), could be done to render the 2009 Directive more effective as a means to achieve its objectives?

EQ7: Does the legal form (Directive versus Regulation)[31] have an influence on the effectiveness with which the objectives are reached?

Efficiency

EQ8: What aspects of the 2009 Directive are the most efficient or inefficient, especially in terms of resources that are mobilised by stakeholders during the different phases of the process? What does this represent in terms of administrative and reporting burdens on stakeholders and/or other actors?

EQ9: How could costs/administrative burdens be reduced? Are there any unnecessary sources of administrative burdens for enterprises, especially SMEs?

Coherence

EQ10: Are there overlaps/complementarities between the 2009 Directive and any pieces of EU legislation or Member State acts in the relevant areas, in particular with regard to the limit values for chemicals set out in the 2009 Directive? Are there contradictions?

EQ11: What can be done to optimise the relationship between them?

EU added value

EQ12: Is there an additional value resulting from the 2009 Directive, compared to what could be

[31] While a "regulation" is a binding legislative act to be applied in its entirety across the EU, a "directive" is a legislative act that sets out a goal that all EU countries must achieve, leaving the individual countries decide how to achieve them.

achieved at merely national level?

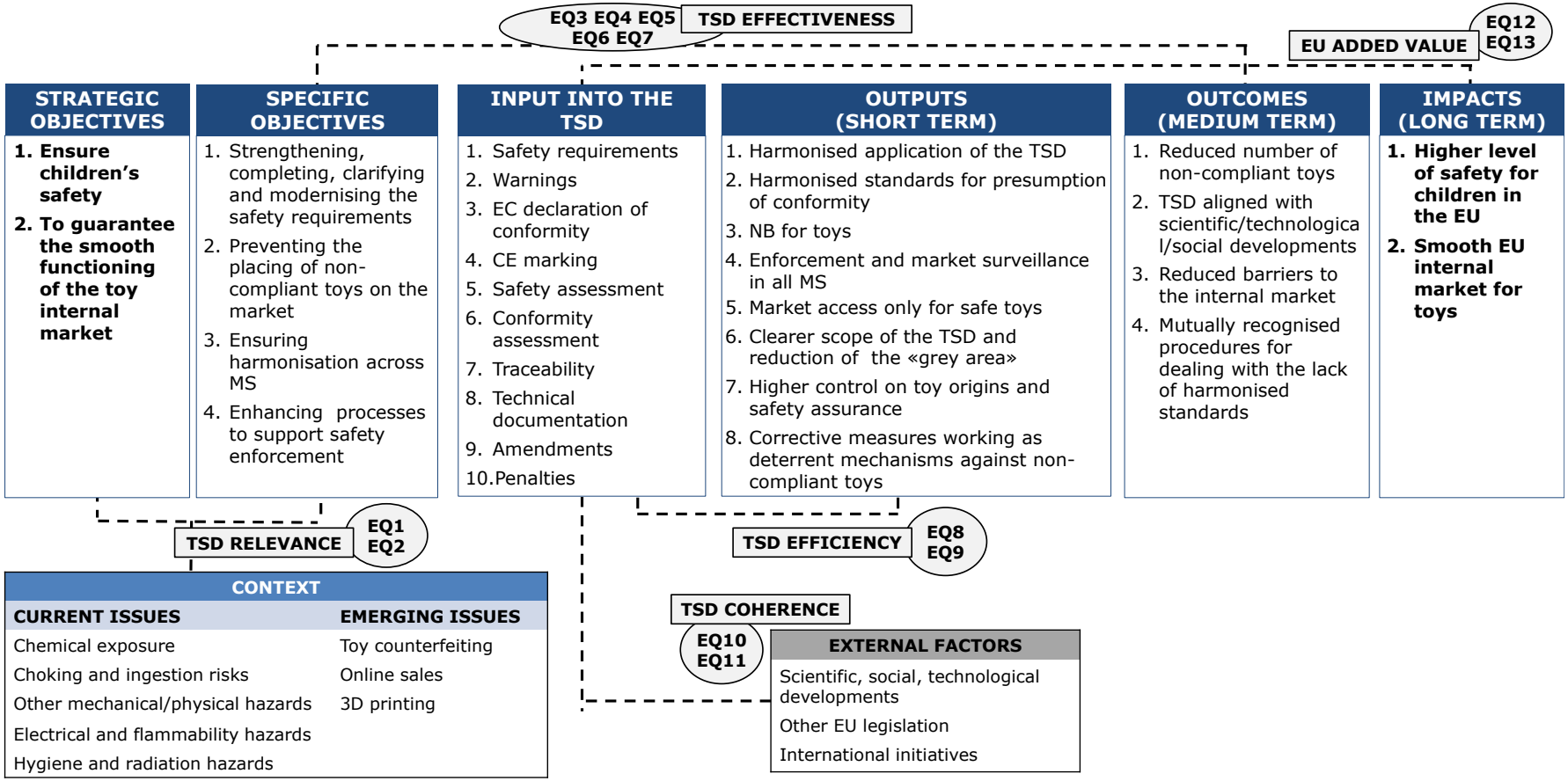
EQ13: What is the added value of the 2009 Directive for stakeholders?

The evaluation criteria were understood to mean:

- **Relevance**: whether the objectives of the Directive still correspond to current problems, needs and challenges. In particular, the study assessed to what extent the scope and mechanisms of the Directive allowed for addressing of the main issues arising in regard to the safety of toys and from the sector, while following up - and adapting to – technological, scientific and social developments (evaluation questions 1 and 2).
- **Effectiveness**: whether and to what extent the targets have been achieved so far at both national and EU level, by considering the strategic objectives related to the safety of toys and the functioning of the internal market. The assessment of the overall achievements has been carried out by taking into account the different areas of intervention of the Directive and the specific provisions contributing to the general goals (evaluation questions from 3 to 7).
- **Efficiency**: whether the TSD has proportionally delivered its results in terms of resources used. The analysis included a qualitative assessment of the costs as perceived and reported by stakeholders, with a particular focus on the impacts on SMEs (evaluation questions 8 and 9). The market analysis performed validates stakeholders' perceptions, through the assessment of the Directive's impact on manufacturers' overall costs.
- **Coherence**: whether the TSD is consistent with other EU pieces of legislation and to what extent the divergences (if any) prevent the achievements of the overall objectives of the Directive. The analysis also included the scope and nature of any overlapping and/or contradictions among different legislations (evaluation questions 10 and 11).
- **Added value**: to what extent the results of the EU action are additional to the value that would have resulted from action at Member State level (evaluation questions 12 and 13).

Figure 2 displays the interrelations between the TSD intervention logic as presented in section 2.2.1, the evaluation criteria and the evaluation questions.

Figure 2 - The TSD intervention logic and its interrelations with the evaluation criteria and evaluation questions



4 METHODOLOGICAL FRAMEWORK

4.1. Process/Methodology

4.1.1. 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 internet search. These documents included relevant literature on toy safety and the sector, the policy context and the legal framework of reference.

4.1.1.1. Literature on toy industry and safety issues

Sources

The relevant literature that fed the current study is presented in Annex 9.7.

As regards the **toy industry**, the main source of information has been the ECSIP Report (2013),[32] as it specifically focuses on the toy industry.

The source of data used for the market analysis - as presented in section 6.3.1.3 - is the Amadeus – Bureau Van Dijk database. Specifically, the analysis 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. For the purpose of the analysis the relevant period considered is between 2006 and 2013 (latest available data).

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 ToR, 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 commissioned by international institutions – e.g. the United Nations - press releases, data and alerts for dangerous products (e.g. RAPEX weekly reports[33]) elaborated by relevant organisations at EU level - such as PROSAFE,[34] EuroSafe,[35] Toy Industries of Europe (TIE)[36] among others.

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[32] ECSIP Consortium (2013). Study on the competitiveness of the toy industry – Final Report.

[33] http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/index.cfm?event=main.listNotifications

[34] PROSAFE (Product Safety Forum of Europe) is a non-profit professional organisation for Market Surveillance Authorities and officers from throughout the EEA. Its primary objective is to improve the safety of users of products and services in Europe. For more information please refer to: http://www.prosafe.org/index.php?option=com_content&view=article&id=33&Itemid=128

Use

The relevant literature fed the initial framing of the current safety risks (section 5.1.1), of the toy free movement (section 5.1.2) and of the emerging issues related to toys (section 5.1.3).

Amadeus has been used to conduct the market analysis, as presented in section 6.3.1.3. The aim of the market analysis 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 TSD. 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 TSD with the reasonability of these costs as perceived by stakeholders enhanced the overall evaluation of the Directive's efficiency.

4.1.1.2. Policy framework

Sources

Insights on the policy context have been gathered through relevant information concerning infringement procedures[37] and reports on the ongoing work of the European Commission on toy safety, NB-Toys protocols and recommendations, the requests for standardisation and the amendments to the TSD.

Another information source to understand the current policy context consisted in the national reports drafted by national competent authorities.

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 (section 2.2.2). As a source for the desk research, national reports are used in section 5.1.2, which concerns the analysis of toy free

[35] EuroSafe is a non-governmental organisation, representing organisations and individuals working to prevent injury and to promote safety. This includes policies and actions for promoting child safety, consumer safety, safety for seniors, safety of vulnerable road users, safety in sports and the prevention of violence and self-harm. Source: http://www.eurosafe.eu.com/

[36] Toy Industries of Europe (TIE) is the trade association for the European toy industry, providing relevant information both for and on the EU toy industry.

[37] The Commission launches infringement proceedings when Member States do not communicate transposition measures for a Directive by the deadline for transposition (the so-called "non-communication cases"). According to information received from the Commission on December 19th, 2014, in the case of the 2009 TSD, non-communication cases were opened against 16 Member States. 13 of them were closed after 6 months, as soon as the transposition measure was communicated. 2 more were closed after 12 months for the same reason. The 16th case is currently still pending, and relates to Germany not having communicated transposition measures for the limit values of arsenic, antimony and mercury. The first amendment of TSD also triggered non-communication cases against 4 Member States; all of them were closed within 5 to 9 months. An infringement procedure not based on non-communication, but on complaints from citizens, was also opened against the Netherlands. The case was closed in September 2014 after the Netherlands took corrective measures.

movement. Moreover, the national reports provide findings on the Directive's implementation and enforcement as presented in section 5.2, expressing the perspective of public authorities dealing with the Directive.

4.1.1.3. Legal framework

Sources

The legal framework included the legislation relevant for toys, as provided in the 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.

Source: DG GROW website

Use

The legal framework was of crucial importance to analyse possible overlapping and/or duplications between the TSD 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.

4.1.2. Field research

Sources

The field research relied on both face-to-face and skype in-depth **interviews** with relevant stakeholders.[38] The stakeholders' list was drafted according to the following main categories:

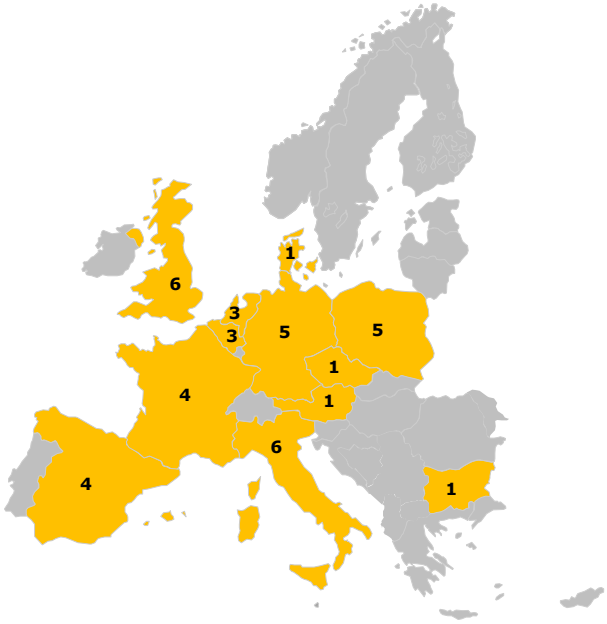
- EC officials (only for scoping interviews);
- Selected representatives from industry - manufacturers and importers, distributors, SMEs, and industry associations;
- Selected representatives from consumer associations;
- NB-Toys, CEN, CENELEC.

Further information on key stakeholders to be involved has been collected during the inception phase, based on both the preliminary desk research and the scoping interviews with EC officials. The final list of stakeholders – as reported in annex 9.5 - includes interviewees chosen at both EU and national level.

Two main selection criteria were considered in drafting the final list of stakeholders. The first criterion was the **geographical coverage** - including Northern, Southern and Eastern EU Member States – so as to take account of possible geographical differences in the policy and production systems in place (see Figure 3).

[38] No online survey or public consultation was conducted.

Figure 3 – EU coverage and number of stakeholders involved per Member State[39]



The second criterion was the **balanced representation** of stakeholders, so as to take account of possible different impacts of the TSD on different types of stakeholders (see Table 3).

Table 3 - Interviews performed

Categories of stakeholders	No. of interviews
Large manufacturers	9
Micro and SME manufacturers	11
Distributors/importers	5
Industry associations	14
Consumer associations	3
Notified Bodies	2
Standardisation Organisations	2
Expert on toy safety	1
Total	**47**

Interviews 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 study.

It should be noted that only European stakeholders have been interviewed. Therefore, "importers" in the course of this study refers either to European operators importing toys produced in a third country, or to European manufacturers having delocalised or subcontracted their production in a third country, thus playing the role of importers when placing toys on the EU market.

[39] Please note that, in addition, 7 EU organisations, which are not reported in the map, were interviewed (i.e. 2 consumer associations, 2 industry associations, 2 standardisation organisations, 1 Notified Body).

Use

Based on the in-depth literature review, the relevant issues for the evaluation process have been identified. The interviews served the purpose of confirming, investigating and better understanding the main topics that emerged from the desk research. Further insights have been gathered through the review of the national reports that played a twofold role. Firstly, the reports provided the Member States' perspective on the Directive, including suggestions, difficulties and requests on the main issues considered during the evaluation process. Furthermore, the reports allowed for triangulation of information provided by Member States with the points of view of both economic operators and consumer associations, as expressed during the interviews.

In some cases, the same question was addressed to several stakeholders in order to get different perspectives on a specific issue. This also allowed for triangulation of information among different categories of actors. In other cases, the interview questions have been tailored to the specific category of stakeholders.

To conclude, it is worth underlining that the relatively low number of interviews conducted has not represented a 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 during the interviews and no major contradiction has been raised. Therefore, a larger number of interviewees would only have been of limited added value.

Annex 9.4 presents the guidelines that have been used for the interviews. The guidelines include questions on **knowledge**, **behaviour**, and **value** issues, in order to get at the same time facts and opinions about specific topics.

4.2. Limitations – robustness of findings

As specified in section 1.2, the evidence collected in this report is based on the application of the TSD since mid-2011, when the Directive's provisions entered into application.[40] The evidence is even more recent for chemicals provisions that were to be applied only as of mid-2013.[41] Notwithstanding the relatively short timeframe of reference for the evaluation, the stakeholders' feedback on their four-year experience with the Directive provided nuanced insights.

4.2.1. Lack of statistics on toy-related injuries

Before presenting the evaluation findings, it is important to highlight the difficulties in retrieving data on safety issues, particularly concerning toy-related accidents and injuries across Europe.

The 2008 Impact Assessment - as presented in section 2.1.2. - pointed to the very limited availability of such data. Specifically, the document stated that:

[40] With reference to the market analysis mainly grounded on ECSIP (2013), data are previous to 2011.

- There were no consistent EU-wide statistics on toy-related accidents;
- Only three Member States – Denmark, the Netherlands and the United Kingdom[42] - had injury systems with potential ability to provide useful data;
- In these national systems, the exact cause of accidents was not available, and the link with the toy or its manufacturer could not be concluded;
- Not all products included in these databases were toys within the meaning of the TSD;
- Finally, accidents and incidents not involving hospital visits or consultation of a medical doctor were not reported.

The lack of available data has been highlighted in various reports[43] and by several organisations.[44] For example, the need for enhanced injury surveillance was recognised in the EU Recommendation 2007/C 164/01[45] and in the Parliament's Own Initiative Report 2010/2085 (INI) on the Revision of the GPSD and Market Surveillance.[46]

A better availability of injury and accident data would be important due to the possibility for public authorities and other stakeholders to identify possible risks and to spot what types of products may pose a threat.

Over the past years, there have been several projects supported by the European Commission with a view to facilitate EU-level exchange of injury data. In 1999, the European Injury Database was set up by DG SANCO[47] under the Injury Prevention Programme.[48] This database covers a sample of around 100 hospital emergency departments across 20 EU Member States that provide comparable injury data.

Another DG SANCO co-funded project is the Susy Safe registry, which aims at establishing an international surveillance system for suffocation injuries.[49] The system is able to provide a risk-analysis profile for each of the products causing harm. This surveillance method relies

[42] It is worth noting that the UK database was discontinued in 2002.

[43] 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

Impact Assessment (SEC(2008)38) for the revision of the 1988 Directive.

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.

[44] 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

[45] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32007H0718%2801%29

[46] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2011-0033+0+DOC+XML+V0//EN

[47] Directorate General for Health and Consumers.

[48] http://ec.europa.eu/health/data_collection/databases/idb/index_en.htm

[49] http://www.susysafe.org/

on medical practitioners to report injuries on a voluntary basis. In 2012, there had been over 8,000 cases registered from the EU and another 8,000 internationally.

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.[50] However, several consumer and business associations have 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.[51] 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 accident data.[52]

The use of US statistics in this study is limited to the identification of main toy-related issues. Toy-related injuries that occurred in the USA 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 USA and in the EU, the relevance of these risk categories has been assessed based on the interviews with stakeholders and on the relevant literature covering the EU context.

The analysis of the non-EU legal framework for toys is out of the scope of this evaluation, thus no comparison among different legal systems in place is provided. When comparative assumptions have been made by specific stakeholders, they have been appropriately included in the report clearly specifying the information source (see for instance footnote 175).

4.2.2. Lack of statistics on costs caused by the TSD

The **evaluation of costs** and burdens caused by the 2009 TSD is mainly qualitative. A more quantitative approach was indeed not feasible in the context of this 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 technological 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.

[50] http://ec.europa.eu/health/data_collection/docs/idb_report_2013_en.pdf

[51] http://www.tietoy.org/docrestreint.api/997/0665d076398338407bab575bd7dce8512981fb1d/pdf/joint_call_for_a_pan-european_accident_injury_data_system.pdf

[52] Ibid.

The evidence emerged in the qualitative analysis was then confronted with an analysis of the costs of production reported in the financial statements. Therefore, the assessment of the Directive's costs and burdens mainly relied on data retrieved from the stakeholders' qualitative perceptions gathered through interviews. With regard to Member State Authorities, the report template did not include any specific section on costs and burdens. Any time an input was provided on the Directive's efficiency, it has been taken into account when triangulating information provided by different stakeholders on specific issues. In any case, it is worth noting how Member States generally do not point to significant costs relating the implementation of the Directive.

In addition, a more structured analysis concerns the different types of costs entailed by the Directive and the stakeholders concerned as presented in section 6.3.

5 STATE OF PLAY

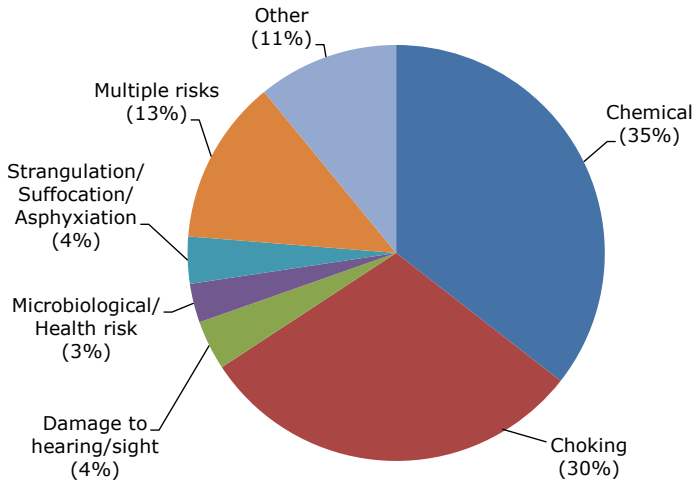
5.1. Main issues concerning toys

5.1.1. Current safety risks

In what follows, the different risk categories are detailed, with the aim of providing an indication of their nature and scope. Risk categories prioritisation has been based on the analysis of RAPEX notifications, which - among other things - give insights on the types of risk associated to notified toys.

The relevant literature on the safety of toys has further confirmed this ranking. Figure 4 below shows the main risk categories associated with toys as notified in RAPEX over the period 2009-2014.

Figure 4 - Types of risks associated to toys notified in RAPEX over the period 2009-2014[53]



Source: Author's calculations based on RAPEX database

According to the European Injury database,[54] around 1% of all home and leisure accidents concern toys. Accidents most frequently occur in and around private houses and schools, with children between 0 and 48 months accounting for 40% of all injured. In addition, "annually in the EU 28 Member States approximately 52,000 injuries to children of 0-14 years involving toys result in a visit to the emergency department".[55]

5.1.1.1. Chemical exposure

Chemical exposure is the biggest risk category (35% of RAPEX notifications) associated with the use of toys ***(finding 1)***.

[53] Over a total of 2,878 notifications. Please consider that "Other" category includes risks of injuries, cuts, burns, fire, electric shock, electromagnetic disturbance, environment and other.

[54] The European Injury Data Base (IDB) is a data source that contains standardised cross-national information on the external causes of injuries treated in selected emergency departments in the EU. http://ec.europa.eu/health/data_collection/databasesdatabases/idb/indexindex_en.htm

[55] http://www.childsafetyeurope.org/publications/info/product-safety-guide.pdf

The Quarterly European Notification and Recall Index shows that, for Q3 2014, 44% of toy recalls are related to violations of chemical requirements.[56]

Exposure to chemicals in toys is a significant concern due to a number of factors. Children take in more air, water, and food per unit of body weight per day than adults, and they also have differences in the absorption, distribution, metabolism, and excretion of chemicals and chemical residues that are dependent on their age. Specific behaviours - such as crawling and hand-to-mouth activity - create additional pathways for toxic chemicals in toys to enter the body.[57] In addition, children may be particularly vulnerable to toxic effects of substances due to the early stage of development in which they are.

The risk of chemical exposure is extremely hard to quantify, because it is difficult both to identify the source of chemicals and to determine the timing of exposure. Hazardous chemicals can indeed be present in a range of consumer goods such as clothing, building materials, cleaning products, cosmetics and baby bottles, in food and drink and in the environment (air, water, soil). As such, the risk of chemical exposure cannot be easily attributed to the use of a particular toy.

Moreover, adverse health effects from exposure to chemicals often materialise only in the medium - long term. This is of particular concern in the case of children, as they have more time than adults to develop chronic diseases due to their younger age. Adverse effects of, for instance, lead ingestion are not likely to be immediately detected;[58] overexposure to lead may result in developmental disabilities in childhood, but it may also increase the risk of neurological degeneration in adult life, such as Parkinson's disease.[59] Many diseases that may be triggered by exposure to dangerous chemicals in early childhood, such as cancer and neuro-degenerative syndromes, are now understood to evolve over time.[60] Pre-natal exposure to other chemicals such as phthalates and bisphenol A has been linked to behaviour abnormalities, such as attention deficit disorder in boys.[61]

Thus, both because the source of the risk cannot be detected with certainty and because of the timing of the effect, even when a symptom appears, it can hardly be connected to a particular product (such as a specific toy).

Nevertheless, literature suggests that significant attention should be paid to chemical exposure (please refer to Annex 9.7). The importance accorded to chemicals in toys is further confirmed by the broad attention they attract both at European and national level, as shown by the existence of steering groups and technical committees covering the issue. A good example is the Strategic Approach to International Chemicals Management (SAICM).

[56] http://recall.stericycleexpertsolutions.com/wp-content/uploads/sites/2/2014/11/Q3-2014-ES-Report-EU-V5.pdf

[57] http://pubs.acs.org/doi/pdf/10.1021/es1009407

[58] 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

[59] See for instance: http://www.ncbi.nlm.nih.gov/pubmed/20807691.

[60] http://content.healthaffairs.org/content/30/5/842.full

[61] See for instance: http://www.ncbi.nlm.nih.gov/pubmed/19748073 and http://www.sciencedirect.com/science/article/pii/S0013935113001126

The SAICM is a policy framework adopted by the International Conference on Chemicals Management in 2006 to foster the sound management of chemicals, having toys as one of its priority product areas due to the 'possible adverse health effects from chemicals migrating out of toys into children during their normal play or foreseeable misuse'.[62] Similarly, the court case related to Germany (see section 5.1.2) also demonstrates how chemical exposure due to toys is a current focusing issue.

5.1.1.2. Choking and ingestion risks

Choking hazards have been identified as the second major risk category associated with toys ***(finding 2).*** In particular, small toys and detachable small parts and components can represent a serious risk of suffocation or choking, considering the ease with which they can be ingested, and be life-threatening, in particular for children under three years of age who "mouth everything".

A scan through RAPEX reveals that, between 2012 and 2015, 615 toy notifications - out of 1,558 - related to choking hazards. The Quarterly European Notification and Recall Index shows that, for Q3 2014, 33% of toy recalls related to choking risks.[63] The Susy Safe project, which records injuries to children in the range of 0-14 years of age across Europe and internationally, found that 29% of all non-food injuries relate to the ingestion of pearls, balls and marbles,[64] and 4% of the non-food cases relate to toys.[65]

Toys in food – namely toys contained within food, co-mingled with food or where the food must be consumed to get to the toy - represent a specific category of choking hazard ***(finding 3)***. Toys in food are only permitted when the toy has its own packaging, which has to be sufficiently large not to be swallowed or inhaled.

Even if less frequent than choking, **ingestion** also constitutes a safety risk ***(finding 4)***. The ingestion of magnets was highlighted in the 2008 Impact Assessment as a particular concern. US data[66] estimate that, between 2009 and 2011, there were 1,700 emergency room cases nationwide involving the ingestion of high powered magnets. More than 70% of them involved children between the ages of 4 and 12. Small toy magnets can indeed be swallowed, representing not only a risk of ingestion, but if more than one high powered magnet is ingested, the magnetic attraction between pieces can also cause twisted/knotted intestines, intestinal perforation or blockage.[67] Ingestion of other parts of the toy, such as batteries, can also cause damages to the oesophagus.[68]

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[62] http://www.saicm.org/index.php?option=com_content&view=article&id=454&Itemid=691

[63] http://recall.stericycleexpertsolutions.com/wp-content/uploads/sites/2/2014/11/Q3-2014-ES-Report-EU-V5.pdf

[64] It should be noted that not all of these were necessarily toys.

[65] Lockefeer JH. (1990). Vitamin D poisoning; real and spurious, *Ned Tijdschr Geneeskd,* Oct 6;134(40):1931-4.

[66] http://www.uspirgedfund.org/reports/usf/trouble-toyland-2013

[67] Ibid.

[68] Takagaki K., Rothbaum Perito E., Folashade A. J. and Melvin B. Heyman M.B. (2011). Gastric Mucosal Damage From Ingestion of 3 Button Cell Batteries, *J Pediatr Gastroenterol Nutr*, 53(2): 222–223.

Data available for the UK show that **soft toys,** such as teddies and dolls, cause more than 1,500 injuries each year ***(finding 5)***. Children under 36 months of age are most at risk, and small parts that become loose such as eyes, buttons or pieces of stuffing cause many of these incidents.[69] Between 1990 and 2011, there were more than 109,000 cases of children under 60 months inhaling or swallowing objects, which is the equivalent to 14 cases every day. Between 2001 and 2012, more than 90 children died from choking in the US.[70]

5.1.1.3. Other mechanical and physical hazards

The 2008 Impact Assessment identified hazards related to **toys emitting noise *(finding 6)***.

In 2013, US data showed that 1 out of 5 US children will have some degree of hearing loss by the age of 12. This would be partly due to children using toys and other nursery products that emit noise.[71] However, there are no injury data connecting hearing loss and toys.[72] As with chemical exposure, it is difficult to establish the correlation between hearing loss and the use of a particular toy. Noise-induced hearing loss can be caused by a one-time exposure to a loud sound, but it is also cumulative and gradual, making it difficult to trace a single source of origin.

Scooter toys have been singled out as posing risks ***(finding 7)***. As documented in a US Consumer Product Safety Commission study,[73] riding toys[74] - and in particular non-motorised scooters - were related to more injuries than any other category of toy in 2013. These data find further confirmation in a study conducted by the Centre for Injury Research and Policy[75] at Nationwide Children's Hospital where researchers found that, over the period 1990-2011, riding toys accounted for 42% of injuries in children aged 5 to 17 in the US.[76] From year 2000, foot-powered scooters have been responsible for an injury every 11

[69] http://www.childsafetyeurope.org/publications/info/product-safety-guide.pdf.

[70] There are no more detailed statistics related to choking injuries exclusively caused by toys for the US.

[71] US PIRG (2013). *Trouble in Toyland The 28th Annual Survey of Toy Safety.* http://www.uspirgedfund.org/sites/pirg/files/reports/USP%20Toyland%202013%201.3.pdf

[72] Sight & Hearing Association (2015). *Noisy Toys.* http://www.sightandhearing.org/news/healthissue/archive/hi_1111.asp

[73] US Consumer Product Safety Commission, *Toy-related deaths and injuries calendar year 2013.* http://www.cpsc.gov/Global/Research-and-Statistics/Injury-Statistics/Toys/ToyReport2013.pdf

[74] "Riding toys" include: non-motorized scooters; tricycles; unpowered non-wheeled riding toys; children's wagons; powered riding toys; unpowered wheeled riding toys.

[75] http://www.nationwidechildrens.org/injury-research-and-policy

[76] Mejia P. (2014). "Every Three Minutes, a Child Sustains a Toy Related Injury: Study". Newsweek. http://www.newsweek.com/every-three-minutes-child-sustains-toy-related-injury-study-288299

minutes.[77] Another study by US W.A.T.C.H.[78] points out the harmful potentials of riding toys.[79]

5.1.1.4. Electrical and flammability hazards

Electrical hazards may result in a risk of electrocution and burn ***(finding 8)***. The revised Directive recognises the technical progress made with electrical toys that has made it possible to exceed the limit of 24 volts set in the old Directive, while guaranteeing the safe use of the toy. Internal voltages may only exceed 24 volts DC (or the equivalent AC voltage) if it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken.[80]

As for **flammability**, problems relate to toys made of materials that can be ignited in the case of contact with flame, spark or with other potential source of fire ***(finding 9)***. After catching fire, these toys can quickly burn or explode thus causing injuries to children. Over time, several methods have been developed to limit the spread of flame or to maximise the "after flame time". This is intended to allow the child to drop the toy or to distance the product. One of the most important characteristics of toys is the rate of spread of flame, which - as specified in EN 71:2 - should not exceed 30mm/s. Furthermore, standard EN 71-2:2011 prohibits the presence in toys of celluloid materials and pile fabrics that exhibit surface flash characteristics. For toys with electrical components, their resistance to flammability is also of particular concern.

5.1.1.5. Hygiene

Toys quite easily become contaminated with microbes and these are passed from child to child, which increases the risk of **contamination** if children put them into the mouth ***(finding 10)***. According to the International Scientific Forum on Home Hygiene,[81] soft toys can be contaminated with bacteria, including some potentially pathogenic species, whereas hard toys can contribute to outbreaks of diarrhoea and vomiting. Another study found that nowadays toys can harbour harmful bacteria for periods of time that are longer than previously, increasing the importance of regular cleaning and hygiene precautions.[82] Within

[77] Ibid.

[78] World Against Toys Causing Harm, inc. http://toysafety.org/about/need-for-action/

[79] W.A.T.C.H. (2014). W.A.T.C.H. nominees for the 42nd Annual "10 Worst Toys" Report. http://toysafetytoysafety.org/wp-content/uploads/2014/12/Press-Release-and-Nominees-2014-Toy-List-Photos.pdf

[80] Bureau Veritas (2012). Toy Safety in the European Union. Complying with Requirements of the New Toy Safety Directive. http://www.bureauveritas.com/wps/wcm/connect/f5c0a79c-f568-48bc-96dc-b520a64e3ebb/BV+WP+EU+Toy+Safety.pdf?MOD=AJPERES

[81] International Scientific Forum on Home Hygiene. http://webcache.googleusercontent.com/search?q=cache:T1n9qylbSLMJ:www.ifh-homehygiene.org/system/files_force/publications/Toys_and_home_hygiene.doc%3Fdownload%3D1+&cd=6&hl=en&ct=clnk&gl=uk

[82] Goldbaum E. (2013). Toys, books, cribs can harbour bacteria for long periods, study finds. http://www.buffalo.edu/news/releases/2013/12/030.html

RAPEX, most hygiene-related notifications relate to micro-biological contamination of liquid toys such as bubble blow liquid and the like.[83]

5.1.1.6. Radiation

The risk of **radiation** is associated with the use of materials containing radioactive elements, which can lead to acute radiation syndrome ***(finding 11)***.[84] No examples of radiation poisoning due to radioactive materials in toys were raised through the review of the relevant literature. Radiation is therefore believed to be of very low occurrence.

5.1.2. Free movement of toys

The free movement of toys is particularly relevant to be ensured, given the extent of toy intra-EU trade. According to ECSIP (2013),[85] intra-EU trade in toys was equal to €4.2 billion in 2011, accounting for almost 40% of the EU total toy trade. Germany (around 21% of intra-EU trade), the Czech Republic (around 13%), Italy (around 8%), Denmark (around 8%), the Netherlands (around 6%), the UK (around 6%) and France (around 5%) are the most important exporters of toys within the EU.

According to the majority of Member States, a relevant issue for the internal market of toys is the **low consistency in the implementation of the TSD** at national level. The biggest problem relates to the adoption by Germany of different chemical rules ***(finding 12)*** than those established in the Directive, which is deemed as a great barrier to trade by two Member States.

Box 4 - The German case[86]

On January 20th, 2011, the German Federal Government requested permission to the Commission to maintain the existing national provisions for five elements: lead, arsenic, mercury, barium and antimony, and for nitrosamines and nitrosatable substances released from toy material.

With decision 160 of March 1st, 2012 the Commission rejected the permission for antimony, arsenic and mercury. The values established by Directive were considered to be '*based on a consistent and transparent scientific-toxicological approach to ensure safety'* (Decision 2012/160/EU, par. 60), and therefore more appropriate. Measures for nitrosamines and nitrosatable substances were approved by the Commission as the request was recognised to be *'based on a real concern with regard to children's health and not constituting a disguised restriction on trade between Member States'* (Decision

[83] As mentioned earlier, the Notified Bodies have issued Type Approval Protocol N 2 on this issue. See: http://ec.europa.eu/DocsRoom/documents/5713/attachments/1/translations/en/renditionstranslations/en/renditions/native

[84] Grynkiewicz-Bylina B. (2012). "Life as a factory of toy safety", *Management and Production Engineering Review*, Volume 3, Number 3.

[85] ECSIP Consortium (2013). Study on the competitiveness of the toy industry – Final Report.

[86] On 9 July 2015, the European Court of Justice (ECJ) rejected the German government's request to maintain different limits for arsenic, antimony and mercury in toys, in its implementation of the TSD. This decision is based on the fact that Germany has not been able to provide evidence that a higher level of protection for public health would be granted by imposing different requirements. As a consequence, the German case is expected not to represent any more an issue in the future. However, as the evaluation is based on data gathered before the ECJ decision, references to the German case are provided in the report. This is in accordance with the scope of the evaluation that covers the five years following the Directive's implementation.

2012/160/EU, par. 88). Finally, as regards lead and barium, the German limit values were approved *'since the scientific background for setting the values evolved'* (par. 86) and uncertainties existed *'with regard to the level of protection offered by the Directive'* (par. 87). The German request was thus considered to be based on a real concern for children's health and at the same time not hampering the functioning of the internal market. The Commission therefore approved the national values. This approval was nonetheless subject to a limitation in time, namely the date of entry into force of EU provisions setting updated limits for lead and barium in toys or 21 July 2013, whichever would come first.

Germany applied for annulment of Decision 2012/160/EC. The General Court issued its judgment on the annulment request on May 14th, 2014 that confirmed the Commission Decision with regard to antimony, arsenic and mercury. The German Federal Government appealed against the judgement; however the Court confirmed the Commission's refusal to allow Germany to retain its limit values for arsenic, antimony and mercury in toys on 9 July 2015.[87]

According to Member States, another trade barrier consists in the low consistency in national approaches to enforcement, as regards both the number and the type of control procedures. A Member State highlights that some Customs Authorities ask for test reports and other evidence of product compliance rather than simply the declarations of conformity ***(finding 13)***. This is a significant problem for those companies that use the manufacturer's safety assessment to demonstrate compliance and therefore cannot provide test reports. Another Member State denounces that sometimes also distributors unreasonably request manufacturers and industry associations to provide test reports ***(finding 14)***.

According to a Member State, further trade barriers relate to the importers' and distributors' lack of awareness as concerns the internal production control procedure to assess conformity ***(finding 15)***. Importers and distributors often require the manufacturer to provide an EC-type examination certificate, being astonished when receiving the declaration of conformity. They do not seem to be aware of the possibility for the manufacturer to carry out the conformity assessment himself. This is an even bigger problem in case of SMEs, as third party testing would be very difficult to implement due to its high cost. In this regard, an interesting practice is provided by one Member State, where inspectors and employees of the Directorate for Sanitary Inspection provide on-site training to importers and distributors.

Further obstacles to the free movement of toys across the EU follow from the different interpretations as regards the "grey area" (or "grey zone"), i.e. products for which the definition of toy is not clear enough to decide on their classification as being toys or not, thus requiring additional criteria to be taken into consideration ***(finding 16)***.[88] Annex I of the 2009 TSD presents a non-exhaustive list of products that are not considered as toys but that could cause confusion. However, ten Member States declare that the definition provided

[87] Court of Justice of the European Union, Press Release No 81/15, Luxembourg, 9 July 2015, Judgment in Case C-360/14 P, Germany v Commission. http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-07/cp150081en.pdf

[88] Some indicative criteria are: the place of selling, the target audience of the advertising and packaging, the price, the small-size, the double use, the passive use. See: EC (2007). Guidance Document No. 4 on the application of the directive on the safety of toys (88/378/ EEC). p.2 http://ec.europa.eu/DocsRoom/documents/5573/attachments/1/translations/en1/translations/en/renditions/native

by the Directive is still not sufficiently clear. For this reason, they sometimes have doubts about whether to classify a product as being a toy or not.

Still with regard to the low consistency in the implementation of the TSD at national level, a Member State denounces that the same toy is not always correctly marked as intended for children under 36 months of age in some Member States, this potentially resulting in different levels of toy safety ***(finding 17)***.

Finally, three Member States highlight that the lack of unified methodologies increases the complexity of **toy testing**, as there are no common terms of reference ***(finding 18)*** especially when imported toys are concerned. One Member State also reports that usually non-EU manufacturers perform the testing in accordance with outdated EU standards. Another Member State claims that many non-EU manufacturers seem to focus on compliance with standards rather than ensuring that the product actually meets the Directive's safety requirements.

5.1.3. Emerging issues related to toys

5.1.3.1. Toy counterfeiting

Even though toy counterfeiting is not a new phenomenon, the emerging issue concerns the increasing relationship between counterfeit toys and toy online sales ***(finding 19)***. This finds confirmation in the 2011 Memorandum of Understanding aimed at establishing a code of practice in the fight against the sale of counterfeit goods over the internet.[89]

With toys increasingly sold online,[90] the problem is that the growth of e-commerce can also facilitate the supply of counterfeit products. When buying online, customers' choices are highly influenced by brand and reputation. However, fraudulent websites sometimes make it difficult to distinguish between original products and counterfeits. In a survey of 1,303 people, the consumer rights group *Which?*[91] found that, between 2009 and 2011, nearly one out of ten respondents had bought a fake product by mistake. Nearly a quarter of fake goods were bought from websites, including online giants such as Amazon and eBay.[92] Yet, the rise in internet sales and web users has multiplied trading opportunities and now allows customers to access a wide variety of goods across the European Single Market.

Besides the link with the internet sales, toy counterfeiting still represents an issue in itself. The 2008 Impact Assessment estimated the costs of counterfeit toys to the industry at hundreds of millions of euro in lost profits. More recent estimates suggest that the counterfeit market represents 10% of total annual sales of toys.[93]

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[89] http://ec.europa.eu/internal_market/iprenforcement/docs/memorandum_04052011_en.pdf

[90] http://www.tietoy.org/news/article/2014-toy-sales-reached-record-high

[91] https://www.gov.uk/national-pupil-database-apply-for-a-data-extract

[92] On this point, a national report declares that some sites such as Amazon and eBay often continue to sell toys that have been recalled. Therefore, the Member States call for an intervention at EU level in order to better address online selling.

[93] ECSIP Consortium (2013). Study on the competitiveness of the toy industry – Final Report.

As reported by TIE,[94] the 2013 European Union statistics[95] show that toys are over 7% of all counterfeit products seized by EU customs. Between 2010 and 2011, 872 counterfeit toys with a retail value of €16 million were registered by DG TAXUD.[96] In 2013 EU customs registered 86,854 cases of detentions of goods (almost 36 million articles) suspected of infringing an Intellectual Property Right (IPR) at the EU's external border. 1,077 of them concerned toys, almost 0.6% more than those registered in 2012. Over 2.7 million toy articles were detained (excluding games/electronic games), a decrease of 70% compared to detainments registered in 2012.[97] The domestic retail value of the seized toys (had they been genuine) was €23,199,855. In 2013, the Anti-Counterfeiting group,[98] a non-profit trade association, estimates that 12% of toys for sale in the UK are fakes, with 91.9% of all detained toys coming from China.[99]

These impressive figures represent a concern with regard to both the toy industry and the safety of toys, as further confirmed by three Member States denouncing problems related to counterfeit toys originating from third countries, especially from China.

Counterfeit toys may be unsafe as they can escape risk and conformity assessments and be marketed even if not compliant with toy safety legislation.[100] Moreover, they may represent serious hazards with small loose parts, long cords and materials that are toxic or not conforming to non-flammability standards. When including electrical components, counterfeit toys can lead to electric shocks, fires and explosions.[101] In 2014, a record of 32 RAPEX notifications on chemical and flammability hazards relating to children's fancy dress costumes were issued, triggering concerns that unsafe and poor quality costumes were sold on the European market.[102] Yet, the fire hazard in regard of fancy dresses has been identified as a problem that is linked - but not limited - to counterfeit products, as they may not comply with the safety standards as to flammability.[103]

[94] TIE (2014). The Toy Sector and Intellectual Property Rights.

[95] European Commission (2013). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2013. http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2014_ipr_statistics_enipr_statistics_en.pdf

[96] Directorate General Taxation and Customs.

[97] In the TIE's words, «The fact that the number of cases increased while the number of articles decreased is probably due to more consumers buying goods online and having them delivered directly to their homes» (2014, p. 2).

[98] http://www.a-cg.org/

[99] TIE (2014). The Toy Sector and Intellectual Property Rights, p.2.

[100] Sacco D. (2012). Counterfeit toys: how firms are fighting the fakes, Business Analysis of the Toy Industry, Toy News and European Commission (2013). Avoiding counterfeit toys at Christmas: give the gift of safety, Memo. http://www.tietoy.org/news/article/over-eur16-million-worth-of

[101] The Trading Standards Institute. http://www.tradingstandards.gov.uk/extra/news-item.cfm/newsid/1683

[102] http://www.tradingstandards.gov.uk/policy/policy-pressitem.cfm/newsid/1672

[103] Ibid.

Besides being a problem related to toy safety, counterfeiting is directly linked to IPR issues.[104] Toy counterfeiters do not incur expenses to build a brand as they just steal it. This allows offering counterfeits at lower prices than genuine toys, to the detriment of fair manufacturers. All of these economic damages reduce manufacturers' investments both in toy safety and R&D, with potential negative effects on the toy sector innovation.

Another issue related to counterfeit toys regards the protection and enforcement of consumer rights. When realising that the bought products were counterfeit, buyers tried to return them but they are often unable to get a refund, exchange or a credit voucher.[105] As clearly stated by Paul Kitson, head of personal injury at law firm Russell Jones and Walker, '(…) *if you buy from an individual for example through an online auction or through small ads, your only right is that the goods should be 'as described'. Either way, enforcing your consumer rights is almost impossible as sellers of fake toys and other counterfeit goods are difficult to track down, so it's always best to report it to your local trading standards department, who can take action*'.[106]

5.1.3.2. Online sales

Across Europe, most toys are sold in traditional retail outlets such as specialised toy stores and supermarkets.[107] However, evidence shows that the main trend in retail of traditional toys and games across the EU is the rise of the online sales.[108] According to NPD Group – a UK business consultancy - online toy sales represent one quarter of all toys bought in the five major markets (France, Germany, Italy, Spain and the UK) in 2014.[109]

In this regard, it is worth noting that national differences exist. For instance, while online sales account for almost 16% of toy sales in Germany, only 0.5% of toys are sold online in Spain.

Thirteen Member States perceive the rise of the online sales of toys as an emerging issue particularly as regards the effectiveness of enforcing the TSD ***(finding 20)***. Also traceability is seen as more difficult in the case of online toy shops as the information on the manufacturer or the importer may be difficult to identify before the purchase. Moreover, the warnings and the CE marking are often hardly visible prior to purchase, making it difficult for Market Surveillance Authorities to check conformity upfront.

[104] TIE (2014). The Toy Sector and Intellectual Property Rights and TIE (2005). Counterfeiting and product piracy: a threat to consumers, a threat to jobs.

[105] https://www.gov.uk/national-pupil-database-apply-for-a-data-extract

[106] http://www.theguardian.com/money/2011/dec/07/christmas-shopping-counterfeit-toys

[107] TIE (2013). "The European Toy Industry: Facts and Figures".

[108] ECSIP Consortium (2013). Study on the competitiveness of the toy industry. Final Report.

[109] http://www.tietoy.org/news/article/2014-toy-sales-reached-record-high

5.1.3.3. 3D printing

Though still at an infant stage, 3D printing is emerging as a potential new toy market practice. It is believed that affordable 3D printing will become increasingly widespread in line with rapid technological developments.[110]

There is evidence of an increasing attention paid by the toy industry representatives to – actual and potential – 3D printing developments. A new 3D printing software is currently being developed by Disney, enabling animated characters to be converted into 3D-printed mechanical toys; a partnership has been recently established between Hasbro and the 3D printing company "3D Systems" to co-develop innovative play printers; the British charity Kids Company worked with agency AMV BBDO and 3D printing firm Ultimaker on a pop-up shop in London, printing toys when visitors made a donation;[111] customisable doll brand Makies is the first example of actually 3D-printed toys.[112]

3D printing is very appealing for the toy industry as it allows higher levels of product personalisation and customisation than the traditional sector. For instance, in 2014 Hasbro in partnership with the "3D plus me" printing company launched the "Super Awesome Me Campaign" that allows consumers to become action figures of their favourite super heroes.

However, despite outstanding expectations expressed by economic operators and consumer associations, 3D printing raises concerns in terms of both market competition and citizens' safety ***(finding 21)***. As regards market fairness, 3D printing-related issues are very close to those that occurred with the musical industry only a few years ago. 3D-printed products are built on digital models able to freely circulate over internet. Digital models can be modified by anyone, even if changes have not been approved by the legal owners of the property rights. This links 3D printing directly to counterfeiting and IPR issues.[113]

With regard to toy safety, the limited literature points to two potential sources of risks:[114]

- Consumers may print their own toys that might not adhere to safety standards, such as small, detachable parts that could cause choking or sharp objects that could inflict cuts. There is also the concern that children may print out toys for distribution among friends, as for example party favours;
- Consumers may create their own toys for sale. This would require these products to comply with the requirements under the Directive; however, it is reasonable to assume that consumers' knowledge of the regulation might be limited.

As raised by large toy companies, consumers' 3D-printed toys are more unpredictable than traditional toys as concerns product quality, durability and safety. As in self-made

[110] http://www.sciencedirect.com/science/article/pii/S2212868912000050

[111] http://www.theguardian.com/technology/2014/feb/17/hasbro-3d-printing-children-kids

[112] http://quib.ly/qu/will-we-see-more-3d-printed-toys-in-2014

[113] http://www.paristechreview.com/2014/12/16/3d-printing-ip-rights/

[114] http://www.scientificpapers.org/wp-content/files/1462_KinsleyBrooksOwens-International_LegalLegal_and_thical_Challenges_Related_to_the_Use_and_Development_of_3D_—TechnologyTechnology_in.pdf

manufacturing the consumer chooses the materials to be used, it is not possible to ensure toys compliance with safety and quality standards.[115]

5.2. Management of the Directive at national level

5.2.1. Implementation

5.2.1.1. Cooperation among the different actors concerned with the Directive's implementation

All **Member States support economic operators** to properly implement the TSD ***(finding 22)***. Assistance can be provided in different ways. With just one exception, Member States have organised seminars, meetings and workshops aimed at providing specific training to economic operators. A dedicated website with information on toy safety and on legal requirements is generally set up and economic operators are provided with a dedicated contact. Other types of support include the use of online material - such as brochures – as well as of the mass media as a channel to convey messages and information on toy safety.

Two interesting practices have emerged, the former is related to the spread of information directed to industries, the latter targets consumers. In the first case, study days are annually held and organised for economic operators, with around 80-100 industry delegates attending these events. In the second case, the national Market Surveillance Authority held an information session for secondary school pupils in February 2011. The session covered toys typical of the carnival season, with specific focus on their labelling and general principles of the CE marking and its meaning. As for the cooperation among different actors concerned with the TSD, fourteen Member States participate in **CEN** TC52,[116] while only five participate in **CENELEC**. Only four Member States participate in **ISO** TC181,[117] and only one participates in IEC **(finding 23)**.[118]

5.2.1.2. Problems encountered when implementing specific provisions

Fourteen Member States have never dealt with a toy presenting a risk not covered by the particular **safety requirements**, thus never had to apply the general safety requirements ***(finding 24)***. The only reported cases include:

- Toys having a strong smell due to the presence of harmful chemicals, which evaporated to room air and may have caused health hazard;
- Gustative toys, which met all TSD specific safety requirements, but as a result of the presence of food ingredients did not comply with the 'foodstuff regulations'. This issue has been addressed and further clarified in EN 71-13:2014, which focuses on toys

[115] http://3dprintingindustry.com/2013/12/17/will-lego-3d-printing/

[116] CEN Technical Committee 52 "Safety of toys".

[117] International standardisation organisation Technical Committee 181 "Safety of toys".

[118] International Electro-technical Commission.

involving DIY kits for cosmetic and food, as well as game set for learning smell and taste;[119]

- Rattle toys, which are mainly intended for infants but contain small parts that could be ingested.

Beyond problems with the "age classification" (***finding 17***), twelve Member States denounce problems with the **warnings,** particularly as concerns the language of labels, their clarity and legibility. Further problems relate to the pictogram standing for "suitable only for children over 36 months of age", [120] which is not always properly used ***(finding 25)***. The Directive requires the warning to be legible, but does not establish a specific font size, and this is perceived by five Member States as a relevant problem for the marketing departments in charge of the labels and of size.

One Member State criticises the requirement set in article 11(2) for warnings to be preceded by the word 'Warning', since this should not apply in case the pictogram is used as this would not have any further impact on consumers. Further problems relate to the indication for "adult supervision", which is often misleading as it suggests dangers that are not actually present. This also points to the low awareness of economic operators about the provisions regarding the warnings.

Warnings are presented as a concern also in the already cited[121] "W.A.T.C.H. nominees for "10 worst toys"". The main point raised in the report regards toys 'marketed with a litany of instructions that make compliance unrealistic in real-life situations'. Furthermore, in three out of ten worst toys ranked there are no warnings at all; in two there are no warnings on the toy and in one case the warnings are placed "on the bottom of the package".

Four Member States denounce problems with the **CE marking *(finding 26)***. In particular, one Member State reports the marking of dual-purpose products to be unclear while another Member State deems as unclear the marking of toys made of several parts. It is important to underline that the explanatory guidance on the 2009 TSD[122] published by the European Commission firstly in 2010 - and then repeatedly updated – detailed all the requirements and procedures relating to the CE marking. In addition, in 2011 TIE published a brochure specifically focused on the CE marking scope and rules.[123] Both documents address some of the issues raised by Member States. Therefore, the problem seems not to consist in the low availability of guidance, but rather in the insufficient dissemination of existing documents. For this reason, awareness should be raised to increase the use of all available instruments that can help understanding the working mechanisms of the Directive.

Twelve Member States have never notified a measure under **Article 42(4)** defining the procedure for dealing with toys presenting a risk at national level ***(finding 27)***. As for the

[119] EN 71-13: 2014 Safety of toys – Olfactory Board Games, Cosmetic Kits and Gustative Games. Referenced for the first time in the OJEU on June 13th, 2014.

[120] Part B of Annex V of the TSD.

[121] See footnote 79.

[122] EC (2015). The Toys Safety Directive 2009/48/13. An explanatory guidance document, REV 1.8.

[123] TIE (2011). CE marking for the toy industry, *TIE publications*.

others,[124] only three Member States provide some details on their experience with this provision. Between 2011 and 2014, one Member State sent 17 notifications, which were followed up with appropriate measures aimed at withdrawing the toys concerned from the market and imposing a ban on their distribution. Another Member State sent 27 notifications over the same period, while the third Member State notified 65 serious risks and 16 non-serious risks, along with 10 cases for information, while no information has been gathered in the other cases.

Other frequent implementation issues concern the too heavy requirements for **SMEs**, particularly as regards the costs of the risk and safety assessments and the lack of clarity of the rules to affix the CE marking, especially when imported goods are concerned ***(finding 28)***.

5.2.1.3. Requests for clarification on requirements

Several Member States highlight a need for clarification on different issues ***(finding 29)***. As concerns the **chemical requirements**, one Member State thinks that 'they are worded in a very convoluted way and are barely comprehensible', while another Member State claims that chemical requirements need a more precise and transparent structure and a simpler wording. Furthermore, one Member State observes how economic operators often find it difficult to understand which regulation (e.g. TSD rather than REACH) should apply for limits in chemicals.

Also the **definition of toy and related exemptions** pose problems – particularly as regards the exclusion of slings and catapults and the cases when scooters and bows are considered to be toys. On this point, a standardisation mandate has been addressed by the Commission to CEN, in January 2011, stating that only slings and catapults as such are excluded from the TSD scope, while adding a sling or a catapult to a toy (as it is the case with catapult airplanes) does not exempt the combination from being a toy.

Finally, requests for clarification on **microbiological properties** have been recently addressed through a protocol updated by the NB-Toys in 2014 on "Microbiological safety of toys containing aqueous media".[125] The protocol clarifies the microbiological requirements, limits and test procedures in order to ensure microbiological safety.

Box 5 - Specific requests for clarification raised by Member States

Other requests for clarification regard the exclusion from the toy category of:

- Playground equipment intended for public use, particularly as concerns the distinction from activity toys. These include trampolines and other toys to be used not only domestically but collectively, which may pose other security issues as they are put to an intensive use for which they have not been designed;
- Products for collectors, as it can be difficult to distinguish them from toys;
- Reproduction of real firearms which, according to two Member States should be included in the

[124] Two Member States did not reply.

[125] NB- toys/2014/071, EC-Type approval protocol No. 2: Microbiological safety of toys cont-aining aqueous media Rev 2.

scope of the TSD. On this point, the previously mentioned W.A.T.C.H. study expresses an opposite position. The non-profit corporation deems that children should not be provided with reproduction of real firearms, as they are too dangerous to be considered as toys. In regard to toy guns, a Member State asks for further clarification on the exclusion of compressed gas-operated pistols;

- Puzzles with more than 500 pieces;
- Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment;
- Decorative items;
- Aquatic equipment and fashion accessories;
- Electrically driven vehicles;
- The formulation "24 volts direct current or the equivalent alternating current";
- The link between article 42(4) and RAPEX;
- Radioactivity and chemical compounds;
- Appendix C on specific limit values for chemicals used in toys intended for use by children under 36 months of age or in other toys intended to be placed in the mouth;
- Whether all toys have to be marked with an age or weight class and if the use in a nursery school shall be deemed as "domestic";
- Transition periods, as toys made available on the market in these time spans continue to be purchasable also after the end of the period.

Overall, five Member States ask for a clearer and unambiguous wording of the Directive, with limited information and precise requirements, particularly as concerns the provisions for authorised representatives and for importers acting as manufacturers ***(finding 30)***. Rather than drafting new guidelines, the request is to keep the existing guidelines updated in order to avoid confusion and duplication, while simplifying the understanding of evolving provisions.

5.2.1.4. Problems when amending the Directive

The main obstacles encountered in the transposition of the TSD concern its **amendments *(finding 31)***. Seven Member States denounce the amendments have been too numerous, especially when considering the short time span to transpose them into the national law.

Furthermore, three Member States deem the Committee procedure as too much red-tape and time-consuming.

5.2.2. Enforcement

5.2.2.1. Cooperation among the different actors concerned with the Directive's enforcement

All **Member States** with the exception of one have established cooperation mechanisms with stakeholders to promote the enforcement of the TSD ***(finding 32)***. In seven Member States these mechanisms embrace technical committees or working groups specifically dealing with the enforcement of the TSD and aiming to implement joint and/or common initiatives for market surveillance activities.

Inter-institutional cooperation between Customs and Market Surveillance Authorities includes participation in meetings and seminars (seventeen Member States); regular contacts - e.g.

via e-mails, *ad-hoc* queries (ten Member States); documents, data and general information sharing (fifteen Member States); joint projects and common strategies for market surveillance activities (ten Member States). In seven Member States, Market Surveillance and Customs Authorities are represented within the same body.

In order to guarantee a continuous information flow, one Member State requires customs to draft monthly reports on their activities for Market Surveillance Authorities, while Notified Bodies are required to inform them with annual reports on their activities.

As for the participation of Market Surveillance Authorities in the activities of **national standardisation bodies**, they are either members of national standardisation bodies (in three Member States), or they actively participate in national standardisation activities by means of dedicated technical committees (in ten Member States), or they are directly involved in common cooperation and communication activities with the national standardisation bodies (in thirteen Member States) ***(finding 33)***.

Finally, an unofficial e-mail administered forum for informal contact has been established involving ten Member States.

Four Member States declare they have no established communication channels between **Notified Bodies** and the **Notifying Authority** or the **Market Surveillance Authority** to find solutions to practical problems. In other cases, communication channels could be statutorily regulated (three Member States) or voluntary (seven Member States). Communication mechanisms embrace experience exchange groups (two Member States), working groups at national level where Notified Bodies are required to participate (four Member States), coordination meetings or laboratories (two Member States). Continuous information (three Member States) and possibilities of consultation (one Member State) are also provided ***(finding 34)***.

While in five Member States there is no **administrative cooperation with other Member States** apart from the regular ADCO[126] meetings hosted by the European Commission, in the other cases important cooperation experiences have been pointed out, as detailed in Box 6 below ***(finding 35)***.

[126] ADCO stands for Administrative Cooperation Group, including representatives of Member States who meet to exchange information and discuss about issues regarding the enforcement of the Directive.

Box 6 – Cooperation within EU Member States

- Membership in PROSAFE for twelve Member States;
- Cooperation between Nordic countries (Denmark, Finland and Sweden) in the "Nordisk Produkt Forum" which deals, among other matters, with toy safety issues;
- Cooperation between Estonia, Lithuania and Latvia;
- Cooperation via RAPEX and the Information and Communication System on Market Surveillance (ICSMS).[127]

Source: National reports

Seventeen Member States are not engaged in any action on toy safety with **third countries**. As shown in the following box, other Member States implemented initiatives consisting in experience and good practices sharing, joint projects, cooperation platforms and exchange visits ***(finding 36)***.

Box 7 - Member States actions on toy safety with third countries

Two Member States participated in EU twinning projects, one in Armenia and the other in Moldova. These EU-funded projects, which ran for almost two years, allowed for the transfer of successful experiences in helping Armenia and Moldova draw up national legislation regulating the surveillance of the market in non-food products and harmonising this with EU standards and the best practices of the EU Member States.

In 2011 and 2012, another Member State involved some Balkan area countries (Bosnia, Kosovo, Macedonia, Montenegro and Serbia), Albania and Turkey in a local initiative enabling constructive exchange of experiences in the sector of product safety, in particular toys. The Member State has also shared its experience in operational projects to the Kosovar Customs Authority.

One Member State participates in the steering group for one of SAICM's (Strategic Approach to International Chemicals Management) priority areas – information on chemicals in products. Work is currently under way to draft a programme with the aim of facilitating companies to exchange information on the content of products. Toys are one of the organisation's four priority product areas, and the work has also involved trade organisations from other parts of the world, primarily the USA.

One Member State has an extensive collaboration with China. The aim is to establish an efficient and effective market surveillance system in China - with a particular focus on export control. China is indeed responsible for a significant proportion of the toys retailed in Europe. A Working Group on Product Safety was established between China and the Member State as a permanent platform for dialogue. Finally, five additional Member States are involved with China on matters of product safety via PROSAFE.

Source: National reports

To conclude, under the EU support mechanism **TAIEX**,[128] several activities have been carried out. These include thematic seminars focused on specific provisions and topics of the

[127] ICSMS is the internet-supported information and communication system for the pan-European market surveillance.

[128] TAIEX is the Technical Assistance and Information Exchange instrument. It supports public administrations within the EU and in some specified third countries with regard to the approximation, application and

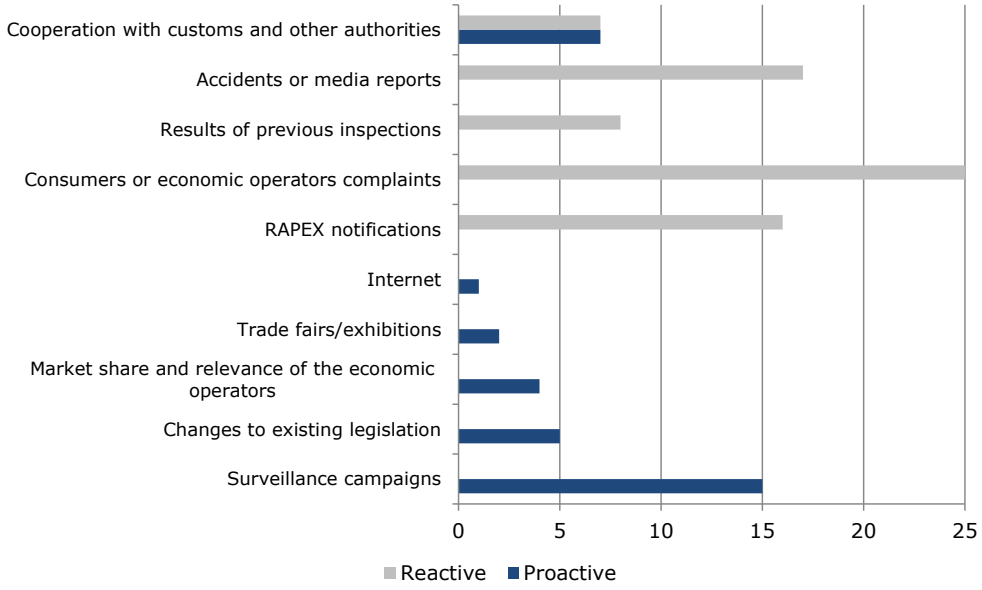
TSD, training specifically addressed to toy testing procedures, exchanges between national delegations of different Member States aimed at sharing information and good practices and at providing specific information following *ad-hoc* requests (e.g. at the request of the delegation from Lebanon and Tunisia, information on toy safety inspections in France was provided in 2013 and 2014).

5.2.2.2. Strategies for market surveillance activities

All Member States have mandatory national **market surveillance programmes** and most of them have settled specific strategies for dealing with the toy sector surveillance ***(finding 37)***.

Market surveillance strategies can be either planned proactive inspections, or unplanned reactive *ad-hoc* checks. All Member States make use of both methods. The following figure summarises proactive and reactive measures used in different Member States.

Figure 5 - Proactive/reactive measures and number of Member States implementing them



Source: National reports

Proactive inspections can be set up as surveillance campaigns, based on the danger that a particular product might entail, on the risks found through *ad-hoc* checks and on the information obtained from previous campaigns. Inspection campaigns are carried out with respect to particular toy categories (e.g. inflatable toys, skates, projectile toys) or in specific sales premises of toys (e.g. open-air markets). Another reason triggering proactive inspections are amendments to current regulations requiring Member States to transpose them into national legislation. In these cases, Market Surveillance Authorities take care to verify that economic operators are aligned with the new requirements. According to four Member States, the market share and relevance of an economic operator influence the

enforcement of EU legislation as well as facilitating the sharing of EU best practices. It is largely need-driven and delivers appropriate expertise to address issues at short notice. http://ec.europa.eu/enlargement/taiex/what-is-taiex/index_en.htm

frequency of inspections. The larger the market share of an economic operator, the easier it is to control it and the more it will be subject to inspections ***(finding 38)***. Finally, trade fairs or exhibitions are further occasions were Market Surveillance Authorities conduct controls. In one Member State, internet is checked for signals and complaints every day, while another Member State is used to perform proactive surveillance in particular on toy guns (laser light beam, kinetic energy and suction cups).

Main reasons for **reactive inspections** include RAPEX or ICSMS notifications, the results of previous inspections or of market surveillance projects, consumers' or economic operators' complaints, accidents or media reports and cooperation with Customs Authorities.

There are four main procedures for inspection and investigation activities at national level. Eighteen Member States carry out **visual and physical product and packaging inspection**, verifying toy compliance with the TSD requirements (e.g. conformity marking and pictogram; warnings; name and registered address of the responsible economic operator; general safety requirements; etc.). **Documentation verification** - assessing for instance safety instructions and the technical documentation - represents the procedure used by sixteen Member States. The third procedure – as reported by eighteen Member States - consists of **sample laboratory testing**, to further check the compliance of toys with particular safety requirements. Finally, seven Member States refer to **inspection of economic operators' premises**, aimed for instance at testing the (raw) materials used and their traceability (e.g. procurement documents, distribution lists), using invoices and delivery notes.

5.2.2.3. Problems encountered when enforcing specific provisions

Twenty Member States report **difficulties in obtaining information to be included in the technical documentation** (such as safety assessment, test reports, names of suppliers, etc.) from economic operators, particularly when imported toys are concerned ***(finding 39)***. In particular, ten Member States denounce that **safety assessments** are often not included in the technical documentation, as they are seen as a too complex and merely formal requirement. Moreover, according to one Member State, economic operators often lack knowledge on what information they are required to provide. In many cases, it is not possible to link the documentation to the toy, the documentation thus being worthless.

One Member State highlights problems related to the **wording "*prior to placing on the market*" *(finding 40)***. According to the Directive "placing on the market" means the first making available of a toy on the Community market. Based on the Blue Guide interpretation of this definition, '*placing on the market is considered not to take place where a product is introduced from a third country in the EU customs territory and has not been released for free circulation. This includes the cases of products in transit, placed in free zones, warehouses or temporary storage*'.[129] Consequently, importers can choose to meet their obligations in their warehouses after the products have been put into circulation. Moreover, toys without an appropriate identification of the importer may be released on the market.

[129] DG ENTR (2014). The "Blue Guide" on the implementation of EU product rules, p. 18.

Other Member States denounce problems with the **declaration of conformity *(finding 41)***. According to a Member State, declarations of conformity have often a date subsequent to the product placing on the market. This shows that importers/distributors do not have an EC declaration of conformity at their disposal, but that they request it from the manufacturer only when so required by the competent authority. Declarations of conformity are sometimes incomplete, with descriptions of the toy not corresponding to that written on the conformity assessment or even missing at all. In other cases, the picture is lacking or not sufficiently clear, so that it is impossible to link the document to the relevant toy. Sometimes the declarations of conformity do not contain any information on who issued the document, making it impossible to identify the manufacturer. There are cases of declarations referring to obsolete or incorrect standards, or missing references to other relevant EU legal acts when a toy is not subject to the TSD only.

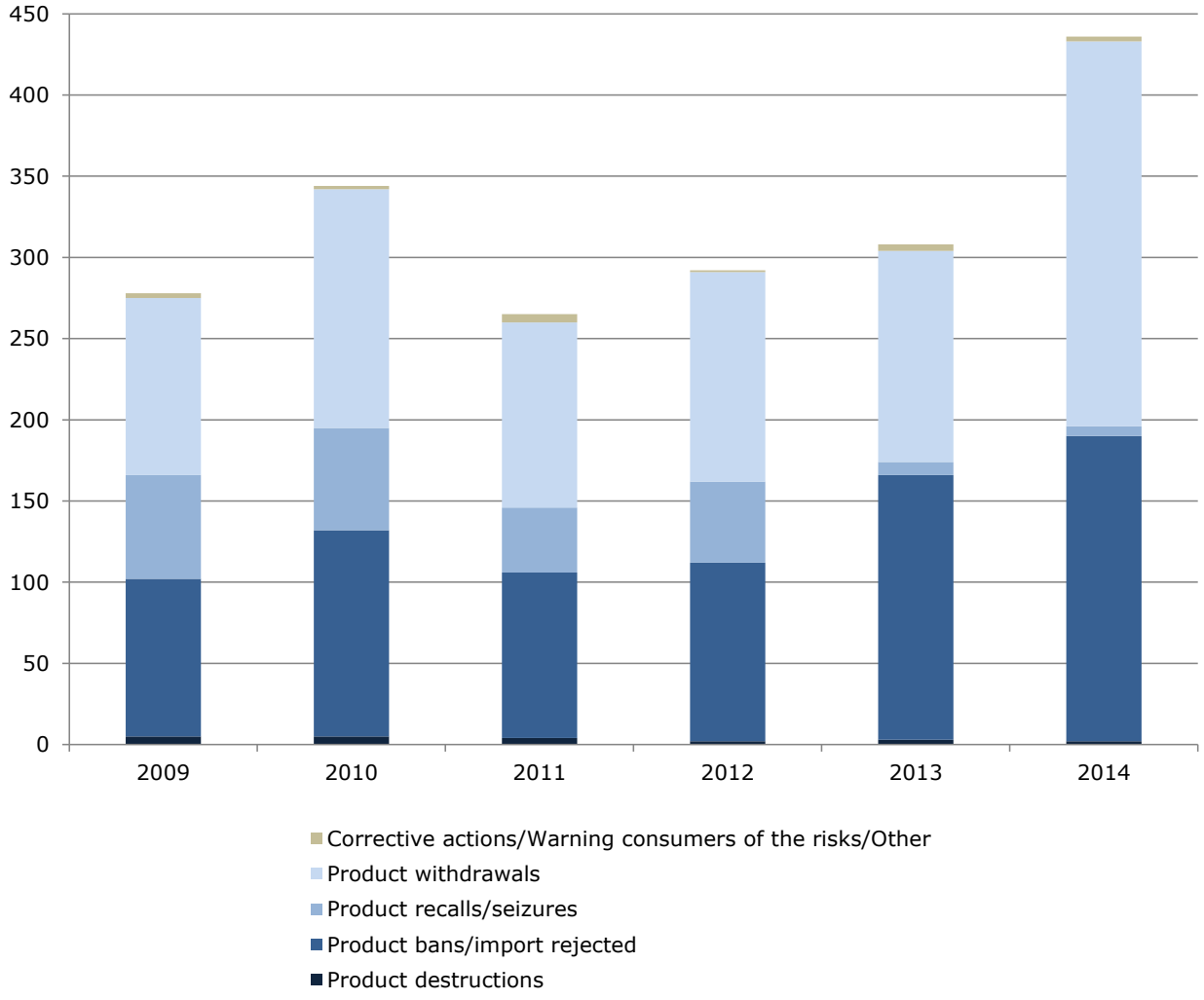
According to eight Member States, SMEs are particularly concerned with the costs related to the safety assessments and this hinders the overall quality of the assessment procedures that are often incomplete and missing relevant information. For instance, detailed descriptions of the toy design and manufacture, including the list of components and used materials (in particular the safety data sheets on chemicals) are often missing. Since many documents are poor of information, the control authorities have difficulties in carrying out the risk assessment. This information is often obtained only after the Authority has made a specific request, which slows down the administrative processing.

5.2.2.4. Sanctions and penalties available to Market Surveillance Authorities

While administrative **sanctions** are established in all Member States, only in thirteen Member States sanctions can also be penal ***(finding 42)***.

Figure 6 shows the measures adopted by competent authorities - or by economic operators when required by a competent authority - over the period 2009-2014.

Figure 6 - Number of compulsory corrective measures related to toys and implemented over the period 2009-2014 in the EU28



Source: Author's calculations based on RAPEX database

Table 4 gives an overview of the sanctions imposed to economic operators due to infringements related to toys, showing that applied sanctions have been quite differentiated across Europe, with Member States differently punishing toy-related infringements ***(finding 43)***.

Table 4 - Application of sanctions across EU Member States over 2011-2014[130]

MS	Application
1	Criminal proceedings in approximately 3-5% of cases; administrative penalties or corrections, in around 20-25% of cases (of all toy samples examined in the year, including suspect samples)
2	213 fines
3	Criminal proceedings initiated in 3 cases Administrative proceedings initiated in 4 cases
4	734 fines were imposed, with a value of €319,969
5	16 fines
6	None
7	55 fines
8	None
9	In 2011: fines for €2,328.00 In 2013: fines for €8,632.50 In 2012: fines for €10,695.00 In 2014: fines for €2,355.00
10	98 fines. Average amount: €784. Minimum amount: €29; maximum amount: €2,134. In 2014: 6 administrative cases opened
11	In 2011: 335 fines for €207,183 In 2013: 931 fines for €587,471 In 2012: 703 fines for €369,003 In 2014: 507 fines for €379,385
12	18 fines

Source: National Reports

5.2.2.5. RAPEX

Table 5 below shows RAPEX notifications for toys between 2009 and 2014. On average, "toys" are related to the second highest number of notifications among all products - only preceded by "clothing, textiles and fashion items". The two categories considered together represent 51% of all RAPEX notifications over the period, with toys being equal to 24% ***(finding 44)***.

Table 5 - Number of notifications by product category over 2009 - 2014

Product category	2009	2010	2011	2012	2013	2014
Chemical products	44	29	38	54	69	62
Childcare articles and children's equipment	67	72	66	43	68	81
Clothing, textiles and fashion items	395	625	423	668	583	530
Communication and media equipment	10	6	5	15	23	12
Construction products	n/a	n/a	104	5	8	19
Cosmetics	86	66	104	86	106	74
Decorative articles	14	10	9	11	27	21
Electrical appliances and equipment	138	158	153	205	207	217
Food-imitating products	40	51	16	22	40	13
Furniture	17	12	9	15	22	13
Gadgets	6	4	2	2	1	1
Gas appliances and components	15	8	7	12	6	16

[130] Please note that data for 15 Member States were not available. Furthermore, the timeframe has been provided as reported in the national reports.

Product category	2009	2010	2011	2012	2013	2014
Hand tools	2	1	1	3	n/a	n/a
Hobby/sports equipment	49	42	24	19	55	38
Jewellery	7	7	12	22	28	63
Kitchen/cooking accessories	14	5	8	11	8	16
Laser pointers	8	15	11	30	37	16
Lighters	30	35	14	18	43	36
Lighting chains	39	23	12	49	53	24
Lighting equipment	52	48	53	50	77	79
Machinery	7	17	15	21	23	26
Motor vehicles	146	175	171	149	160	194
Other	19	33	34	68	47	47
Pressure equipment/vessels	n/a	n/a	1	1	n/a	1
Protective equipment	12	29	31	20	41	44
Pyrotechnic articles	n/a	n/a	n/a	11	46	38
Recreational crafts	5	3	13	3	3	5
Stationery	5	1	n/a	2	3	5
Toys	**472**	**488**	**324**	**366**	**580**	**650**

Source: RAPEX Annual Reports

As shown in Table 6, most of recalled toys come from China ***(finding 45)***.

Table 6 – Number of recalled toys between 2009 and 2014 and countries of origin

Country of origin	2009	2010	2011	2012	2013	2014	Total
Bosnia and Herzegovina	0	0	0	0	1	0	**1**
China	135	106	78	79	74	112	**584**
EU28	6	20	16	4	11	6	**63**
Hong Kong	3	0	0	2	1	9	**15**
Japan	0	0	0	0	1	0	**1**
Malaysia	0	0	1	0	0	0	**1**
Mexico	0	19	0	1	0	0	**20**
Philippines	0	2	0	0	0	1	**3**
Republic of Korea	0	0	1	0	0	0	**1**
Russia	0	1	0	0	0	0	**1**
Sri Lanka	1	0	0	0	0	0	**1**
Taiwan	2	2	5	0	1	1	**11**
Thailand	1	1	1	0	3	0	**6**
Ukraine	0	1	0	1	0	0	**2**
United Arab Emirates	0	0	0	0	1	0	**1**
United States	0	3	1	0	0	0	**4**
Vietnam	0	0	8	0	0	1	**9**
Unknown	6	10	1	7	6	2	**32**
Total	**154**	**165**	**112**	**94**	**99**	**132**	**756**

Source: RAPEX database

Twenty-four Member States declare to routinely notify dangerous toys to the **RAPEX** system when the criteria for a RAPEX alert are met. Twenty-two Member States are generally used to follow up the information on toy risks that is published via RAPEX ***(finding 46)***.

However, notifications are often lacking the risk assessment, due to several reasons ***(finding 47)***. Sometimes, risk assessment is not carried out as limit values are clearly set out in the TSD, or because the decision is based on an existing experts' assessment at EU level, or in case the risk is self-evident – e.g. with excessive content of phthalates.

6 ANSWERS TO THE EVALUATION QUESTIONS

6.1. Relevance

6.1.1. EQ1: To what extent do the objectives of the 2009 Directive (still) correspond to current needs/issues?

The objectives of the 2009 Directive still correspond to current needs as identified in the desk research and reported by stakeholders. As for the **internal market**, the relevance of the TSD 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 for toys.

Box 8 – The European market for toys and games in brief[131]

The European market for traditional games and toys is the largest worldwide (it was valued €15.8b in 2011), and increasing over time. European trade in toys and games is also impressive. Europe is the first importer of toys and games (37% of total world imports) and the second exporter of toys and games (19% of total world exports), following China (74%). Intra-EU trade accounts for 15% of total world trade in toys. In 2010, there were over 5,300 manufacturing enterprises producing toys and employing around 53,000 people in the EU. Most manufacturers are micro and SMEs.

Source: ECSIP Consortium (2013)

The impressive numbers of toys crossing both the internal and external European borders require legislative certainty on the applicable rules for placing toys on the internal market and their free movement therein.

The Directive sets common requirements for all actors concerned with toys across Europe, by clarifying roles and responsibilities of economic operators thanks to its very clear and familiar structure.[132] Only a German industry association claims that while setting clear requirements for manufacturers, the Directive could better specify the obligations for importers and distributors. The harmonisation of national requirements is crucial to enhance the internal market for toys. The Directive indeed requires that all toys placed on the EU market comply with the same safety requirements, thus reducing possible barriers that would stem from different regulatory systems at national level. In addition, the Directive represents a safety guarantee for the increasing import of toys from third countries. This twofold role of the Directive is widely recognised by Members States, economic operators and industry associations.

As for toy-related **safety issues**, some changes occurred since the Directive came into force, but either the TSD has already effectively addressed them, or it has been promptly modified accordingly (sections 2.2.2.3 and 6.1.2).

The main areas of concern at the origin of the 2009 Directive included soft toys and dolls, ride-on, rocking and riding toys, small toys and small parts from toys and projectile toys,

[131] The figures reported in Box 8 include also games that are out of the Directive's scope.

[132] All the directives implemented under the New Legislative Framework – including the TSD – follow the same structure, with provisions drafted according to a standard format. This facilitates the stakeholders' understanding of legislative requirements as these are always presented in the same way.

activity toys and toys in food.[133] Other safety hazards regarded physical and mechanical properties – including noise and speed limits for ride-on toys; chemical properties - concerning CMR substances and allergenic fragrances in particular; and electrical properties, with particular attention to lasers.[134] These hazards still correspond to the most frequent risk categories currently linked to toys (as presented in section 5.1.1), confirming the Directive to be a relevant policy measure to address these hazards and risks.

Overall, the relevance of the TSD in ensuring toy safety is not questioned, even though diverging opinions have been expressed by economic operators, consumer associations and Member States.

Economic operators and their associations raise no evidence of any major hazard not properly covered by the Directive. Besides a German manufacturer declaring that the area of PAHs (Polycyclic Aromatic Hydrocarbon) should be better regulated, radioactivity is the only risk raised by an Italian industry association as not completely covered by the TSD, yet so rare to be negligible.

Notwithstanding the positive feedback generally provided by economic operators, the TSD presents some controversial points mainly related to the relevance of chemical risk in toys ***(finding 1)***. **Consumer associations** and **Member States** however express a different view with regard to particular safety requirements, reporting that several hazards are not properly covered – or not covered at all – by the Directive.

According to two European consumer associations and five Member States, even though the 2009 Directive has introduced much progress - such as a stricter regulation of toys in food, better provisions on market surveillance, and the quinquennial evaluation of the safety of toys by the Member States as required by article 48 - the provisions addressing chemical exposure are still deemed to be inadequate.

CMR substances overall represent one of the most critical aspects. In the 2009 Directive, the presence of CMRs in toys is limited to a maximum concentration corresponding to the values established for the classification as CMR in mixtures.[135] Derogation to this limit is accepted

[133] 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, p. 52. http://ec.europa.eu/DocsRoom/documents/1756/attachments/1/translations1/translations/en/renditions/native

[134] Impact Assessment (SEC(2008)38) for the revision of the 1988 Directive. http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_20082008/sec_2008_00380038_en.pdf

[135] According to CLP Regulation, Annex I, the generic concentration limits of ingredients of a mixture classified as CMRs that trigger classification of the mixture are:

- 0.1% for Carcinogens category 1A and 1B, Germ cell Mutagens category 1A and 1B;
- 1% for Carcinogens category 2 and Germ cell Mutagens category 2;
- 0.3% for Reproductive toxicants category 1A and 1B;
- 3% for Reproductive toxicants category 2.

These concentration limits apply to solids and liquids (w/w units) as well as gases (v/v units). However, generic concentration limits only apply if no specific concentration limits are set in Annex VI to the CLP Regulation. If a specific limit is set therein, then it also applies for the purposes of the TSD.

only when a CMR substance is present in inaccessible parts of toys[136] or a decision permitting its use has been taken.[137] However, as noted by a European consumer association, nothing ensures that these substances cannot leak out. According to the stakeholder, CMRs should be reduced to a minimum in toys, as it is impossible to set a specific safety level.[138] In addition, several stakeholders[139] claim that the migration levels for lead should be lowered.

Allergens are another issue considered as too softly regulated.[140] Consumer associations and three Member States think that the list of sensitising fragrances as set out in the TSD is "*clearly outdated*", while all 129 contact allergens identified by the Scientific Committee on Consumer Safety (SCCS)[141] should be banned from toys. Requirements for allergenic fragrances are also deemed to be deficient as in some cases only labelling is required, and sensitizers other than allergenic fragrances are not covered.

Furthermore, consumer associations and six Member States express concerns as regards *preservatives*. This point finds further confirmation in a study by the Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection stating that '*no specific requirements for preservatives are set in the new Toy Safety Directive – except for preservatives classified as CMRs and except for the general statement that chemical substances used in toys must not present a risk of adverse effects to human health*'.[142]

Finally, a European consumer association and a Czech Notified Body and testing laboratory request to better define *organotins and nitrosamines*, in order to properly identify those that are highly harmful. In particular, the testing laboratory denounces the lack of a clear scientific and procedural framework to identify and assess hazardous toys, particularly when chemical mixtures are concerned.

As concerns *mechanical and physical hazards*, one Member State points out risks not covered by any particular safety requirement such as the kinetic energy of toys that are used to propel objects without any accumulated energy. One Member State underlines the inadequacy of the European standard EN 71-1, as it does not deal with the situation where, for example, a sharp metal or plastic part of an internal toy mechanism breaks off and falls out through an opening in the case. Three Member States think there is the need for introducing a biting test for toys intended to children under 36 months of age. Furthermore, a Member State together with a European consumer association claims that the level of

[136] Directive 2009/48/EC on the safety of toys, Annex II, Part III, point 4(b).

[137] Directive 2009/48/EC on the safety of toys, Annex II, Part III, point 4(c).

[138] ANEC (2014). Position paper. Hazardous chemicals in products. The need for enhanced EU regulations. http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

[139] Two Member States and three consumer associations.

[140] Three Member States and a representative of consumers.

[141] SCCS (2011). Opinion on fragrance allergens in cosmetic products. http://ec.europaeuropa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf SCCS/1459/11, 2011 – Table 13-1 to Table 13-3.

[142] Bmask (2013). Chemical Requirements for toys, European Parliament (2010), p. 97.

noise in the new TSD should be further addressed.[143] Finally, one Member State points out that the fragility of seams of soft toys and dolls should be taken into account.

With regard to *electrical and flammability* hazards, three Member States denounce cases not covered by any safety requirement. In one case, it is highlighted that no particular safety requirements exist for toys with detachable magnets that fit entirely within the small-parts cylinder - as referred to in EN 71-1 8.2 - and have a magnetic flux index exceeding the EN 71-1 limit of 50 kG^2mm^2. This concern finds confirmation in a factsheet by the European Child Safety Alliance,[144] where small toy magnets are indicated as the cause of several incidents to children between 1 and 10 years of age around the world.[145] Another case relates to a toy intended for children under 36 months of age and powered by a power source (batteries), which did not conform to the requirement of the European Standard EN 62115 since the battery compartment was accessible. The third case concerns particular types of super balls containing liquids. The liquid caused light rays to meet at the focal point (as with a magnifying glass) that became so hot that it caused a danger of fire.

Finally, six Member States ask microbiological properties to be better specified.

Beyond chemicals, two Member States raise the need for setting specific and clearer requirements for toys contained in - or co-mingled with - food and to regulate the surveillance of these toys at EU level. Moreover, two Member States and two consumer associations call for nanomaterials to be regulated according to the definition of nanomaterials as included in the Commission Recommendation No. 696 (2011)[146] and to be banned in any toy.

Besides known issues related to the toy sector and safety, toy counterfeiting, online sales and 3D printing represent further areas of concerns ***(finding 19, finding 20, finding 21)***.

A Spanish and a Bulgarian industry association observe that **counterfeiting** is a problem as counterfeits do not comply with regulations and violate IPR. TIE claims that counterfeiting is strictly linked to "rogue players".[147] This might be particularly worrying since 94% of RAPEX notifications in 2012 were related to toys produced by companies that were not members of

[143] Currently, the TSD sets no specific limit noise value in toys, generally specifying that 'toys which are designed to emit a sound shall be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing' (Annex II, part I, point 10).

[144] The European Child Safety Alliance groups more than 30 countries across Europe, which are working together to reduce the leading cause of death, disability and inequity to children in every Member State in the region - injury. http://www.childsafetyeurope.org/aboutus/index.html

[145] European Child Safety Alliance, EuroSafe, Johnson & Johnson (2009). Childhood Choking, Strangulation and Suffocation. http://www.childsafetyeurope.org/publications/info/factsheetsfactsheets/choking-strangulation-suffocation.pdf

[146] 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.'

[147] 'Rogue players' in this context are defined as those economic operators who do not belong to any toy industry association.

a national toy association.[148] This point is also confirmed by an Italian distributor, who is used to select its suppliers only among those firms that are members of national associations, since they are expected to have higher quality and safety standards, sometimes even stricter than those provided in the Directive. Economic operators indeed devote particular attention to the protection of brand reliability and reputation, which is a good incentive to maintain high quality and safety standards.[149]

A large Italian manufacturer deems counterfeiting to be even more dangerous than non-conforming toys, since counterfeits are not only contrary to the Directive's requirements, but they also damage the reputation of reliable manufacturers. If citizens purchase products thinking the product brand is authentic, the brand loses market reliability in case any problems occur. This in turn implies that firms who find their brands widely copied also incur additional costs of legal investigation and action.[150] While consumer associations ask to be better informed about the risks of counterfeit toys, economic operators would like to see faster mechanisms to be protected from counterfeiting, with the exception of an Italian industry association deeming counterfeiting not to be a relevant issue for toys.

As regards **online sales,** three Member States think that they should be more closely regulated, particularly as regards warnings and the other information to be provided to consumers prior to purchase. This is particularly true since an increasing number of toys are bought on the internet. A different opinion has been reported by a European industry association and by a large UK manufacturer, both deeming the TSD to be appropriate in facilitating online sales and the Digital Single Market agenda[151] of the European Commission. Toy industry associations[152] further strengthen this point, claiming that internet sales are well regulated by the Directive, online shopping being more a problem of enforcement than of weak regulation. Only one German manufacturer thinks that the Directive should better take into account that toys are increasingly moving to the digital domain.

Economic operators and a European consumer association agree that **3D printing** should not represent a future issue as long as 3D-printed toys will be subject to the same requirements as traditional toys. In addition, an Italian industry association and a large Italian manufacturer highlight how 3D printing represents a great opportunity both for economic operators - as production costs would be significantly reduced - and for consumers - as it will give the possibility to customise and personalise products.

One UK expert on toy safety expresses a serious concern on the feasibility to legislate on 3D-printed toys, as the consumer should be regulated in order to ensure the safety of the final product. This concern is also shared by a large Danish manufacturer and by a large UK

[148] http://www.tietoy.org/news/article/european-commission-s-rapex

[149] A large Italian and Dutch manufacturer.

[150] TIE (2014). The Toy sector and Intellectual Property Rights.

[151] The Digital Single Market strategy aims to open up digital opportunities for people and businesses and enhance Europe's position as a world leader in the digital economy. https://ec.europa.eu/digital-agenda/en/digital-single-market

[152] A European, an Italian, a Bulgarian, a Dutch and a Spanish industry association.

manufacturer, who wonder whether a private consumer will be considered as a manufacturer when producing toys by means of a 3D printer.

To conclude, the Directive proved to be relevant for both its strategic objectives – i.e. to maintain a high level of safety for children and protection against health threats due to toys while allowing toy cross-border movement. The evaluation highlights indeed a high correspondence between the current needs and the Directive's provisions. However, while stakeholders all agree on the Directive's relevance for the internal market, some concerns have been raised with regard to safety requirements, with consumer associations questioning the Directive's capacity to exhaustively address current safety needs.

6.1.2. EQ2: To what extent do the adaptation mechanisms of the 2009 Directive follow technological, scientific and social developments?

Between 2012 and 2014, the Directive has been amended five times to respond to emerging issues (as presented in section 2.2.2.3). All the amendments concerned limit values for chemicals and relied on scientific opinions of recognised organisations. These opinions have been based on studies recently conducted both in Europe and in the US,[153] thus taking into account new scientific parameters and protocols established after the Directive's implementation.

In four out of five amendments, limit values for chemicals have been lowered, according to new toxicity data and safety thresholds derived from them. On the contrary, nickel – that has to comply with the CMR requirements set out in Annex II, part III, point 5 (see footnote 135) – has been exempted from this limitation when used in toy components intended to conduct an electric current. Nickel is indeed carcinogenic only when in the form of inhalable fumes. As nickel metal fumes are not expected to be released from toys, the exemption was possible without compromising children's safety.[154]

In addition to the Directive's amendments, three standardisation mandates were issued by the Commission from 2009 to 2011 (as presented in section 2.2.2.1). A first mandate aimed at aligning the European harmonised standards to the new requirements set in the 2009 Directive.[155] The second mandate was intended to address newly identified risks - i.e. the

[153] EFSA (2013). Draft Scientific Opinion on the risks to public health related to the 4 presence of bisphenol A (BPA) in foodstuffs.

EFSA (2009). Cadmium in food. Scientific Opinion of the Panel on Contaminants in the Food Chain. Question No EFSA-Q-2007-138. Adopted on 30 January 2009.

SCHER (2012). Assessment of the Tolerable Daily Intake of Barium.

SCHER (2012). Opinion on tris(2-chloroethyl)phosphate (TCEP) in Toys.

Dannwolf, U., Ulmer, F., Cooper, J. and Hartlieb, S. (2010). "Chemicals in Products, Toys Sector Case Study for UNEP".

[154] SCHER (2012). Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys.

[155] M/445 Standardisation mandate addressed to CEN and CENELEC within the framework of Directive 2009/48/EC revising Directive 88/378/EEC.

"loss of support" in certain inflatable aquatic ride-on toys.[156] Finally, the third mandate addressed "possible eye and skin injuries" that may be caused by "items that are propelled into free flight by a child releasing an elastic band".[157]

While amendments and mandates aim at adapting the Directive to external developments, protocols help stakeholders in finding suitable solutions for such developments (as presented in section 2.2.2.2).

When assessing the relevance of the Directive's adaptation mechanisms, stakeholders express divergent opinions according to the different categories they belong to.

Economic operators widely acknowledge the value of the adaptation mechanisms, which make the Directive flexible to adapt to new safety hazards. In general, no major issue has been pointed out for revising the Directive.[158] Only a German industry association claims that the Directive is not flexible enough to track scientific progress, so that both its scope and the chemical requirements can easily become outdated. The stakeholder therefore suggests setting the chemical limit values in a harmonised standard rather than in an annex to the Directive, so as to update them in a quicker and more transparent way. According to a large Danish manufacturer, mandates play a great role in keeping the regulation around toys up to date and responsive to technological, scientific and social developments. In particular, a large UK manufacturer and a French industry association praise the comitology procedure, which allows aligning chemical limit values to scientific developments. Nevertheless, some concerns have been raised since political interests - rather than scientific evidence – seem sometimes to trigger and drive amendment procedures and results.[159]

Consumer associations stress that the TSD is not flexible enough to address possible changes and new risks. They question the too limited scope of the Committee procedure as it only applies to Annex I;[160] points 11 and 13 of Part III of Annex II;[161] Annex V;[162] Appendix A on the permitted use of CMR substances; and Appendix C on the specific limit values for chemicals intended for use by children under 36 months or in toys intended to be placed in the mouth - as reported in section 2.2.1. Moreover, standards are deemed to be inadequate to ensure adaptation to the latest scientific and technological developments, since adapting or creating new standards is a long process, and it could be too slow to promptly address new risks. Furthermore, consumer associations denounce how standardisation procedures are strongly managed by big economic players, while consumer

[156] M/484 Standardisation mandate addressed to CEN to amend EN 71-1:2005 + A9:2009 "Safety of toys – part 1: mechanical and physical properties" with regard to certain aquatic toys.

[157] M/482 Standardisation mandate addressed to CEN to amend EN 71-1:2005 +A9:2009 "safety of toys – part 1: mechanical and physical properties" with regard to items that are propelled into free flight by a child releasing an elastic band.

[158] A European, a Polish and a Bulgarian industry association, a large Italian manufacturer, an Italian and a Polish distributor.

[159] A large UK and a large Belgian manufacturer, a French and an Italian industry association.

[160] Annex I consists in the list of products that are not considered as toys within the meaning of the Directive.

[161] Part III of Annex II concerns chemical properties of materials used for toys.

[162] Annex V regards warnings.

representatives are only marginally involved. In addition, 'standardisation is increasingly being performed at international level (in parallel work with ISOs),[163] and the possibility for European consumer associations to take part in this work is further reduced due to the low recognition they have at ISO level'.[164]

Member States generally confirm the relevance of all the adaptation mechanisms in aligning the TSD to the evolving context. However, three Member States agree with consumer associations on the need to broaden the scope of the Committee procedure.[165] Furthermore, there are cases of competent authorities reporting difficulties with issues already covered by protocols and recommendations. Some examples include the requests for clarification on limits for microbiological properties of toys[166] and on the exclusion of "slings and catapults" from the scope of the Directive.[167] As for the latter, also a large UK toy manufacturer and a European representative of Notified Bodies ask to include "slings and catapults" into the scope of the Directive, or at least to clarify why they have been excluded. This indicates that protocols and recommendations – though publicly available - should be further disseminated to the wide public and not only addressed to Notified Bodies. They are indeed a very useful instrument that could be better exploited simply through an effective and timely communication. Furthermore, competent authorities encountered some problems with the "age classification" ***(finding 17)***, even though this aspect has been addressed by specific guidelines.[168] Thus the problem does not lie in the relevance of the TSD adaptation mechanisms, but rather in the effective dissemination of the changes they introduce.

To sum up, the adaptation mechanisms of the Directive proved to be an effective policy tool to align the TSD to steady scientific and technological developments. While economic operators and Member States generally confirm this, consumer associations ask to broaden the scope of the comitology procedure, so as to include all kinds of toys and all kinds of dangerous substances. Moreover, consumer associations ask to use available adaptation mechanisms to amend current limits for some chemicals – for instance CMRs - in order to make them stricter. In any case, this evaluation study has not any raised evidence on the need to amend sections of the TSD not subject to the comitology procedure. In addition, consumer associations denounce that, as standardisation is a long process, there could be new risks temporarily not covered by any harmonised standard. However, a transition period is unavoidable for each legislative process and this evaluation study raised no evidence of major safety risks that could not be addressed by the available adaptation mechanisms.

[163] An International Standardisation Organisations.

[164] A European consumer association.

[165] As specified in section 2.2.2.3, the Committee procedure only applies to Annex I; points 11 and 13 of Part III of Annex II; Annex V; Appendixes A and C of the TSD.

[166] Partly covered by NB- toys/2014/071, EC-Type approval protocol No. 2: Microbiological safety of toys containing aqueous media Rev 2.

[167] M/482 Standardisation mandate addressed to CEN to amend EN 71-1:2005 +A9:2009 "safety of toys – part 1: mechanical and physical properties" with regard to items that are propelled into free flight by a child releasing an elastic band.

[168] EC (2009). Guidance document No. 11 on the application of the Directive on the safety of toys (88/378/EEC).

6.2. Effectiveness

6.2.1. EQ3: To what extent has the 2009 Directive contributed to the enhancing of the level of safety of toys while maintaining the smooth functioning of the internal market for toys?

The Directive proves to be an effective policy tool to enhance the safety of toys, while ensuring their free movement. This consideration is true although the lack of toy-related accident data - as presented in section 4.2 - makes it difficult to completely assess the Directive's effectiveness. Only few stakeholders[169] are of the opinion that the Directive led to no major improvement in safety. They link this to the impossibility of establishing any correlation among actual hazards and mandatory requirements due to the lack of accident data.

Economic operators generally have a very positive opinion regarding the functioning and exhaustiveness of the Directive. In terms of **internal market**, the Directive turned out to be highly effective for the EU trade of toys, by harmonising procedures and requirements among Member States and economic operators. Even though representing a significant concern, the German setting of different chemical limit values remain an isolated case ***(finding 12)***.[170] At the same time, no issue has been raised as concerns the **import of toys**, which does not seem to be hindered by the TSD requirements. Only a medium-sized German manufacturer and distributor reports the Directive to have impacted the way European companies interact with non-EU commercial partners. According to the stakeholder, manufacturers have reduced their commercial relations with third-country suppliers, as the latter often provide incomplete documentation hindering the assessment of toy compliance ***(finding 39)***.

With regard to the **innovation** of toys, even though there is no evidence of a direct contribution of the TSD, the toy industry remains a highly innovative sector.[171] However, besides a small Spanish manufacturer declaring to innovate every year within the same kind of products - though only in an incremental way – there are some concerns on the Directive's (negative) impact on innovation. Some stakeholders[172] state that the TSD has no effect on the industry capacity to innovate since, market demand or technical progress are the only drivers for innovation. On the contrary, a Spanish SME and a Polish industry association claim that the high compliance costs are affecting firm investment in R&D, as the highly expensive conformity tests force manufacturers to reduce R&D budget. Moreover, a French manufacturer reports obstacles to innovation with particular regard to toys for children under 36 months of age.[173] Finally, a UK SME points out that the severity of the

[169] A large French manufacturer and distributor, a medium-sized German manufacturer and distributor, a UK expert on toy safety, a UK SME and a Polish industry association.

[170] A European and an Italian industry association, a European standardisation organisation.

[171] According to TIE, the toy industry is one of the most dynamic business sectors in Europe: around 60% of toys placed on the market each year are newly developed.

[172] A UK expert on toy safety, a German industry association and a large Polish manufacturer.

[173] According to six Member States, this may be due to the higher number of safety requirements for these toys. In order to avoid risk of non-compliance, manufacturers tend to put the age pictogram also when not required,

Directive generally hinders the innovative capacity of the toy industry. In this respect, it is worth considering the short time since the Directive's requirements entered into force, particularly the new chemical limit values. This can indeed have an influence on industry innovation, as compliance costs have often negative effects in the short run, while they may foster product innovation only in the long term.[174]

As for the **safety** of toys, **economic operators** deem the Directive as a highly pertinent measure thanks to the introduction of strict requirements and testing procedures, while ensuring that both toys produced in Europe and in third countries must comply with the same legislation (as presented in section 2.2.1, a). They recognise that it helped in making Europe the place where the safest toys are sold, as '*the safety level is much higher in Europe than it is in the US and in China*'.[175] Some economic operators think however that the Directive's requirements are even stricter than what is actually needed to ensure toy safety.[176] As a major example, several stakeholders point to a mistake contained in the RIVM report.[177] The report aimed at assessing whether the limit values for certain elements contained in toys as laid down in the 1988 TSD were to be revised, and whether other elements were to be added to the list. Based on the report results, the migration limits for nineteen heavy metals have been set in the TSD (as explained in Box 1). The report considered the daily rather than the weekly ingestion of substances, stating that for the latter more research was needed. As a result, some stakeholders consider that the chemical limit values for liquid and for dry, brittle, powder-like and pliable materials as set out in the Directive are stricter than they should be.[178] In this regard, in order to base the amounts of ingestion of toy materials on a better scientific basis, the Commission has requested the SCHER for an opinion.[179] Finally, a French manufacturer claims that the TSD broadens the scope of the criteria to classify books as toys, as many of the current toy books were not classified as toys in the old Directive. As a consequence, toy-book manufacturers are now obliged to apply not only the GPSD[180] requirements, but also the specific requirements for toys.

Consumer associations are generally more sceptical about the Directive's capacity to effectively deal with toy safety and trade. They identify shortcomings in the limits set for several hazardous substances, in the scientific parameters of reference for carrying out conformity and safety assessments and in the low harmonisations of assessment

irrespectively of the type of toy concerned. Consequently, toys for children younger than 36 months are increasingly based on very basic designs, as the more complex and innovative prototypes are, the higher the number of requirements is.

[174] https://www.nesta.org.uk/sites/default/files/the_impact_of_regulation_on_innovation.pdf

[175] A European Standardisation Organisation and a large Italian manufacturer.

[176] A Large Italian and a Dutch manufacturer, a French industry association.

[177] RIVM (2008). Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements.

[178] A Polish SME, a Czech Notified Body, a large French manufacturer, two European standardisation organisations.

[179] http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_108.pdf

[180] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN

procedures. As already presented in section 6.1.1, limits for CMR substances are deemed to be too high, while the list of allergenic fragrances is considered outdated. Furthermore, consumer associations claim that the TSD covers only a small number of chemicals, with some limits being either inadequate (e.g. nitrosamines and nitrosatable substances) or missing (e.g. skin sensitizers, preservatives, endocrine disruptors and nanomaterials). Finally, a consumer association denounces that the Commission agreement on some of the stricter German chemical limit values could be considered as an implicit acknowledgement of the inadequacy of the limit values set in the Directive.[181] In addition, according to two European consumer associations, multiple exposures and combination effects should be considered.

Finally, the large majority of **Member States** deem the TSD to be effective in ensuring children's safety and in enabling the free movement of toys, despite the difficulties encountered with its implementation ***(finding 18, finding 25, finding 26, finding 28, finding 31)***. Competent authorities recognise the appropriateness of particular safety requirements and of conformity assessment procedures to ensure the safety of toys within the EU, deeming the safety assessments as an asset in ensuring compliance with essential requirements. Only two Member States are of an opposite opinion. One Member State observes that German limit values for chemicals are more appropriate to ensure children's safety than those set in the TSD. Another Member State stresses that the free movement of toys is hindered by different Member States' interpretations of the TSD, especially as regards the "grey area".

To conclude, the Directive proved to be an effective policy measure to enhance the safety of children while facilitating the free movement of toys, despite the room for improvement as detailed in the previous sections. The lack of exhaustive statistics on toy-related injuries prevents a quantitative assessment of the Directive's contribution to toy safety. However, the qualitative evaluation based on stakeholders' opinions as reported during the interviews reveals no major safety issue. On the contrary, stakeholders are generally satisfied with the Directive's working mechanisms, with the exception of chemicals that are considered by consumer associations and by some Member States as inadequate to ensure the safety of children.

6.2.2. EQ4: What are the barriers to effective application and enforcement, in particular through surveillance of toys on the market, if any? How could any such barriers be overcome?

No major barriers to the Directive's effective implementation were identified during the evaluation process. However, stakeholders stress the existence of some obstacles to the Directive's enforcement.

Some of these obstacles stem from the surrounding context in which the Directive is implemented, while others relate to specific provisions. Major "external" issues affecting the Directive include problems with market surveillance - and particularly the limited resources at the disposal of competent authorities - the "grey area" and the internet sales. As for

[181] See footnote 86.

"internal" problems, the main difficulties concern warnings, technical documentation, safety assessments and sanctions.

In what follows, the main issues emerged during the study as barriers to the Directive's implementation are presented. For each issue, possible solutions are reported as provided by stakeholders during the interviews and in the national reports.

6.2.2.1. Barriers related to the effective enforcement of the Directive

Issue 1

Several stakeholders underline that a general **lack of adequate financial resources and competences** available to Member State authorities hinder the effective enforcement of the Directive.[182] Customs Authorities, in particular, seem to only slowly acknowledge changes in the legislative framework, continuing to ask for test reports as required by the previous legislation, instead of the EC declaration of conformity ***(finding 13)***.[183]

Suggestion(s) to overcome the issue

In order to increase competent authorities' awareness, a Spanish industry association regularly carries out **training sessions** to public inspectors. In this regard, it is worth mentioning that economic operators[184] in different Member States ask for greater investments in training and refresher courses.

Issue 2

Several stakeholders[185] denounce the high **fragmentation** of market surveillance – especially in terms of sanction levels and control procedures - that is left to the responsibility of each Member State ***(finding 43)***. This increases the risk of shortcomings as the failure of one Member State has negative spillover effects in all the others, facilitating the circulation of dangerous toys across Europe. Manufacturers ask for more extensive and in-depth controls by Market Surveillance Authorities in order to identify non-compliant toys as soon as they enter the EU market, thus enhancing overall safety while reducing unfair toy marketing.

Manufacturers denounce also that Market Surveillance Authorities are not motivated to control non-EU manufacturers and distributors - such as Chinese shops - as they are too difficult to be identified and communication is difficult. One Member State points out that major problems concern imported toys when found not to be compliant, because they are difficult to be traced back to their original manufacturers who are often temporary merchandisers. For the same reason, several Market Surveillance Authorities seem to focus their checks on large, reputable companies who are more keen to provide technical

[182] Two large Italian and one UK manufacturer, two Polish SMEs, , six industry associations, an Austrian and a European consumer association, two Notified Bodies.

[183] An Italian distributor, a large Italian, a Danish and a UK manufacturer, a small Dutch, a UK and a Polish manufacturer, an Italian, a French, a Polish and two European industry associations. The EC declaration of conformity has been indeed introduced by the 2009 TSD. Under the 1988 TSD, the test report was the only document attesting the safety of toys.

[184] Two Polish and a Spanish SME, an Italian distributor, a large Belgian manufacturer, a German, a Polish and a Spanish industry association.

[185] Two consumer associations, eight economic operators and six among their associations.

documentation and to pay due fines ***(finding 38)***.[186] In this regard, a Polish toy association and a Polish SME claim that controls are so disproportionate in the country that manufacturers are "harassed" by intermediate checks. Other stakeholders[187] ask Market Surveillance Authorities to target those operators who are more likely to place unsafe products on the market.

Suggestion(s) to overcome the issue

In order to ensure a more effective and "smart" market surveillance, several stakeholders[188] suggest **reducing the number of controls performed on firms with a strong track-record of compliance**, thus having a very good reputation. It is interesting to note how this mechanism already exists in the Netherlands: a public programme is in place to perform audit controls on a sample of companies proportionally to an assessment of their level of risk and, therefore, limiting controls on firms that have had a good compliance track record.[189] However, only two companies have been selected so far and the programme is currently on hold.

Issue 3

The "**grey area**" is another obstacle to an effective TSD enforcement as it leaves room for interpretation to economic operators to decide whether a product is to be considered as a toy or not ***(finding 16)***.[190] This potentially makes the same product subject to different requirements in different Member States, hence hindering the free movement of toys. As problems with toy classification already emerged with the previous TSD, the 2009 Directive aimed at providing a clearer definition of toy (art. 2(1))[191], and included a list of toys to which the TSD does not apply (art. 2(2)) and a list of products that are not considered to be toys (Annex I).

Even though fifteen Member States agree on the progress made with the 2009 Directive, the "grey area" seems not to be completely eliminated. One Member State thinks this is due to the words "whether or not exclusively", while another attributes this flaw to the wording "for use in play". Overall, five Member States think the new definition of toy has even broadened the "grey area".

Moreover, a European industry association reports this definition causes a problem of interpretation: in case of products that have a small toy attached to them (e.g. a pencil

[186] Four Member States, Dutch, an Italian and two European industry associations, a large Italian manufacturer, a UK association of distributors.

[187] A European, a Dutch, a German, a Polish and an Italian industry association, a large Italian manufacturer, a Spanish and three Polish SMEs, a UK association of distributors, a large Belgian manufacturer, distributor and importer, a large Belgian manufacturer and distributor.

[188] A large Italian and a large Belgian manufacturer, two Italian industry associations, a European and a Dutch industry association, a Member State, a large Belgian manufacturer.

[189] A Member State, a Dutch industry association and a large Dutch manufacturer.

[190] A large Italian manufacturer, a medium-sized Italian distributor, a medium-sized German distributor and manufacturer, two Polish SMEs, a large German distributor, an Italian, a UK, a Polish and a Spanish industry association, ten Member States.

[191] This point is confirmed by twenty Member States.

case), some stakeholders would indeed claim that this makes the whole item a toy, while others would consider the toy as a toy and the rest of the product as a non-toy. As reported by an Italian distributor, in case of doubt about the correct classification of a product, the firm is used to check how it has been classified in other circumstances or by other economic operators, thus spending a lot of time in gathering information. Other stakeholders[192] prefer to adopt the strictest classification, thus considering the product as a toy whenever faced with a doubt about its classification.

In any case, even though Member States authorities and economic operators in certain cases still have doubts about the classification of a product as being a toy or not, no one expressed major concerns relating to the issue and according to the majority of them the existence of a "grey area" is unavoidable.

Suggestion(s) to overcome the issue

In general, Member States consider the drafting of **guidelines/guidance documents** as being the best procedure to deal with the "grey area". Stakeholders[193] stress the importance of involving all relevant stakeholders in this process and to provide a **translation of the guidance material** in all official EU languages. One Member State suggests including further **examples and photographs** of toys for a more effective explanation, while other stakeholders recommend providing more details on the **exceptions listed in the guidance**.

Issue 4

Internet toy shops could further hinder the effective TSD enforcement ***(finding 20)***. As online products are not physically accessible, five Member States and one Polish importer complain it is difficult to check their safety compliance at reasonable costs. Six Member States denounce also several cases of non-compliant toys sold online, or report toys being sold although the product line had been recalled from the market.

Even greater difficulties relate to internet shops located outside the EU, further hindering market surveillance. According to an Italian industry association and a UK expert on toy safety, non–EU online shops represent an issue since the consumer virtually acts as an importer, therefore sharing the responsibility for importing non-compliant toys with online vendors. As stated by some UK stakeholders,[194] the existence of fulfilment houses[195] further complicates the identification of responsibilities.

[192] A large Italian manufacturer, a UK industry association, a large German distributor.

[193] A European and a French industry association, a representative of a Notified Body, an Austrian consumer association, two Member States.

[194] A UK industry association, a UK SME and a UK competent authority.

[195] Fulfilment houses are intermediaries between the online vendor and the customer in charge of delivering the products. Fulfilment houses receive the products from the online supplier receiving the orders from the clients. They then take care of packaging and shipping the order to the latter.

Suggestion(s) to overcome the issue

According to a number of stakeholders, [196] internet toy shops should not be an issue. The TSD already covers online sales and requires toys sold on the internet to be compliant with its requirements. Confirmation on this point comes from the "European Toy Safety Information Seminar 2013-2014: Questions and Answers", where it is clearly stated that toys sold online are entirely subject to the TSD. Therefore, '*when selling toys online, it is recommended to display toys in such a way that the CE marking is visible to the Market Surveillance Authorities, to whom it is addressed*'.[197] Furthermore, warnings must be clearly visible to consumers prior to purchase; this includes displaying them directly on the website.

Issue 5

Besides obstacles related to specific provisions, some problems have been raised with the wording "***prior to placing on the market***" ***(finding 40)***. A large Italian manufacturer deems the interpretation provided in the Blue Guide as "*far from reality*", since it implies that product conformity matters only as long as toys are sold. Therefore, in case of legislative changes, an importer has to retroactively verify whether all stored products meet the new requirements. A UK association for distributors also criticises the definition of "*placing on the market*" as provided in the Blue Guide, asserting that it is not consistent among Member States.

Suggestion(s) to overcome the issue

According to the interviewee, for the sake of pragmatism, UK economic operators usually consider goods that are still kept in the warehouses as already "placed on the market".

6.2.2.2. Barriers related to specific provisions of the Directive

Issue 1

Warnings requirements emerged as posing several difficulties ***(finding 25)***, with only seven Member States reporting no problems in their use. Warnings are often written in too small a font size, which is not easily readable, and are not always provided in all relevant languages. This is confirmed by a large German manufacturer denouncing problems when small products are to be labelled in a number of languages, thus ending up with very small texts that are not readable.

Furthermore, according to a large Italian manufacturer and a UK expert on toy safety, there is not always full correspondence between the actual risk identified in toys and the warnings placed on them. This is particularly true as concerns the pictogram indicating a toy as not intended for use by children under 36 months of age. If the pictogram is missing, manufacturers incur strict sanctions, but they often place it also on toys not raising any risk for very young children, just to protect themselves from infringement sanctions.[198] Further

[196] An Italian, a Spanish and a European industry association, a UK expert on toy safety.

[197] European Commission, TIE, European Toy Safety Information Seminar 2013-2014: Q&A. From the toy safety education events organised by TIE and financed by the EC in Greece, Croatia and the BENELUX countries, and the webinars organised for Hungarian and Slovak economic operators. http://www.tietoy.org/publications/

[198] Five Member State authorities, economic operators, consumer associations, UK expert on toy safety.

problems have been raised by one Member State with regard to imported toys, as inspectors are sometimes unable to determine whether the labels have been placed on the toy before or after the import.

Suggestion(s) to overcome the issue

In order to increase the impact of warnings on consumers, a UK expert on toy safety and a Spanish industry association suggest introducing a series of pictograms instead of written words. Several stakeholders request languages and font size to be better regulated at EU level.[199] In any case, according to a Dutch SME, a compromise needs to be found between the requirement for warnings to be readable and the size of warnings on small toys.

With regard to the age classification, a German industry association and a German SME suggest **identifying more age categories** instead of only one for children under 36 months of age. This may solve the problem of manufacturers using the age pictogram even if not appropriate ***(finding 25***, footnote 173***)*** and the difficulties encountered by Member States in the age grading ***(finding 17)***.

Other specific suggestions concerning warnings have been provided. One Member State proposes aligning **Annex V to the warnings listed in the EN 71 standards series**, as the warnings translation into the national language is not always consistent with the warnings in EN 71, causing problems to businesses and to Market Surveillance Authorities.[200] In this regard, it is worth recalling the opposite opinion of a European representative of NB-Toys and a Dutch SME manufacturer, who think that the harmonisation of warnings between the TSD and standards has improved as compared to the past. According to the former, 'the EN 71-1 includes best practices on visibility and legibility of warnings', taking into account, for instance, that warnings need to be printed in different languages, or that the packaging size needs to be minimised due to environmental requirements.

Another suggestion concerns toys **firing projectiles**, which shall have a specific warning stating that "only the objects included in the packaging must be fired". Moreover, according to an Italian distributor, the TSD should foresee warnings on **magnets and magnetic toys**, as the risk related to these products is evident.

One Member State recommends avoiding the use of "**universal labels**" as the warnings should be adapted to the playing function of a particular toy. Finally, a Bulgarian toy industry association and a Member State assert that, as regards toys contained or co-mingled with food, it shall be made clearer in Annex V, Part B, point 7 of the TSD that warnings are to be placed on the outside of the food packaging and not on the toy itself.

[199] Seven Member State, a large German manufacturer, three consumer associations.

[200] For instance, the Member State highlights how the term 'scooter' was translated with a term referring to a specific type of motorcycle and not to a riding toy. In addition, the wording of warnings in the national translation of the TSD is inconsistent with European standard EN 71-1 for aquatic toys, functional toys, skates, roller skates, in-line skates, skateboards, scooters and toy bikes. For example, the warning for aquatic toys stipulated in the Directive reads 'Only to be used in water in which the child is within its depth and under adult supervision', while the EN 71-1 standard stipulates 'Warning! Only to be used in water with depth appropriate to the child and under adult supervision'.

Issue 2

The provision on **technical documentation** poses problems to both Member States ***(finding 41)*** and economic operators. As for the latters, a UK association of distributors points out that further harmonisation is needed on the term "upon request". Importers and distributors have indeed the obligation to ensure that the technical documentation can be made available to Market Surveillance Authorities "upon request" or "further to a reasoned request". However, the stakeholder underlines that the timeframe given to importers and distributors to respond to the request of Market Surveillance Authorities can vary considerably from one Member State to another, and that it becomes even more difficult to comply with requests when the file is not electronically held and the manufacturer is a non-European economic operator.

A UK expert on toy safety confirms that safety assessments are not systematically included in the technical documentation ***(finding 39)***, thus making it difficult for Market Surveillance Authorities to estimate what risks should be covered to ensure toy compliance.

Manufacturers[201] and industry associations[202] denounce that distributors often require the whole technical documentation instead of the simple declaration of conformity. This poses problems as the technical documentation may contain confidential information that if disclosed may damage manufacturers' competitiveness.

Suggestion(s) to overcome the issue

With regard to the confidential information included in the technical information, a French manufacturer reported the existence of confidentiality agreements between suppliers and testing laboratories, requiring the testing laboratories not to disclose the technical documentation provided by the suppliers.

Issue 3

The existence of **different testing methodologies** applied by Notified Bodies ***(finding 18)*** represents another problem since some toys may not be considered compliant in one Member State while they are in another. It may occur, for instance, that manufacturers and distributors do not necessarily use the same Notified Body, this potentially resulting in different appreciations of safety. This is confirmed by some economic operators pointing to manufacturers that, in order to pass the testing, turn to Notified Bodies that are known to have less strict procedures. Therefore, the outcome of a toy conformity assessment may depend on the institution that performed it.[203] As stressed by some stakeholders,[204] this significantly hinders the free movement of toys within the internal market.

[201] A Dutch, a Spanish and a Polish SME, a large Dutch, a French, an Italian and a UK manufacturer.

[202] An Italian and a Polish industry association.

[203] A Czech Notified Body, a French industry association, a large Italian manufacturer.

[204] Two large Italian manufacturers, a Czech Notified Body and a Polish industry association.

Another aspect that further polarises these discrepancies is the existence of **different levels of competences of Notified Bodies**, as reported by a large Dutch manufacturer and by a large Italian manufacturer and distributor. Finally, a German industry association highlights the existence of an important issue to be taken into account. The TSD places the full responsibility for guaranteeing toy safety on the manufacturer, who is obliged to rely on external testing laboratories when lacking the technical skills; however, testing laboratories are not held responsible for their certificates.

Suggestion(s) to overcome the issue

Some stakeholders[205] claim testing methodologies should be defined either by the European Commission or by means of a European standard. According to both large economic operators and consumer associations, the development of common testing methodologies – that should involve Notified Bodies in order to make the standardisation process more effective - would work as a benchmark for toy manufacturers, making them able to perform the conformity assessment even in the absence of harmonised standards. This would also ease testing procedures for SMEs, which seem to particularly suffer from compliance costs ***(finding 28)***. In this regard, an Italian industry association for SMEs declares that its associates are willing to be compliant with the Directive as it is seen as a guarantee of safety. However, it is worth mentioning the opinion expressed by a European consumer association and a large Italian manufacturer suggesting the introduction of mandatory EC-type examination to ensure full product compliance with the Directive, particularly when imported toys are concerned.

Finally, the need for certified reference material for toy testing has also been highlighted by a Czech Notified Body. Reference material is fundamental for test laboratories, as it provides a benchmark for delivering accurate and comparable results. Furthermore, test laboratories use certified reference materials to calibrate measuring instruments, to evaluate test methodologies and for quality control purposes.[206]

Issue 4

Sanctions have direct impacts on the TSD effectiveness due to their twofold role of punishing infringements and preventing them. Ensuring consistency in both the type and level of punishment applied at national level would enhance the deterrent effect of sanctions since the same infringement would be equally punished irrespective of the Member State(s) where it occurs. Significant differences have been found in the sanctions established at national level for infringements related to the Directive's provisions ***(finding 43)***. According to a number of stakeholders,[207] sanctions are often given for very formal and marginal infringements (e.g. the word "warning" missing). For this reason, sanctions are considered not proportionate and too high by six economic operators and three industry associations.

Suggestion(s) to overcome the issue

[205] A Czech Notified Body, a large Italian manufacturer, an Italian industry association, two Member States.

[206] EU Joint Research Centre website. https://ec.europa.eu/jrc/en/research-topic/certifiedcertified-reference-materials

[207] A Bulgarian, a Dutch, an Italian, a Spanish and a European industry association, an Italian distributor, two Spanish SME manufacturers.

A UK industry association suggests the introduction of different levels of fines, to ensure proportionality to the size of the economic operator. Also consumer associations stress the need to harmonise sanctions across Member States, while ensuring they are high enough to prevent abuses.

6.2.3. EQ5: Are there any aspects/means/actors that render the 2009 Directive more or less effective, and – if there are – what lessons can be drawn from this?

One important mechanism impacting the TSD effectiveness consists in the **level of responsibility** given by the TSD to different categories of stakeholders. Manufacturers are the main players concerned by the Directive, being most extensively in charge of the safety of toys. Some stakeholders[208] underline that, after the new Directive came into force, they experienced a higher number of controls. As a consequence, they are continuously refining their production processes, performing more testing, and increasing their product safety budgets. In contrast to this, importers and distributors seem to be less active players in ensuring the effective application of the Directive. This is suggested by the large number of RAPEX notifications for toys coming from third countries ***(finding 45)*** and by the difficulties encountered by Market Surveillance Authorities in obtaining the technical documentation for imported toys ***(finding 39)***.

Moreover, as confirmed by different economic operators,[209] big distributors are less familiar with - and aware of - the Directive ***(finding 14***, ***finding 15)***. As an example, a Spanish medium-sized manufacturer reported having to draft often additional documents, in order to explain the Directive paragraph by paragraph and to demonstrate how the toys they supply comply with it. This problem is also stressed by a large UK manufacturer, denouncing the waste of time to educate and convince distributors that the internal production control procedure for conformity assessment is adequate and third party verification is not mandatory.

In this regard, TIE has provided training and education to businesses on the application of the Directive – e.g. how to comply with requirements or how to use standards. Furthermore, the European Commission entrusted TIE with the organisation of two education campaigns (2012-2014) to explain the requirements of the 2009 TSD in Member States. As part of these two campaigns, TIE organised many events throughout Europe, which attracted over 1,000 participants from almost all Member States. For these events, TIE invited all toy-related economic operators, standardisation bodies and national authorities to participate.

RAPEX is certainly a mechanism that renders the TSD more effective, particularly as regards enforcement. As shown in Table 5 in section 5.2.2.5, the number of RAPEX notification has significantly increased in the last years. In general, the high number of toy notifications may be due to the sensitive nature of children's safety that leads stakeholders to pay considerable attention to the safety of toys. This is confirmed by a UK expert on toy safety, highlighting how toy safety is an "emotive subject", which has a lot of relevance in the media. Furthermore, as shown in Figure 5, RAPEX is widely used by Market Surveillance

[208] Two large Italian and two Belgian manufacturers, a German and a Polish industry association.

[209] A Spanish and a Polish SME, a Spanish industry association for SMEs, a Polish industry association.

Authorities in order to reactively start investigations. In addition, it is routinely used by Member States to notify restrictive measures on dangerous toys and by all stakeholders in general for information gathering purposes ***(finding 46)***.

However, there are also stakeholders asking for a better management of RAPEX in terms of a limitation of the notifications that are placed on the public RAPEX website.[210] As the high number of RAPEX notifications risks to damage the image of the toy industry, they would like to limit notifications to highly dangerous toys, without including marginal irregularities. According to this opinion, RAPEX would not be a good tool to estimate the issue of non-compliant toys. Indeed, the high number of toy notifications in RAPEX can have a twofold interpretation. First of all, it clearly demonstrates an increase in controls and awareness, while confirming the high extent to which RAPEX is known, used and trusted. Secondly, a high number of notifications may also stand for a high number of non-compliant toys and thus for a shortcoming in the Directive's effectiveness. These issues point to the need for stricter quality requirements to justify notifications, preventing notifications not meeting these quality criteria. However, this opinion has to be put into perspective. RAPEX already distinguishes among different risk levels and there is no evidence justifying the exemption of minor risks out from the system. This evaluation indeed does not indicate that RAPEX notifications have been damaging the toy sector. However, according to a UK association for distributors, RAPEX should provide more detailed information on the type of risks associated with each notified toy. This would enable distributors to benchmark their own products with those that have been notified, and check whether the products they are selling also present the same safety risks.

Moreover, according to a UK SME and to a UK expert on toy safety, manufacturers and/or importers and their customers are not immediately informed when toys are notified to RAPEX. This happens particularly when the notification involves two different Member States (i.e. a supplier/importer in one Member State being notified by the Market Surveillance Authority of another Member State). In this scenario, the supplier/importer's "right of reply" is not immediately available. The problem appears to be due to two main reasons. Firstly, the time between the market surveillance activity (e.g. test sample purchase and investigation) and the publication of a notification on RAPEX may vary considerably. Manufacturers, importers and their customers can thus suffer economic losses as toys cannot be sold while they are under scrutiny. Secondly, the analysis of the notification appropriateness may sometimes be time consuming and brand reputation can be damaged whilst the process is still ongoing. In some cases, customers insist on return/refunds for notified products despite the fact that discussions about the appropriateness of a notification are still ongoing, thus making costs even more significant. According to a UK expert on toy safety, a formal appeal process for RAPEX notifications should be introduced and clear guidance is needed to assist all those involved.

National differences in the Directive's implementation hinder to some extent the TSD effectiveness in ensuring the smooth functioning of the internal market. The major example of such inconsistencies is the German application of different chemical limit values ***(finding***

[210] A Spanish industry association, a UK SME and a UK expert on toy safety.

12).[211] According to a Polish SME, this has an 'enormous impact on industry (especially SMEs) without improving toy safety'.

Another aspect that renders the TSD less effective is the adoption of different procedural requirements by Customs Authorities ***(finding 13)***, which may induce importers to privilege importing channels where controls are less strict, thus raising issues of unfair competition. This is confirmed by a French industry association, which links the existence of different levels of control also to budget availability. This problem is clearly not attributable to the design of the Directive and it does not relate to the toy industry exclusively. However, it further confirms the need for a more integrated governance framework for enforcement authorities across Europe.

Finally, as regards the amendments to the Directive, economic operators[212] stress the role of the national **industry associations** in helping their affiliates to keep up with new legislation. This is done by ensuring prompt and easy access to information, and through the organisation of thematic seminars. In Italy, for instance, this information is provided to industry by the national industry association on a weekly basis. Moreover, as mentioned in section 6.1.1, firms that are part of an industry association are generally considered as ensuring higher quality standards, this confirming the great role these actors can play in enhancing the effectiveness of the Directive.

The **overall lesson** stemming from this section is twofold. Firstly, there is no evidence of a need to revise the Directive, its design being exhaustive and it working well. Secondly, the Directive's positive effects can be maximised through communication and dissemination mechanisms. Room for improvement emerges in terms of actors' empowerment and awareness. RAPEX and national industry associations represent therefore two examples of information vehicles that have proved to enhance and support the Directive's implementation. Information spreading represents a mechanism to make actors aware of the Directive's requirements. Actors' awareness increases the overall attitude to compliance, as proved by the high commitment expressed by manufacturers, who remain the main actors in charge of complying with the Directive's requirements. After all, stakeholders attach high importance to information and communication mechanisms. This is detailed in the following section, where major suggestions provided by stakeholders regard soft regulation mechanisms, including guidance and other supporting policy tools.

6.2.4. EQ6: What, if anything (including non-legislative action), could be done to render the 2009 Directive more effective as a means to achieve its objectives?

As regards procedures to identify hazardous substances, the introduction of a **positive list**[213] has been pointed out as helping to better control the safety of products, to increase

[211] See footnote 86.

[212] An Italian distributor, two large Italian manufacturers, an Italian micro manufacturer, a Polish and a Spanish SME.

[213] According to two consumer associations and to one representative of a Czech Notified Body and test laboratory, the development of a positive list of allowed chemicals in toys would be much more effective and clear than the actual negative list, which contains the chemicals that are forbidden in toys.

the clearness of the Directive and to help the industry and testing laboratories.[214] After all, as reported by a Czech Notified Body, 'the positive list has proved very effective under the Food Contact Regulation,[215] hence there are no reasons to not include it also in the TSD'. In contrast to this, according to a UK expert on toy safety, the positive list system would be a very restrictive way of legislating and it will necessarily remain incomplete. He underlines indeed the impossibility to list anything allowed and to update the list frequently enough to take into account all possible scientific developments that would require it to be either enlarged or narrowed.

Safety assessment procedures have been identified as a process that could be improved to enhance the Directive's effectiveness. According to a large Italian manufacturer, the European legislator concentrates too much on chemical issues, while a more comprehensive safety assessment would represent a higher guarantee of toy safety. A toy can indeed be completely compliant with all safety requirements and still result dangerous as children's behaviour is eventually unpredictable. For this reason, the company, together with another large Italian manufacturer, involves different categories of experts – including psychologists - when performing the safety assessment, in order to fully take account of the play value complexity. These higher safety and compliance parameters can be attributed to the incentive of renowned manufacturers to protect the reputation and accountability of their brand. It is remarkable that also a Member State competent authority recommends the involvement and assistance of medical professionals in the safety assessment process.

Guidelines and supporting material are generally considered as really useful to enhance the TSD effectiveness by Member States, economic operators and their associations. In this regard, economic operators[216] recommend the European Commission to ensure better access to relevant information and possibly more training opportunities. They indeed often have the impression of neither being sufficiently up-to-date or to properly master all the existing information. On the contrary, a UK SME and a UK industry association observe that, though valuable, guidance documents are too long and complex. For this reason, the latter provides its associates – and particularly SMEs – with summaries of the EU documents.

The establishment of **communication and collaboration** channels among Member States and with the European Commission – including the organisation of additional meetings, seminars or workshops with the participation of national specialists/experts – are suggested as another non-legislative measure to improve the TSD effectiveness. Notified Bodies in particular wish for more cooperation between the Commission, toxicologists, laboratories and industry, ensuring the involvement of all relevant stakeholders and also taking account of other international experiences, particularly as concerns standardisation.[217]

A European consumer association suggests increasing the exchange of information across Market Surveillance Authorities in order to immediately detect harmful toys. Moreover, five

[214] ANEC (2014). Position paper. Hazardous chemicals in products. The need for enhanced EU regulations. http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

[215] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

[216] An Italian and Polish industry association, a large Italian distributor, a Polish SME.

[217] This last point being shared also by a Dutch and a German SME.

Member States suggest the setup of a chat room/forum for advice and sharing of practices, where Member States having doubts about a toy/subject may submit their questions, which will be answered by the European Commission and commented by the other Member States.

In order to improve the effectiveness of ADCO meetings, one Member State claims they should be preceded by contacts among Member States and between them and the European Commission, in order to anticipate problems and to define the meeting agenda in advance, thus well focusing and optimising the meetings while avoiding lengthy discussions.

Apart from the regular ADCO meetings, seven Member States note that the use of both CIRCA[218] and ICSMS should be improved. In addition, according to a representative of CEN, the cooperation between ESOs and the European Commission should be reinforced in order to better identify new standardisation needs and to clearly define the transition periods until the entry-into-application of new standards.

6.2.5. EQ7: Does the legal form (Directive versus Regulation) have an influence on the effectiveness with which the objectives are reached?

Since Member States are in principle not allowed adopting different requirements than those provided in the TSD, the legal form cannot have a major influence on the transposition of the Directive at national level. Once the TSD is transposed by Member States into national legislation, the safety requirements are entirely applicable as they would be in case of a regulation.

However, national transpositions of amendments to the Directive often turn out to be excessively burdensome and time-consuming ***(finding 31)***. This would not occur with a regulation, as amendments would then be directly applicable at national level.[219] For this reason, a large German manufacturer and three Member States argue that amendments should be introduced via a regulation to avoid delays by national transpositions. Moreover, the preference for a regulation is motivated by the desire to ensure consistency in all Member States, thus preventing differences in the application of provisions on the safety of toys ***(finding 16***, ***finding 17)***.[220]

On the contrary, a UK industry association thinks that the lengthy 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. Furthermore, though recognising the easiness of applying a regulation, an Italian industry association observes that a Directive grants much more flexibility without regulating into detail, leaving technical specifications to harmonised standards.

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[218] Communication and Information Resource Centre Administrator (CIRCA) is a simple and effective group-ware, developed by the EC. It is a web-based application providing online services that offer a common virtual space for Workgroups, enabling the effective and secure sharing of resources and documents. http://ec.europa.eu/idabcidabc/en/document/6540document/6540.html#what

[219] While Directives set out general rules to be transferred into national law by each country as they deem appropriate, a Regulation is directly applicable in all EU countries. http://ec.europa.eu/legislation/index_en.htm

[220] A European consumers' organisation, a UK association of distributors, a Polish industry association, a German, a UK and a Polish SME and a large Belgian manufacturer, distributor and importer.

In any case, this evaluation has not raised any major need to change the legal form of current EU legislation relevant for toys.

6.3. Efficiency

6.3.1. EQ8: Main efficient/inefficient Directive's provisions and related impacts in terms of administrative and reporting burdens on stakeholders.

6.3.1.1. Expectations of the 2008 Impact Assessment vs. this evaluation's evidence

a. Expected costs

The 2008 Impact Assessment identified a negative correlation between company turnover and the impact of the proposed TSD costs, thus suggesting that the costs associated with the proposed TSD would have disproportionately affected SMEs. On the contrary, minor cost impacts were expected on Competent and Market Surveillance Authorities. In particular, the Impact Assessment identified three main factors expected to influence the costs caused by a revised TSD:

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

Finally, the stricter requirements foreseen for toys in the revision were expected to increase toy prices, thus **impacting consumers**.

This evaluation confirms the cost impacts to have a negative correlation with the turnover and production volume and a positive correlation with the number of product lines of a company.

With regard to the **volume produced,** SMEs seem to have been more affected by the costs caused by the new Directive, since their low production volumes do not allow for economies of scale. A UK SME harshly criticises the TSD, claiming that it tightened safety requirements so much that it is impossible for SMEs to produce toys at reasonable costs. A French industry association even states that '*very small manufacturers are killed*' by the increased toy safety requirements and by the complexity of standards, while a UK industry association claims that SMEs '*have to struggle*' in order to meet TSD-induced costs.

In general, **SMEs** have problems with toy testing because of a limited capacity of their laboratories – as regards both economic resources and competences - and for the lack of harmonised methodologies ***(finding 18, finding 28)***.

To overcome these problems, SMEs have to recur to external testing laboratories or Notified Bodies to ensure compliance with the Directive.[221] In this view, an Italian association of SMEs suggests the European Commission drafting guidelines targeted specifically to SMEs, in order to make them able to get all the information needed to comply with the TSD requirements. This would prevent SMEs to rely on external bodies, significantly reducing overall costs.

The link between the impacts on costs and the **number of product lines** is confirmed by an Italian industry association. The stakeholder deems the costs for SMEs as proportionate, since though their production is small - and thus not benefiting from economies of scale - SMEs have a smaller range of products to test. In support of this, a micro Italian manufacturer producing only one type of toy declares that costs to comply with the Directive are reasonable. It should be noted, however, that this micro enterprise went to the market only in 2012 – therefore a comparison with the previous Directive cannot be provided.

The **product type** has not impacted the cost of the CE marking. However, a French industry association claims that the costs caused by the Directive on manufacturers strongly depend on the categories of produced toys, as different types of toys entail different risks, thus requiring different tests to assess their compliance. Costs are therefore difficult to quantify irrespective of the type of toy produced. In this regard, it is particularly interesting to consider the case of toy books.

Box 9 – Toy books

As pointed out by a French industry association, the 2009 Directive does not directly regulate "toy books", but addresses them through a Guidance document.[222] The definition of toy books - as resulting from the Guidance document - is based on criteria which are not referring to the material, but to the content of the book. In this way, the scope of the criteria to classify books as toys has been considerably broadened (i.e. many of the current toy books were not classified as toys under the old Directive). As pointed out by a large French manufacturer and by a French industry association, this restriction of rules is not even based on current risks or data on accidents.

In this regard, a representative of French publishers thinks that some of the classification criteria are not adequate and too strict, and inconsistencies remain. For instance, while it is fully accepted that books with detachable parts or sensorial elements are toys, also simpler books may fall within the "grey area". Moreover, the application of the classification is different across Europe, meaning that in certain Member States some books are considered to be toys, and in others not. This makes it difficult to sell toy books across the EU.

Finally, the increase in costs experienced by French toy-book producers has been significant with the entry into force of the 2009 TSD. For instance, when considering publishers, the Directive applies to a very small percentage of the titles they produce. In this case, the need for acquiring knowledge on the application of the Directive and the amount of money to test materials and products is too high and not proportionate.

Source: National reports

[221] A Spanish SME and a Dutch and an Italian SMEs association, a German industry association, a large German manufacturer, two Member States.

[222] EC (2013). Guidance Document No 9 on the Application of the Directive on the Safety of toys. Books. http://ec.europa.eu/DocsRoom/documents/5847/attachments/1/translations/en/renditions/native

On average, the increase in production costs with respect to the 1988 Directive has been valued in a range from 20% to 30%.[223] A UK industry association instead states that, with respect to the situation prior to 2009, testing costs have increased by 100%, depending on the test performed. A UK expert on toy safety quantifies the increase in the overall production costs as equal to 200%, provided that all the tests are properly carried out. A large German manufacturer roughly estimates that the costs for complying with the Directive provisions are around 0.3% of the firm turnover, while they were close to 0.2% before 2009.

As for the **impacts of costs on consumers**, according to a UK expert on toy safety and to a UK SME, the increase in costs is particularly reprehensible since there are no apparent benefits to consumers. The lack of statistics on toy-related incidents indeed makes it impossible to quantify their actual reduction (as detailed in section 2.1.2). Moreover, compliance costs have direct impact on the toy final price. Stakeholders generally assert that the 2009 Directive caused an inevitable and consistent increase in the costs for economic operators. Furthermore, these costs impact also consumers, as '*the product sale price inevitably entails the costs for complying with the Directive*'.[224] In this regard, a French manufacturer reports the increased costs to correspond even to 10% of the final product price. Several stakeholders claim that, as consumers often privilege cheap products irrespectively of their quality, more unsafe toys would be sold on the market, since safe toys are necessarily more expensive.[225]

Table 7 – Expected costs in the 2008 IA as assessed by the 2009 TSD and new costs emerged from this evaluation

2008 IA	TSD	NEW COSTS
Major costs falling on SMEs, with negative correlation between the firm turnover and the cost impacts.	Confirmed	• Major costs related to chemicals requirements. • Most inefficient provisions include warnings and amendments. • Major unnecessary costs related to shortcomings in the TSD enforcement, with particular regard to the technical documentation. • Standards cause significant costs as they are expensive, do not cover all the risks, and their development is time-consuming.
Minor costs falling on MS competent authorities.	Not confirmed, as we did not gather enough evidence on that from MS. However, as shown in Table 9, enforcement costs up to MS are linked to less and simpler procedures than other types of costs.	
Large disparity in the CE marking costs between companies producing plush or wooden toys and those producing plastic or metal toys.	Not confirmed. However, as different categories of toys entail different risks, they differently influence costs.	

[223] A European and a Spanish industry association, a large Italian manufacturer.

[224] An Italian and an English industry association, with the latter estimating a general increase of 5% in toy selling price with respect to the previous Directive.

[225] A UK and a Polish SME, a UK association of distributors, a Polish distributor.

2008 IA	TSD	NEW COSTS
Positive correlation between the firm product lines and the cost impacts.	Confirmed	
Positive relationship between the strictness of the requirement and the cost impacts.	Confirmed	

With respect to the **other costs referred to in this evaluation**, different estimates have been provided by stakeholders on the additional costs caused by the 2009 Directive, pointing to legislative compliance as being a significant share of the overall production costs.

In general, economic operators report that most of the costs were due to investments required in terms of technical resources (e.g. software to measure chemical substances) or human resources (e.g. need for new professional roles such as chemists and persons in charge of quality controls).

The table below reports the Directive's procedures required to comply with the main provisions. For the sake of simplification, this analysis took as a term of reference the TSD only – so that each procedure is related to a specific Directive's article. Therefore, the results give only an approximation of all the costs entailed by the Directive, without including costs due to processes indirectly related to the TSD. For instance, the management of RAPEX entails both implementation and administrative costs that are not taken into account in the following analysis.

Nevertheless, these results have been triangulated with stakeholders' opinions gathered through the interviews, and the final picture seems not to be too far from the reality. For each procedure, the stakeholder category bearing the related costs is given.

Each procedure entails a certain type of costs: administrative costs, compliance costs, or enforcement costs. In order to take account of the different effort involved, each procedure is given a weight. The weight can range from 1 to 3: an effort equal to 1 designates a simple procedure, entailing just one activity and limited in time. An effort equal to 3 means a complex procedure, embracing several activities and requiring a large amount of time.

Table 8 – Procedures entailed by the implementation of the TSD, affected target groups and related cost

Provision	Procedure	Stakeholder	Type of costs	Weight	Article
Safety requirements	Ensure the compliance with the TSD requirements	MS	Enforcement costs	3	Art. 10(1)
	Take into account the ability and behaviour of children to use the toy when manufacturing it, in order to ensure toys do not jeopardise users safety or health	Manufacturer	Compliance costs	2	Art. 10(2)
Safety assessment	Carry out an analysis of all the specific hazards that the toy may present/be exposed to	Manufacturer	Compliance costs	3	Art. 18
Conformity assessment	**Internal production control procedure**				
	When applying harmonised standards, perform the internal production control procedure	Manufacturer	Compliance costs	3	Art. 19(2)
	EC-type examination				
	Collect the technical documentation to be included in the application for the EC-type certification	Manufacturer	Administrative costs	1	Art. 20(2)
	Translate the technical documentation for the EC-type examination in a language acceptable to the NB	Manufacturer	Compliance costs	1	Art. 20(5)
	Lodge the application with the NB, including the description of the toy and the manufacture's place and address	Manufacturer	Compliance costs	1	Art. 20(1)
	Evaluate, if necessary together with the manufacturer, the analysis of the hazards that the toy may present carried out by the manufacturer	NB	Enforcement costs	2	Art. 20(3)
	Perform the EC-type examination based on the assessment of the technical documentation and supporting evidence, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product	NB	Compliance costs	3	Art. 20(4)
	Include in the EC-type examination certificate a reference to this Directive, a colour image, a clear description of the toy and a list of the tests performed, together with a reference to the relevant test report	NB	Compliance costs	1	Art. 20(4)
	Ensure that NBs do not grant an EC-type examination certificate for a toy for which a certificate has been refused	MS	Enforcement costs	1	Art. 20(4)
	Review the EC-type examination certificate whenever necessary	NB	Compliance costs	1	Art. 20(4)
	Ensure appropriate conformity assessment procedures have been carried out by the manufacturer	Importer, distributor	Enforcement costs	1	Art. 6(2)
EC DoC and CE marking	Make a colour image of sufficient clarity to enable the identification of the toy	Manufacturer	Compliance costs	1	Art. 15(2)
	Provide references to the relevant harmonised standards used/specifications in relation to which conformity is declared	Manufacturer	Administrative costs	1	Art. 15(1)

Provision	Procedure	Stakeholder	Type of costs	Weight	Article
	Where applicable, provide the NB name and number, the description of intervention performed as well as the certificate issues by it	Manufacturer	Administrative costs	1	Art. 15(2)
	Draft the EC DoC for all toys placed on the market	Manufacturer	Compliance costs	1	Art. 15(3)
	Translate the EC DoC into the language(s) required by the MS where the toy is placed/made available on the market	Manufacturer	Compliance costs	1	Art. 15(2)
	Before the toy is placed on the market, affix the CE marking visibly, legibly and indelibly to the toy, to an affixed label, to the packaging or the counter display based on the specific case	Manufacturer	Compliance costs	1	Art. 16(1)
	Ensure that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set.	Importer, distributor	Enforcement costs	1	Art. 6(2)
	Take appropriate action in the event of improper use of the CE marking	MS	Enforcement costs	2	Art. 16(3)
Warnings	Identify possible user limitation related to age, ability, weight and to the toy categories as listed in Part A of Annex V	Manufacturer	Compliance costs	1	Art. 11(1)
	Mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label, on the packaging or on the instructions for use that accompany the toy	Manufacturer	Compliance costs	1	Art. 11(2)
	Stipulate in which language(s) the warnings shall be written	MS	Compliance costs	1	Art. 11(3)
Traceability	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	Manufacturer, importer	Administrative costs	1	Art. 4(6), 6(3)
	Provide the toy with a type, batch, serial or model number or other elements allowing their identification	Manufacturer	Administrative costs	1	Art. 4(5)
Technical documentation	Ask for the safety data sheets on chemicals used from the chemical suppliers	Manufacturer	Compliance costs	1	Annex IV
	Draft a detailed description of the toy design and manufacture, including a list of components and materials used as well as the safety data sheets on chemicals used	Manufacturer	Administrative costs	2	Annex IV
	Draft a description of the conformity assessment procedure followed	Manufacturer	Administrative costs	2	Annex IV
	Make a copy of the EC declaration of conformity	Manufacturer	Administrative costs	1	Annex IV
	Make copies of documents submitted to a NB, if involved	Manufacturer	Administrative costs	1	Annex IV
	Make a copy of the EC-type examination certificate	Manufacturer	Administrative costs	1	Annex IV
	Provide a translation of the documentation into the language of the MS requiring it	Manufacturer	Compliance costs	1	Art. 21(2)
	Keep the technical documentation at the disposal of MSA for a period of 10 years	Manufacturer	Administrative costs	1	Art. 4(3)

Provision	Procedure	Stakeholder	Type of costs	Weight	Article
	Keep a copy of the EC DoC at the disposal of MSA for a period of 10 years and Ensure that the technical documentation can be made available to MSA, upon request	Importer	Administrative costs	1	Art. 6(8)
	Ensure that the technical documentation can be made available to MSA, upon request	Importer	Administrative costs	2	Art. 6(8)
	Justify in case the technical documentation/translation is required from the manufacturer in less than 30 days	MS	Compliance costs	1	Art. 21(3)
	If the manufacturer does not comply with technical documentation related requirements, require it to have a test performed by a NB at its own expense	MS	Enforcement costs	1	Art. 21(4)
	If not complying with technical documentation related requirements, have a test performed by a NB at its own expense	Manufacturer	Compliance costs	1	Art. 21(4)
Identification of economic operators	Identify any economic operator who has supplied them with a toy and/or to whom they have supplied a toy	Economic operators	Administrative costs	2	Art. 9
	Keep this information at the disposal of MSA for a period of 10 years	Economic operators	Administrative costs	1	Art. 9
Amendments	Where necessary, amend the Directive's parts as listed in art. 46	EC	Compliance costs	3	Art. 46
	Establish a Committee composed of representatives of the MS and chaired by representative of the EC	EC	Compliance costs	2	Art. 47
	Transpose the amendments in the national legislation	MS	Compliance costs	3	Art. 54
Penalties	Lay down rules on penalties for economic operators	MS	Compliance costs	3	Art. 51
	Take all measures necessary to ensure that rules on penalties are implemented	MS	Enforcement costs	3	Art. 51
	Verify whether the relevant economic operator has previously committed a similar infringement	MS	Enforcement costs	1	Art. 51
	Increase the penalty if a similar infringement has been already committed	MS	Enforcement costs	1	Art. 51
	Notify the EC of the established rules on penalties for economic operators	MS	Administrative costs	1	Art. 51
	Notify the EC without delay of any subsequent amendment to rules on penalties for economic operators	MS	Administrative costs	1	Art. 51

Source: EY elaboration

In terms of frequency, Table 9 below shows that administrative costs occur nearly as many times as compliance costs, i.e. in 22 and 23 procedures respectively out of 57 procedures in total. Their weight is however quite different. Compliance costs are related to the most complex and time-consuming procedures (i.e. those weighted as 3), corresponding to a final effort value of 37. By contrast, administrative costs are related to simpler procedures (16 procedures with a weight equal to 1 and 6 procedures with a weight equal to 2), entailing an overall effort valued as 28.

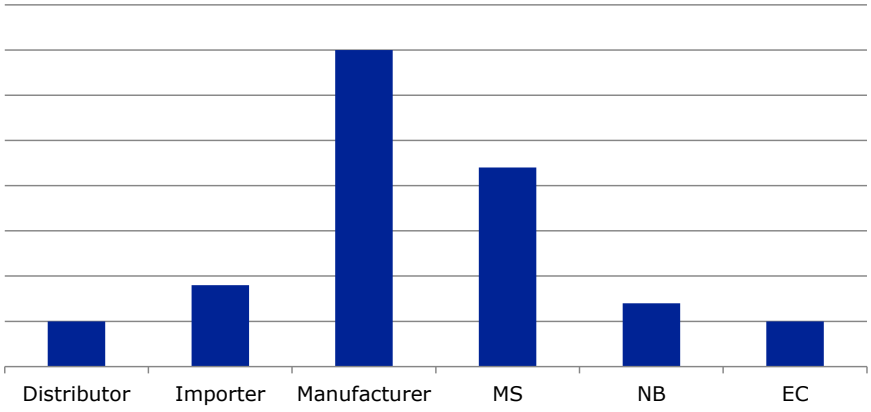
Table 9 – Types of costs, number of procedures the recur in and related effort

Weight / Type of cost	1	2	3	Frequency	Effort[226]
Administrative costs	16	6	0	**22**	**28**
Compliance costs	15	2	6	**23**	**37**
Enforcement costs	8	2	2	**12**	**18**

Source: EY elaboration based on Table 8

The most burdensome provisions are the conformity assessment (with 11 procedures and a total effort of 16) and the technical documentation (with 13 procedures and a total effort of 16). On the contrary, the traceability, the warnings and the safety assessment have the lowest related effort, equal to 3. As a consequence, manufacturers bear the highest effort to comply with the Directive, as Figure 7 below shows.

Figure 7 – Effort of different stakeholder categories to comply with the TSD



Source: EY elaboration based on Table 8

Data in Figure 7 illustrate what both a Spanish industry association and an Italian industry association have stressed, namely that manufacturers suffer an unfair allocation of burdens, as they are overloaded by the Directive's requirements – particularly as concerns the costs to implement risk and conformity assessments - while distributors and importers can comply without incurring significant costs. The concentration of costs on manufacturer is also confirmed by a Bulgarian industry association, reporting the manufacturers' costs to ensure toy compliance with the Directive to be equal to around 30% of overall production costs.

[226] It is calculated as frequency per related weight.

b. Expected benefits

Besides costs, the analysis conducted in this section highlights some discrepancies as concerns the achievement of the expected benefits identified in the 2008 Impact Assessment and reported in the following table.

Table 10 – Expected benefits in the 2008 IA as assessed by the 2009 TSD and new benefits emerged from the evaluation

2008 IA	TSD	NEW BENEFITS
Reduced toy-related injuries, despite the lack of any statistical relationship between specific safety requirements and the number of accidents due to toys.	-	• Stricter regulation of toys mingled with food. • Increased visibility of warnings. • MS quinquennial evaluation of the safety level by the Member States. • Safety requirements aligned with scientific and technological developments. • Enhanced standards and testing methodologies. • Enhanced safety assessment. • Enhanced internal trade and reduced trading costs.
Reduced number of children developing diseases and other chemical-related harmful medium- and long-term effects.	-	
Main benefits falling on consumers.	Not confirmed	
Reduced legal uncertainty as the definitions and roles of economic operators and toys are more clearly laid out.	Confirmed	
Reduced number of 'grey areas', thereby better protecting economic operators from counterfeit products and questionable imports.	Not confirmed	

As already mentioned, the evaluation confirms the lack of a systematic monitoring of toy-related injuries across Europe. Therefore, no exhaustive statistics are available to quantitatively assess the Directive's contribution to reduce the **number of accidents** due to toys. For the same reason, it is not possible to compare figures and trends over time as concerns the overall number of children developing diseases and other chemical-related harmful effects.

Still with regard to the expected benefits, the Directive does not seem to have had an impact in terms of toy **counterfeiting** reduction. Even though this has not been raised as a particular area of concern by stakeholders, literature confirms the relevance of counterfeits toys, particularly when sold online.

A further gap between the Impact Assessment predictions and the evaluation results has been identified with regard to the **toy innovation** that does not seem to have been fostered by the TSD. As reported in section 6.2.1, the stricter safety requirements have been raised as a possible obstacle to the innovation of toys as they absorb a relevant part of the manufacturers' budgets, reducing their propensity to innovate.

Cost impact related to safety requirements has been deemed as an obstacle also for the overall **quality of toys** on the market. Since consumers tend to prefer low cost products, rogue economic operators may place more unsafe toys on the market with reduced compliance costs.

Finally, an increase in **safety** was foreseen in the 2008 Impact Assessment due to improved knowledge of the safety standards. This point is vastly confirmed by stakeholders who, irrespective of the category they belong to, confirm the steps forward made with the new TSD in ensuring the safety of children across Europe.

6.3.1.2. Costs related to key provisions

The most expensive provision concerns the new **chemical limits**. Related requirements are particularly heavy for manufacturers, who had to modify the production processes, to put in place extra software able to collect information all along the supply chain and to engage external contractors, experts and dedicated human resources (e.g. risk assessment managers, chemists). The Directive requires indeed gathering quality information throughout the whole supply chain to ensure that chemical limits are respected. This means to check, for instance, that all the materials provided by different suppliers - and then used for toy manufacturing - are compliant with the Directive, hence further increasing costs, particularly when complex (i.e. multi-material, multi-colour, etc.) toys are concerned. In this regard, a Polish SME states that the production of complex, multifunctional toys is so costly that it is ultimately unprofitable in the EU. Furthermore, economic operators[227] generally deem the requirements on the chemical limit values as not always proportionate, since limits for some substances are so strict that testing laboratories have to invest a lot of time and highly costly materials/software to measure them.

However, when asked about the opportunity to reduce conformity assessment related costs, the majority of interviewees argue that these costs cannot be reduced and that '*the benefits of having the chemical assessment outweigh its costs*'.[228] Interestingly, there is even the case of a large Italian manufacturer reporting no additional costs caused by the 2009 Directive. As most of the new elements were already detectable with the testing methodologies foreseen by the old TSD, the company processes did not undergo significant changes. After all, this big manufacturer already relied on stricter limits for chemicals used in the production process, even if not required by the previous legislation.[229] The stricter requirements were put in place as a preventive strategy to respond to possible legislative changes, thus preventing future cost increases.

As for the costs caused by the safety requirements, it is worth concluding with the relevant experience of another large Italian manufacturer. The interviewee states that the 2009 Directive requirements for safety and conformity assessments - though inducing a significant increase in costs at the beginning of the implementation phase – eventually generated a cost reduction,[230] boosting firms to be more efficient in the implementation of tests. This position is further strengthened by a French industry association, claiming that safety

[227] A Spanish and two English SMEs, a large Belgian, a French and a Dutch manufacture, a large Spanish distributor, a Dutch, a Polish and a Spanish industry association.

[228] A large English manufacturer.

[229] For the same reason, according to a large Dutch manufacturer, the additional costs induced by the 2009 TSD are considered limited.

[230] According to the interviewee, the only exception is the test for chemical risk, which nearly doubled with respect to the previous Directive.

assessment allows manufacturers to address only the aspects that are actually relevant to ensure the toy safety.

Two further provisions have been raised as inefficient because they cause unnecessary costs. A Spanish industry association and a UK expert on toy safety denounce that the Directive requires to provide toys with both the word "**Warning"** and the pictogram ***(finding 25)***, while only the pictogram should be used, as consumers do not read the whole warning message. Moreover, as reported by a UK industry association, despite the two-year transition period, manufacturers experienced additional costs associated with changes in the labelling requirements between the two Directives. These costs resulted from the need to destroy and reprint the toy packaging, which was conform to the 1988 Directive but not to the 2009 Directive.

Adaptation mechanisms can represent a further barrier to the efficient application of the Directive ***(finding 31)***. Several stakeholders[231] denounce that changes to the Directive require continuous adaptations and new investments for companies all along the value chain in short timeframes. In addition, according to a large Spanish distributor, amendments to the Directive have been too many and partial (i.e. only covering some products). This created confusion as toy documentation drafted according to the previous legislation was no more valid. The interviewee also argues that partial amendments cause pressure on manufacturers to change their whole internal safety system.

Furthermore, some stakeholders[232] think that the time for the development of standards to meet the new requirements – estimated by a European industry association and a large toy manufacturer as being around three years – is not always aligned with the short 18-month period[233] granted in the Directive's amendment for the transition. The involvement of multiple stakeholder categories in the process of revision of the harmonised standards makes indeed negotiation very long, even longer than the transition period granted in the Directive's amendment to align to new requirements. This may lead to a sort of vacuum with no harmonised standards available to manufacturers dealing with new requirements. Adaptation can thus be time-consuming, and when standards are not ready within the transition period, manufacturers are forced to prove conformity through other means - i.e. EC-type examination, increasing overall costs. This problem is shared also by a UK association of distributors, claiming that its members may purchase stock of products up to a year in advance and if standards come into force as soon as their references are published in the OJEU, they do not have time to adapt their products to new requirements. Furthermore, legislative changes imply costs to search for - and access - all the relevant information, and to understand new issues and requirements.[234]

Finally, the **technical documentation** – including the declaration of conformity - revealed to be to some extent inefficient, even though the related costs are rather due to its

[231] A Bulgarian, a Dutch and a European industry association, a large Italian, a Belgian and a Dutch manufacturer.

[232] A large French manufacturer, a Polish SME, a large Spanish distributor, a Bulgarian toy association.

[233] TSD, article 54.

[234] An Italian importer and distributor, a UK manufacturer, a UK expert on toy safety, a European standardisation organisation and an Italian toy industry association.

enforcement than to the design of the provision. A small Spanish manufacturer claims this is the greatest burden placed by the TSD on manufacturers. A large Belgian manufacturer states that a duplication of effort sometimes occurs due to the same requests for documentation by different authorities – e.g. at national and local level - within the same Member State. More precisely, the burden is due both to the reporting obligations - that entail the need to gather all necessary information – and to the shortcoming in the market surveillance procedures.

As for the reporting obligation, a large Danish manufacturer and a UK distributor association point out that the main investment following the new TSD was due to the setup of an internal, dedicated IT system. The aim of the system is to ensure that all the information along the production chain can be easily collected and aggregated from different systems into one.

As for the slowness of market surveillance procedures, a Spanish SME complains that, after an inspection has been successfully conducted, Market Surveillance Authorities can take even two years to give clearance to the marketing of products. According to the interviewee, such a delay is a serious legal uncertainty that prevents products to be marketed, thus generating significant losses for economic operators, particularly as inspections are often carried out in busy periods – like Christmas and Easter holidays – expected to be highly profitable for the toy industry.

Moreover, some economic operators[235] point to the so-called "double testing" due to some French distributors only accepting tests made by French laboratories. According to a French association of distributors, this process can take up to four months during which toys are blocked at the customs, thus generating further costs on manufacturers. Finally, a UK SME states that French customs are not acting in accordance with the provisions set out in the Directive as they do not allow import from third countries into France without certification showing conformity with the European Standard EN71-3.[236]

6.3.1.3. Market analysis: possible effects of the TSD on the overall costs of toy manufacturers

As specified in the previous section, a number of stakeholders claim an overall increase of costs due to the introduction of the TSD. The Directive had multiple effects in terms of administrative, operating and production costs (e.g. necessity of new machineries and skilled workers, higher controls over the characteristics of the production materials).

As confirmed during the interviews and in line with the intervention logic of the New Legislative Framework, this evaluation shows that the majority of costs entailed by the TSD rest on manufacturers. The following analysis aims at evaluating the effects of the TSD on toy manufacturers' overall costs and assessing whether the claims of interviewed stakeholders are confirmed.

[235] Spanish manufacturers, a Dutch and a Spanish industry association, a French and a European association for distributors.

[236] EN 71-3:2013+A1:2014 - Safety of toys - Part 3: Migration of certain elements.

Due to the lack of cost data - as described in section 4.2.2 - it was not possible to thoroughly quantify the actual burdens for toy manufacturers entailed by the introduction of the Directive. Nevertheless, the following analysis uses the profit and loss (P&L) accounts of EU toy manufacturers comparing the weights of production costs over revenues before and after the implementation of the Directive. This comparison indicates a discontinuity that, as far as available data allow for, may be partly due to the implementation of the TSD. Such finding confirms stakeholders' claims over the increasing regulatory burden caused by the Directive.

Main assumptions

The deadline for the transposition of the TSD by Member States was January 20th, 2011 effective from July, 2011.[237] It is thus reasonable to assume that toy manufacturers have experienced rising compliance costs in 2011. If this is the case, there should be evidence of this cost increase in their annual profit and loss accounts.[238]

The introduction of the TSD is a market-exogenous event that directly impacts EU-based toy manufacturers. The Directive does not have a direct impact on other manufacturing companies.

Hypothesis and methodology of the analysis

The founding hypothesis of the analysis is that, the Directive being an exogenous event impacting overall costs, its implementation should have caused a significant increase of such costs between 2010 and 2011 leading to an overall "shift" of cost trends after the implementation of the Directive.

The costs of goods sold are proportional to production levels. Thus, instead of considering them in absolute terms, the analysis is conducted on the cost of goods sold ratio[239] that "normalises" costs on company revenues/size. The ratio is calculated on profit and loss accounting figures.

The analysis compares annual medians of the cost-over-sales ratios of the following two groups:[240]

1. Toy manufacturers located in the EU 28;
2. Manufacturers (excluding toy-manufacturing firms) located in the EU 28.

[237] Article 54 (Transposition) of the Toy Safety Directive required MS to transpose the Directive by 20 January 2011 into national law and apply those measures with effect from 20 July 2011. Thus, the Directive was not binding for manufacturers until 2011. It is reasonable to assume, as confirmed by interviews, that manufacturers have incurred in rising costs of compliance between 2010 and 2011 and not before.

[238] Manufacturers' annual financial statements summarise revenues and costs adopting international standards, which allow for a comparison across years, companies and industries.

[239] The Cost of goods sold ratio is (COGS to sales ratio) calculated as the ratio between the « Cost of goods sold » in a specific year and the «Operating Revenue (Turnover)» of the same year showing the percentage of sales revenues used to pay for expenses that vary directly to sales. Variances may either depend on changes of internal production costs, or due to variances of sales of goods.

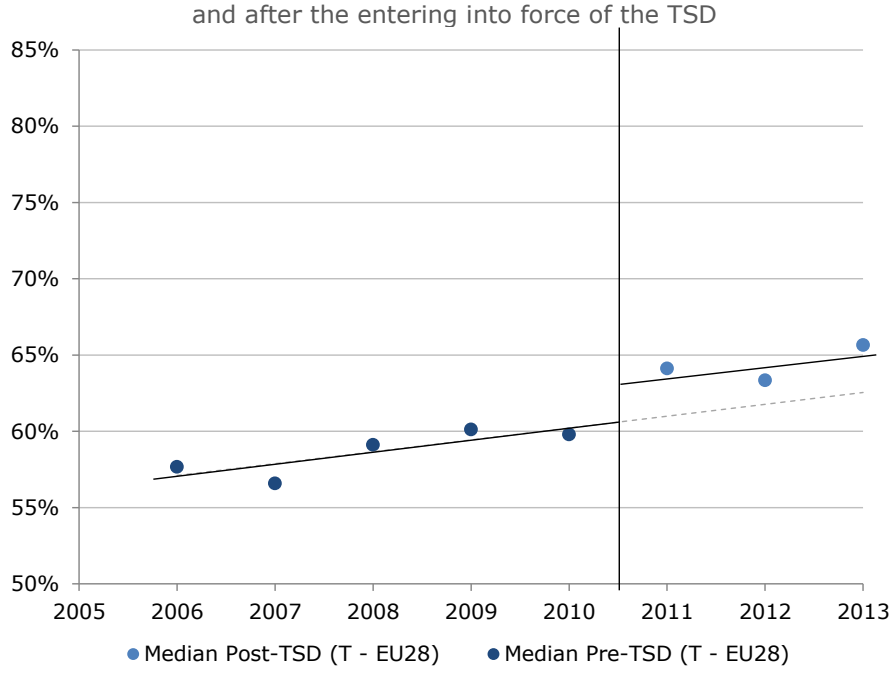
[240] Data source is the Amadeus – Bureau Van Dijk database. The sample groups are composed as follows: 162 companies classified as Manufacture of games and toys (NACE 32.4); 25,845 Manufacturing companies located in EU28 MS (with the exclusion of toy manufacturing companies).

The comparison is made in order to exclude that any shift in trends in the toy manufacturing industry is caused by external economic downturns. Possible economic downturns could indeed influence all manufacturers and not just those operating in the toys industry. A further analysis could envisage comparing cost-over-sales ratios of non-European manufacturers of toys. However, since the Directive applies to all toys imported in Europe, it is not possible to isolate - at company level - the share of revenues and costs of non-EU firms directly attributable to the production of toys destined to the European market from those destined to non-EU markets (in order to have a reliable control group).

Key findings

The analysis of annual market medians of cost/income ratios (Figure 8) confirms a positive inclination of the trend-curves, indicating a higher year-on-year incidence of costs over annual turnovers, confirming the overall perception of increasing costs in the toys sector. However, the trend has started before the implementation of the Directive, thus stakeholders' perception of increasing costs is not completely attributable to its implementation.

Figure 8 - Annual medians of the Cost-over-sales ratio of toy manufacturers located in the EU28 before and after the entering into force of the TSD

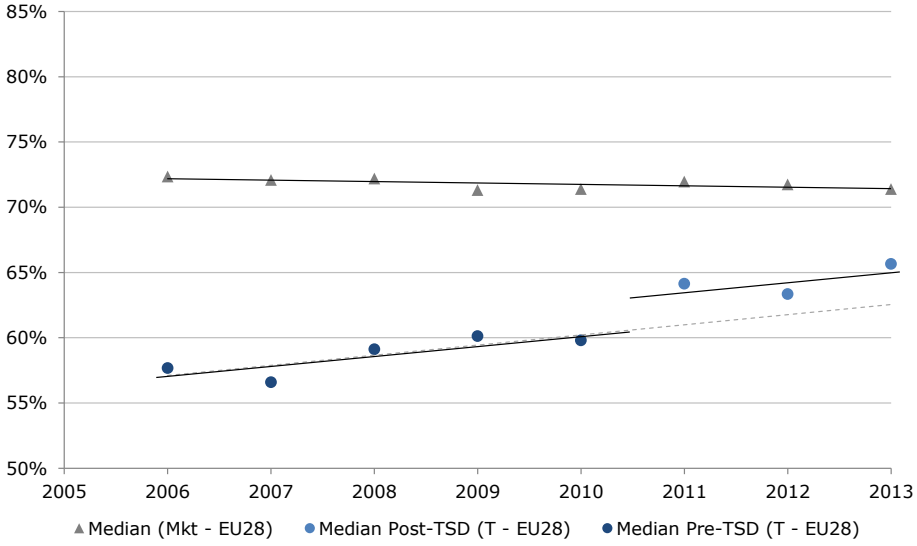


Source: EY elaboration

Between 2010 and 2011, the trend-curve is subject to an upward shift that could be due to the introduction of the new Directive, bearer of new and sudden costs not compensated by increases of revenues. The dotted line in Figure 8 indicates the expected trend of the cost-over-sales ratio after 2011, while the fitted trend-line indicates the actual registered trend.

In order to ensure that such sudden increase was not due to contingent economic shocks in the EU internal market (i.e. overall reduction of demand), figures above were compared to annual cost-over-sales ratio medians of other EU manufacturers not operating in the toys industry (thus not directly influenced by the Directive) (Figure 9 below).

Figure 9 - Annual cost-over-sales ratio of toy (lower line) and non-toy (upper line) manufacturers located in the EU28



Source: EY elaboration

The cost-over-sales ratio of EU manufacturers in the time period taken into account does not exhibit substantial year-on-year changes and no particular shocks emerge between 2010 and 2011. This evidence may suggest that the upward shift in the EU toy industry did not occur in reason of contingent market-endogenous events.

Final considerations

The market analysis is substantially aligned to what interviewed stakeholders claim: the TSD may have led to a sudden increase of compliance costs right after its implementation. However, most recent data refer to 2013, only three years after the implementation, thus it is not possible to assess whether the TSD has only caused a contingent upward shift of costs or has led to a long-term increment of the overall costs.

On the other hand, stakeholders may overestimate the effect of the new Directive on their business due to the overall trend of increasing costs not compensated by annual revenues.

6.3.2. EQ9: Unnecessary costs and suggestions to reduce costs/ administrative burden.

6.3.2.1. Types of costs entailed by the Directive and their legitimacy

As long as efficiency is defined as the ratio of outputs to inputs, no actor has reported the existence of inefficient provisions. However, if the efficiency concept is broadened as comprising the capability to produce specific outcomes with a minimum amount of resources, the evaluation shed light on some unnecessary costs caused by the Directive. To assess whether the Directive's objectives have been achieved at a reasonable cost, the study identified the **costs related to the activities** needed to implement each provision and mapped the different stakeholders involved in – and responsible for – each activity (see Table 8 further above).

The costs analysed embrace direct costs (including compliance costs and administrative costs) and indirect costs (including substitution effects, reduced competition, reduced innovation and uncertainty).[241]

As concerns direct costs, *compliance costs* relate to the procedures needed to implement provisions, for instance those required to perform the conformity assessment. *Administrative costs* are costs imposed on businesses and users, when complying with information obligations stemming from regulation; as an example, administrative costs can be linked to the obligation for economic operators to draft and keep the technical documentation. Finally, *"hassle" costs* relate to obstacles due – for instance – to overlapping or inconsistences among different pieces of legislation or to administrative delays.

As for indirect costs, *substitution effects* relate to changes in people's behaviour due to regulation requirements. For instance, if new standards for a specific typology of toy results in a price increase, it is likely that consumers will buy less of that product, rather preferring a cheaper substitute. *Reduced competition* occurs when new legislative requirements hinder the access to market of specific players like, for instance, SMEs. *Reduced innovation* relates to regulatory costs that discourage firm investment in innovation: it is the case of manufacturers reducing investment in toy innovation because of the higher costs related to the new safety requirements. *Uncertainty* may emerge from frequent regulatory changes, including amendments to current legislation.

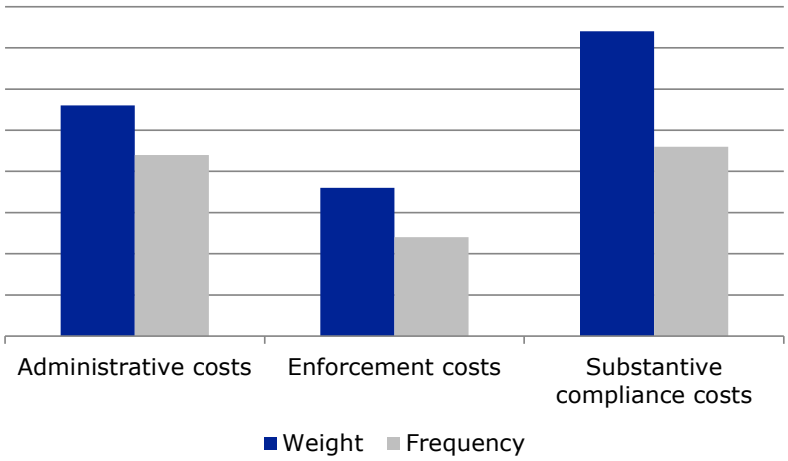
Finally, the study has also taken into account *enforcement costs* supported by Member States to monitor and properly enforce the Directive's implementation, though no substantial complaint has been raised about this type of costs. Since national reports do not include an analysis or assessment of the TSD-related costs and Member States have not been involved during the interviews, the analysis of enforcement costs mainly relies on the two following considerations. Firstly, Member States do not point to issues of efficiency in the national reports, not even when discussing market surveillance activities that are the core of the enforcement costs. Secondly, enforcement costs are entailed by less and simpler compliance procedures, as shown in Table 9 above. Even though this does not allow for a precise estimate or quantification, this partial overview on enforcement costs seems to indicate they are a minor share of the overall costs entailed by the TSD.

Table 8 in section 6.3.1.1 presents the type(s) of costs related to each procedure required to comply with the Directive's provisions. These procedural costs include direct costs - such as administrative and compliance costs - and enforcement costs. Indirect costs have been instead analysed in section 6.3.1. In particular, section 6.3.1.1 presents some evidence gathered on reduced innovation due to the Directive's stricter safety requirements that absorb a relevant part of the manufacturers' budgets. As a consequence, innovative toys may be fewer and more expensive. This may induce substitution effects as consumers, who tend to prefer cheaper products, will buy less innovative – thus cheaper – toys.

[241] The terminology here used refers to: *Assessing the costs and benefits of regulation*, Study for the European Commission - Secretariat General, by the Centre for European Policy Studies and Economisti Associati (2013). http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

As shown in Figure 10, and based on the information reported in Table 8, the majority of procedures needed to comply with the Directive's requirements entail compliance costs, while only few of them induce enforcement costs.

Figure 10 – Types of costs related to the procedures needed to comply with the Directive[242]



Source: EY elaboration based on Table 8

Interestingly, in terms of frequency, compliance costs occur nearly as often as administrative costs, even if the former weigh more, further confirming the opinion of some manufacturers of being overloaded by some TSD provisions. In this respect, Table 8 also demonstrates that the majority of compliance costs fall on manufacturers. The high frequency of the administrative costs is not an indicator of their impact or relevance. Administrative costs might be highly frequent while remaining low in absolute value. For instance, despite the two procedures linked to the "Identification of economic operators" (see Table 8) entailing administrative costs, no stakeholder reports it as a costly provision. On the contrary, the two provisions reported as most costly by stakeholders – e.g. safety requirements and warnings – do not entail any administrative costs. Furthermore, despite their frequency, administrative costs could be perceived by stakeholders as a necessary cost to ensure the Directive's objectives.

Therefore, to assess whether costs may be considered as reasonable in order to achieve the Directive's objectives, it is necessary to go beyond the identification of the main types of costs, including other evaluation criteria. As detailed in section 4.2.2, collected data and information in this regard are mainly qualitative and did not allow quantifying the costs.

Therefore, the following three main **criteria to qualitatively assess** the reasonableness and proportionality of costs have been identified:

1. *Objectives served*: costs incurred to achieve results relating to more than one objective (see the intervention logic in section.1.2) appear to be more reasonable and aligned with the integrated perspective of the Directive;

[242] Please consider that the unit measure for the ordinate axis is the number of procedures entailing the costs.

2. *Frequency counting*: costs mentioned by just one stakeholder category weigh less than costs reported by different stakeholders, thus resulting to be more reasonable;
3. *Stakeholders' perception*: costs perceived as necessary by stakeholders weigh less than costs deemed as outweighing benefits and thus may be considered more reasonable.

In the table below, the costs related to each provision previously identified in Table 8 are assessed towards each criterion, marking with **+** in case they satisfy the evaluation criterion and with **-** in case they do not. More precisely, a **+** is given to provisions serving both the Directive's objectives, being reported as costly by multiple categories of stakeholders. By contrast, a **–** is given to provisions serving just one objective and being reported as costly by just one category of stakeholders. When the objective is served, the related provision is marked with ***'v'***. An overall rating is thus assigned to each provision costs based on a qualitative assessment of the balance between the ratings assigned in relation to each criterion. In case the costs satisfy the majority of the identified criteria, they may be considered as reasonable and are indicated with the letter **'R'.**

Table 11 – Assessment of costs entailed by the implementation of the TSD

Provisions	**Objectives served**			**Frequency counting**	**Stakeholders' perception**	**Overall rating**
	Ensure children's safety	*Guarantee the internal market*	**Overall**			
Safety requirements	*v*	*v*	**+**	-	+	**R**
Safety assessment	*v*	*v*	**+**	+	+	**R**
Conformity assessment	*v*	*v*	**+**	-	+	**R**
EC DoC and CE marking	*v*	*v*	**+**	+	+	**R**
Warnings	*v*	*v*	**+**	-	-	
Traceability	*v*	*v*	**+**	-	+	**R**
Technical documentation	*v*		**+/-**	-	-	
Identification of economic operators	*v*		**+/-**	+	+	**R**
Amendments	*v*		**+/-**	-	-	
Penalties	*v*	*v*	**+**	+	+	**R**

Source: EY elaboration

Table 11 shows that **overall, results have been achieved at a reasonable cost**. The majority of the provisions are associated to results linked to both the strategic objectives of the Directive, namely to maintain a high level of safety for children and protection against possible health threats from toys, while allowing toy cross-border movement. Moreover,

even when frequently reported during the interviews, most of the times costs are positively valued by stakeholders[243] as necessary to achieve the TSD objectives.

6.3.2.2. Efficiency bottlenecks

Even though almost all the costs are more or less collectively perceived as necessary to ensure the safety of toys, the existence of some unnecessary costs has been raised in this evaluation.

Firstly, though the TSD requires authorities' requests for documents to be "reasoned", [244] this is not always the case in practice, with some Customs Authorities by default asking for test reports rather than simply for the declarations of conformity ***(finding 13, finding 14)***, determining an additional burden on manufacturers in particular.[245] As claimed by a European industry association, the issue can represent a sort of vicious circle. Importers and distributors ask for test reports because they have been in turn asked for these documents by some Customs and Market Surveillance Authorities. For this reason, a large Danish manufacturer declares to test any produced toy, in order to be able to deliver a test report whenever required. Under ordinary circumstances, importers and distributors would request only the declaration of conformity, this being the only document they need to verify that manufacturers are compliant with the Directive's requirements. As for the other relevant documents, manufacturers can self-certify their compliance provided they apply harmonised standards. Requests for test reports represent a significant problem due to the confidential information reported in these documents. This explains the reluctance of manufacturers to provide them, as big distributors – that are often also toy manufacturers - would have access to confidential company data with potential impacts on competition.[246]

Another bottleneck regarding the Directive's efficiency has been identified by a French manufacturer in the **lack of harmonised standards** for some risks. In this case, manufacturers have to rely on external experts in order to get the EC-type certificate, thus proving the toy conformity. This is a further burden on manufacturers, particularly for SMEs.

Moreover, significant and recurrent costs relate to the **acquisition of standards**, mainly as ENs change over time. The revision of standards is a continuous process as they need to be aligned with steady technological and scientific developments. In this regard, manufacturers complain about the excessively high costs to adapt to amendments, even when revisions concern very marginal elements of the standard. A UK SME points out that more information should be given whenever a standard is changed. In addition, once new harmonised standards are finalised, the whole toy production chain may need to be aligned with new parameters, thus potentially increasing overall costs.

[243] It is important to note that the national reports do not include a specific section focused on the cost impacts of the Directive. However, when addressing the main difficulties with – and the shortcomings of – the Directive, no Member State points to specific or unnecessary costs.

[244] TSD, articles 4(9), 5(3), 6(9) and 7(5).

[245] A Dutch, a French, a Polish and a European industry association.

[246] A UK manufacturer, an Italian distributor, a Dutch, an Italian, a Spanish and a European industry association.

With regard to the **toy testing**, a Spanish SME reported that in case of technical changes in testing methodologies, toys produced before the change - and sold after it - would be subject to different testing methods, with the risk of being found compliant in one case and not in another. As this causes higher costs, the interviewee claims that some moratorium should be provided to properly address the problem.

Finally, two Italian industry associations – including one for SMEs - suggest to reduce costs establishing a sort of "presumption of conformity mechanism" based on manufacturers' past compliance rates. More precisely, if manufacturers always rely on the same supplier and/or use the same raw materials already declared to be compliant in the past, they should be exempt from repeating safety and conformity assessments.

To sum up with the efficiency analysis, the evaluation highlighted that most of the costs relapse on manufacturers. This is in line with the Directive's strategic approach – and with the New Legislative approach as detailed in section 2.1.1 - posing main responsibilities for toy safety on manufacturers.

Administrative costs represent the most recurrent costs entailed by the Directive. This is due to the high complexity of the Directive and to the high number of actors involved. The involvement of multiple stakeholder categories makes indeed crucial to ensure frequent and well-structured reporting activities so as to share information among different actors and allow monitoring the processes at stake. In addition, the production and share of information required by the Directive are also of importance for the well-functioning of the internal market as they reduce information asymmetries among economic operators.

Besides administrative costs, the Directive entails several other types of costs, including compliance and enforcement costs. This evaluation confirms that the majority of these costs are reasonable to achieve the Directive's objectives, as discussed in previous sections. Chapters seven and eight of this study provide some useful recommendations to increase the overall cost-effectiveness of the Directive, with particular regard to warnings, technical documentation and adaptation mechanisms that emerged as the most inefficient provisions.

6.4. Coherence

6.4.1. EQ10: Are there overlaps/complementarities between the 2009 Directive and any pieces of EU legislation or Member State acts in the relevant areas, in particular with regard to the limit values for chemicals set out in the 2009 Directive? Are there contradictions?

There is no evidence of contradictions between the 2009 Directive and the other relevant EU legislation for toys (see Box 3), as concerns both limit values for chemicals and other provisions.

However, confusion is likely to arise when toys are "indirectly" regulated via legislation other than the TSD. This is true for instance as regards CMR substances. The TSD sets a limit for CMR substances in toys corresponding to the relevant concentration limit established in the CLP Regulation[247] (see footnote 135). However, specific - usually lower - limits for certain

[247] Regulation (EC) No 1272/2008. OJ L 353, 31.12.2008, p. 1.

CMR substances, which are specifically applicable to toys, are also set in the REACH Regulation (see examples in Box 10).

In these cases, economic operators may find it difficult to identify the proper requirements to comply with, particularly when reference is made to several pieces of legislation.

Box 10 – Examples of relevant provisions for toys that are indirectly addressed in other EU legislations

- Benzene is banned according to REACH in toys or parts thereof 'where the concentration of benzene in the free state is in excess of 5 mg/kg of the weight of the toy or part of toy' (REACH Regulation, Annex XVII, point 5);
- Bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), di-"isononyl" phthalate (DINP), di "isodecyl" phthalate (DIDP) and di-n-octyl phthalate (DNOP) are limited in REACH to concentrations not higher than 1,000 mg/kg by mass of the plasticised material, in toys and childcare articles (REACH Regulation, Annex XVII, point 51 and 52);
- Wood treated with creosote[248] is explicitly banned from toys in REACH (Annex XVII, point 31);
- Azo dyes: textile and leather toys may not contain more than 30 mg/kg of the listed carcinogenic aromatic amines released from azo dyes after reductive cleavage (REACH Annex XVII, point 43);
- Polycyclic-aromatic hydrocarbons (PAH): as of 27 December 2015, rubber or plastic components of toys intended to come into contact with the skin may not contain more than 0.5 mg/kg of any of the listed carcinogenic PAHs (REACH Annex XVII, point 50).

As pointed out in a previous study,[249] legislative confusion increases administrative costs for economic operators – and particularly manufacturers - who have to double-check what requirements they are subject to. For instance, as regards the relation between the TSD and REACH, a first assessment is required to identify the requirements manufacturers are subject to under the TSD; a second in relation to restrictions under other legislative texts. This double-check has been indicated as a duplication of costs.[250] Similarly, a large Belgian manufacturer points out that several pieces of legislation relevant for the toy sector require the drafting of the EC declaration of conformity (e.g. RoHS, R&TTE). As a consequence, when more than one Directive applies to a toy, separate declarations of conformity are needed.

However, as also stated by different stakeholders,[251] bearing in mind the vulnerability of the target group - i.e. children - the current framework should be maintained even if it sometimes turns out to be cumbersome and time-consuming. After all, stakeholders do not experience any major contradiction or overlapping between the Directive and other pieces of

[248] Relating to wood treated in industrial installations or by professionals, which is placed on the market for the first time or retreated in-situ. This is permitted for professional and industrial use only, e.g. on railways, in electric power transmission and tele-communications, for fencing, for agricultural purposes (e.g. stakes for tree support) and in harbours and waterways.

[249] Milieu (2012). Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps. Final Report.

[250] Two Polish and one Dutch SME, a German, a Spanish and a UK industry association, a large Italian and a Belgian manufacturer and a Spanish distributor.

[251] Three consumer associations, an Italian industry association, a large Italian manufacturer, a Czech Notified Body.

EU legislation. Also some economic operators[252] stressed that all current pieces of legislation are necessary as they regulate different products or products serving different purposes.

In this regard, it is worth underlining how Member States have generally implemented initiatives aimed at training operators concerned with toys both on the Directive's working mechanisms and on its relationship with other EU relevant legislation applicable to toys ***(finding 22)***. Public support is differently appreciated by economic operators based in different Member States. For instance, a large Italian manufacturer and an Italian distributor have a very positive opinion on the supporting activities performed by national authorities. In contrast to this, two Spanish SMEs declare they would like to receive more information from public authorities.

Finally, a large Italian manufacturer and a UK expert on toy safety appreciate the legislative harmonisation following the implementation of the New Legislative Framework, which increased overall coherence, clarity and simplicity of EU legislation.

6.4.2. EQ11: What can be done to optimise the relationship between them?

As no major contradiction or overlapping was detected, only few points have been raised with regard to the link between the TSD and the other EU relevant legislation for toys.

A **horizontal legislative framework** has been suggested in order to better regulate chemicals in products.[253] Moreover, as outlined in section 6.2.4, economic operators deem it necessary to develop **common EU testing methodologies**, in order to ensure their uniform interpretation – thus enhancing intra-EU trade, lowering costs for testing laboratories and manufacturers, and ensuring an increased level of toy safety.

Finally, stakeholders go beyond the EU scope, pointing out the need for the **harmonisation of technical standards** and legislation between the EU and the US in order to further enhance trade.[254] On this point, a Spanish industry association observes that non-EU countries are used to refer to different approaches to ensure the safety of imported toys. As an example, a large Italian manufacturer reported that Turkish national competent authorities want toys to be tested in a local laboratory before giving clearance to import. For this reason, the interviewee is of the opinion that more effort should be made in order to align Turkish toy import practices with European practices. A large Belgian manufacturer suggests developing agreements or training sessions with non-EU trading partners, to ensure that the Directive is correctly implemented by third countries. In this context, actions undertaken by Member States with third countries in relation to toy safety are particularly relevant ***(finding 36*** and Box 7***)***.

A large UK manufacturer argues that it would be better if the same chemical limits were applied in general to all consumer products. On the same line, a UK association of distributors suggests it would be beneficial to have the same chemical limit values for the

[252] An Italian industry association, a large Italian manufacturer, a Belgian and a Danish manufacturer.

[253] ANEC (2014). Position paper. Hazardous chemicals in products. The need for enhanced EU regulations. http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

[254] An Italian industry association, a large UK manufacturer, a Spanish SME and a European representative of Notified Bodies.

same material across all consumer products, as this would ease the compliance with chemical regulation. Coherence could be improved accordingly if there were no different testing methodologies across different legislations, and the same approach would be used not only to ensure toy safety, but the safety of all consumer products.

Along this line, according to a Spanish industry association, further coherence could be ensured if the legislator paid attention more upstream to the value chain, regulating raw materials rather than the final product. For instance, it is preferable to regulate a certain type of plastic and not the use of this type of plastic in a toy.

Though no contradictions have been detected, according to a European consumer association the legislation on toys should be aligned as much as possible to that of other products, such as food and cosmetics. In this view, the association asserts that it should not be tolerable that some chemical substances (e.g. CMRs and allergens) are allowed in toys at higher levels than in other products.

Finally, a Dutch industry association suggests that, in order to further clarify and ease economic operators' compliance with the whole legislation relevant for toys, more information should be published on the website of the European Commission.

6.5. Added value

6.5.1. EQ12: Additional value resulting from the 2009 Directive.

The added value of the 2009 Directive is clearly proved by issues related to the German case ***(finding 12)***, confirming the value of having one European Directive instead of 28 different Member States laws. The existence of one Member State adopting limits for chemicals different than those set at the EU level makes it clear how divergent requirements on the national level could increase and exacerbate in the absence of a common EU legislation.

In addition, the TSD is a clear example of legislation with good mechanisms to ensure product traceability, as it includes clear identification and traceability requirements that can be inspiring for other sectors.[255]

6.5.2. EQ13: The added value of the 2009 Directive for stakeholders.

All stakeholders recognise the added value of the Directive in ensuring and simplifying the trade of toys within the internal market. The TSD is deemed to have a significant, positive impact in terms of facilitating the internal trade and reducing trading costs for large manufacturers,[256] with a UK manufacturer affirming that the TSD has created a "*pan-European product*". According to a UK association of distributors, this significantly lowers manufacturing and product development costs, whilst ensuring a level-playing field with regard to safety.

[255] GS1 (2013). Research support for an informal expert group on product traceability. Final Report. p. 10 http://ec.europa.eu/consumers/archive/safety/projects/docsdocs/20131023_final-report_productfinal-report_product-traceability-expert-group_en.pdf

[256] A European standardisation organisation, an Italian importer and an Italian distributor.

Notwithstanding the mentioned requests for further harmonisation, stakeholders generally agree on the TSD contribution to homogeneity of testing methodologies and standards. As an example, a Polish SME states that the Directive acts as a *'universal reference document for both buyers and sellers of toys'.* Furthermore, as also pointed out by a European industry association, in the absence of the Directive, differences in national market surveillance approaches would be even higher than they currently are.

According to a large Belgian manufacturer, the TSD improved the firms' approach to - and awareness of - the importance of safety. This in turn had positive spillover effects in terms of brand image and reputation, as the Directive contributed to increasing the quality and safety of European products.

On their side, SMEs denounce very high costs caused by the Directive, particularly as regard the safety requirements. However, there is no evidence on a possible reduction of these costs by means of a national legislation – instead of an EU directive – on the safety of toys, nor do SMEs point to any benefit stemming from national rather than European rules. Very interestingly, an Italian industry association of SMEs states that the existence of a sectorial EU directive for toys directly triggers/activates SMEs to ensure toy safety. SMEs are particularly wishful to be compliant as this is perceived as a *conditio sine qua non* for their internationalisation. For instance, marketing products with the CE mark is considered as a notable distinction by Italian SMEs. As EU institutions in their opinion are deemed to be more reliable than the national ones, EU requirements - even if costly - are generally considered as appropriate and justified, thus enhancing stakeholders' attitude to be compliant. However, according to a European consumers' association and to a Dutch SME, the CE marking should be eliminated, as it has no added value and it can be misinterpreted as a safety mark.

Furthermore, the establishment of the chemical expert group on toy safety[257] is deemed as a very positive EU initiative, though a European consumer association denounces that it currently lacks adequate resources. At the moment, the members' contribution to the group in terms of expertise is voluntary, which is not always sufficient to ensure the group's effective action. The enhancement of the group role and activities would represent a great improvement in the practical implementation of the Directive.[258]

According to a UK association of distributors and to a Polish SME, the TSD added value would notably increase by looking at a mechanism in place in the UK. Businesses there can establish a so-called "primary authority relationships" with a national competent authority on a particular matter. Businesses can seek an "assured advice" from the authority in relation to the compliance with a range of issues (e.g. toy safety). If a firm is found non-compliant, it cannot be prosecuted or fined because it preliminarily sought advice and intended to comply with the relevant legislation. The interviewee would like to see a mechanism as such throughout all the Member States, thus establishing a sort of "European competent

[257] The Working group on chemicals is a sub-group of the Expert Group on Toy Safety (E01360). This sub-group has a temporary duration and 15 members, including both organisations and public authorities. For more information see: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailPDF&groupID=136

[258] Two European and an Austrian consumer association.

authority". This would avoid seeking advice from a national primary authority that could be conflicting with the advice from authorities in other Member States.

To conclude, according to a German manufacturer, the EU added value of the TSD would be strengthened by encouraging manufacturers to invest on social compliance issues. The safety of products could be included in the concept of "corporate social responsibility". As an example, the manufacturer reports his experience with the Business Social Compliance Initiative (BSCI). The BSCI was launched in 2003 as an initiative of the Foreign Trade Association in response to the increasing business demand for transparent and improved working conditions in the global supply chain. It now groups over 1,500 companies around one common Code of Conduct and supports them in their efforts towards building an ethical supply chain by providing them with a step-by-step development-oriented system applicable to all sectors.[259] The stakeholder is of the opinion that a similar EU-legislative mechanism could be foreseen also for the toy sector, as it would be positively judged by consumers and hence it would help producers in further building their reputation.

[259] http://www.bsci-intl.org/about-bsci

7 CONCLUSIONS

7.1. Relevance

The Directive is a relevant policy measure for the safety and the sector of toys. First of all, it sets common requirements for all economic operators concerned with toys across Europe, requiring that all toys placed on the EU market comply with its provisions. Furthermore, it provides specific provisions for the risks related to toys.

As a further proof of the Directive's relevance, its adaptation mechanisms have shown to effectively help the TSD to adapt to technological and scientific developments. The Directive demonstrated to be a flexible policy tool able to align to – and take account of – changes and developments occurring in the external context.

Even though no major issue emerged questioning the Directive's overall relevance, economic operators, consumer associations and Member States express different opinions on the relevance of specific provisions – in particular, limits for chemicals and amendments to the Directive.

While **economic operators** widely recognised the appropriateness of the Directive's safety requirements, **consumer** associations together with a number of **Member States** deem the provisions addressed to chemical exposure to be inadequate, with hazardous chemical substances – such as CMRs - still allowed beyond tolerable limits. In this view, they call for urgent measures in order to further limit – or even ban – hazardous substances. Furthermore, while economic operators and Member States generally confirm the flexibility of the Directive, consumer associations claim that amendments should not be limited to specific provisions, but rather be able to embrace all the safety requirements as to properly address new risks.

Representatives of both economic operators and consumers refer to different scientific opinions supporting their contrasting viewpoints as concerns the (effectiveness and) relevance of current limits for chemicals in toys. All these scientific opinions rely on very technical estimations regarding tolerable limits for hazardous substances, whose comparability and overall assessment is out of the scope of this study. Therefore it would be important to carefully **verify the validity of the requests for stricter requirements for chemicals** so as to in-depth evaluate the appropriateness of current requirements based on scientific and consensual assessment (**SR 1**).

Moreover, as consumer associations and SMEs vastly declare to have little voice in policy decision mechanisms, it would be important to further involve them when amending the Directive. This would ensure **a more balanced representativeness of different stakeholder categories** while enhancing overall consensus around policy initiatives (**SR 2**).

Member States generally confirm the relevance of the Directive, with a couple of them highlighting cases of risks not covered by any safety requirement. However, these risks vary according to the specific situations experienced at national level, with no common risk categories to be addressed. Therefore it is not possible to assess the extent to which such risks actually question the Directive's relevance, as they consist of singular complaints not supported by other stakeholders, preventing any triangulation among problems raised by a few national authorities.

Furthermore, Member States sometimes point out difficulties with issues already addressed by the NB-Toys, and this may illustrate that they are not always aware of the results included in the NB-Toys' protocols. Since those protocols are specifically aimed at clarifying particular legislative requirements to stakeholders, the difficulties raised by Member States indicate there are limits in the role played by the NB-Toys, and highlight the need for **effective and timely communication**. This would be particularly important in case of amendments to the Directive: since legislative changes may entail new requirements to be taken into account, communication mechanisms should include guidance on how to properly manage amendments to the Directive so as to enhance its effectiveness (**SR 3**).

With specific regard to toy counterfeiting, both economic operators and consumer associations call for further information on – and protection from – counterfeit-related risks. In this regard, it is worth noting that EU legislation for the fight against counterfeiting is already in place. For instance, Regulation (EU) No 608/2013 concerning customs enforcement of intellectual property rights (IPR)[260] provides customs authorities with procedural rules for enforcing intellectual property rights with regard to goods liable to customs supervision or customs control". To this purpose, the Regulation highlights the importance of information sharing mechanisms among Customs Authorities to enable better risk management. Furthermore, institutional cooperation against counterfeits is one of the focuses of the EU Customs Action Plan to Combat IPR Infringements for the Years 2013-2017.[261]

In this context, in order to enhance the effectiveness of the EU legislation aimed at combating counterfeiting, soft regulation tools could be established at a double level. **Communication and cooperation mechanisms** could be set up among Customs Authorities to enhance the exchange of information and practices related to counterfeit toys (**SR 4**). Moreover, soft regulation tools like **guidance and explanatory material** can be addressed to a wider stakeholder spectrum – including economic operators and consumer associations – to help them in recognising and preventing counterfeit toys (**SR 5**).

To sum up, counterfeits, 3D printing and online sales do not represent a specific problem for toys. Therefore, they are not an issue for the Directive's relevance, rather requiring a horizontal EU governance framework based on cooperative mechanisms and procedures.

Specific recommendations

- **SR 1**: to check the need for more stringent limits for values for chemicals in order to assess the appropriateness of current requirements.
- **SR 2:** to ensure participation of consumer associations and SMEs in each Directive's amending initiative, in order to ensure fair representativeness of different stakeholder categories.
- **SR 3**: to establish a communication system aimed at timely disseminating information on amendments to the Directive to all stakeholders and institutions concerned, including guidelines to understand and manage the notified changes.
- **SR 4**: to establish communication and cooperation mechanisms among Customs and Market Surveillance Authorities to enhance the exchange of information and practices related to

[260] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2013:181:FULL&from=EN

[261] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:080:0001:0007:EN:PDF

counterfeit toys.

- **SR 5**: to provide stakeholders with non-legislative policy measures – e.g. guidelines and information material - to support enforcing authorities, economic operators and consumer associations in recognising and preventing counterfeit toys.

7.2. Effectiveness

The Directive has proved to be effective in enhancing the level of safety for EU children, while facilitating the internal market for toys.

The **free movement of toys** is ensured thanks to the harmonisation of procedures and requirements, with just the one case of a Member State attempting to set divergent limit values for chemicals as an exception.[262] Moreover, the TSD does not seem to hinder the **import of toys** entering the EU market.

As for **toy safety**, though no major issue emerged questioning the Directive's effectiveness, the assessment of the Directive's contribution to reduce the overall injuries related to toys is prevented by the lack of a comprehensive statistical monitoring and reporting system on data related to accidents. As a consequence, effectiveness can only be assessed qualitatively, by looking at existing complaints regarding the current level of toy safety.

In this regard, the desk and field research carried out during this evaluation have not identified any alarming data on injuries due to toys in the EU. Furthermore, toy safety is a focus at the top of the policy agendas - both at European and national level. There are several organisations – including advocacy coalitions concerned with child safety and scientific organisations concerned with health issues – focusing on toy safety, with different perspectives on the current legal framework in place. However, no evidence has been gathered pointing to major threats to children's safety.

Despite the general satisfaction with the Directive's ability to reach its objectives, stakeholders express some divergent opinions according to the category they belong to. **Consumer associations** together with several **Member States** claim that the limits for chemicals and hazardous substances are too permissive, asking for legislative initiatives to reduce current limits for hazardous substances – like CMRs and allergens among others. In contrast to this, **economic operators** all agree on the appropriateness of the Directive's safety requirements. As both opinions of economic operators and consumer associations refer to scientific evidence (see also section 7.1), the final assessment of the opinions' robustness requires an in-depth comparative analysis of different scientific and technical issues, considering also the lack of data on toy-related health effects. The latter makes such assessment however impossible, suggesting that it would be crucial to establish a **monitoring system** at EU level, providing robust **statistics** on toy-related injuries (**SR 6**).

Some claims have been raised that the numerous and costly safety requirements, though ensuring the Directive's effectiveness, hinder innovation activities in the toy industry, with particular regard to toys for children under 36 months of age whose requirements are particularly demanding. In order to reduce the number of applicable requirements they have to comply with, manufacturers tend to limit the complexity of the toy, thus limiting

[262] See footnote 86.

innovation. This suggests that some incentives could be foreseen for manufacturers investing in toy innovation, such as subsidies for research concerning toys for children under 36 months of age (**SR 7**).

Besides the safety requirements, another area of concern relates to the **testing methodologies** that, as requested by a number of economic operators, industry associations and Member States should be aligned across the EU, so to further harmonise the Directive's implementation. This point leads back to one of the main features of the "New Approach" (see section 2.1.1), that allows external parties to perform conformity assessments according to their own parameters. As this creates unavoidable differences among laboratories applying different testing methodologies, the Recommendations from the NB-Toys Group provide Notified Bodies with recognised methodologies when dealing with essential requirements not covered by any harmonised standards. Nevertheless, despite these Recommendations, the different laboratory approaches have been pointed out as an issue hindering the Directive's effectiveness.

Thus the problem does not seem to lie in a legislative gap, but rather in the proper implementation of the instruments in place. More precisely, two main reasons emerge as possible explanations of current significant differences in testing methodologies. The first one is that Notified Bodies are not fully aware of the documents produced by the NB-Toys. In this case, a better **dissemination of NB-Toys protocols and recommendations** would be needed to further align the methodologies used by different Notified Bodies and thus increase the Directive's effectiveness (**SR 8**).

Cost-opportunity estimates are the second possible reason leading Notified Bodies to apply less strict – thus less expensive – methodologies. In this case, it is important to provide national Notifying Authorities with **common minimum requirements to select Notified Bodies** – beyond the requirements set in article 26 of the TSD.[263] This would prevent the risk of market distortions and safety concerns due to toys having very similar features but resulting different in terms of conformity because of different testing methodologies (**SR 9**).

In addition, the same product can be subject to different requirements also because of different interpretations whether or not it is a toy. Although progress has been made to overcome the problems related to the "grey area", Member States and economic operators still have difficulties with toy categorisation. These difficulties should become the starting point to regularly **update guidelines on toy classification** so as to take into account new and emerging issues potentially affecting the clear identification of a toy as defined by the Directive (**SR 10**). This is even more important as toys represent a very dynamic commercial product, being subject to steady innovation according to social, technological and scientific development and marketing considerations.

Furthermore, economic operators denounce market surveillance activities to be highly different across Member States, both in terms of number of controls performed and in the stiff level of the applied sanctions. Therefore, they ask for common requirements to be followed by Market Surveillance and Customs Authorities across Europe. Given that Member States have exclusive competence in surveillance activities that cannot be regulated at EU

[263] Article 26 establishes specific requirements relating to Notified Bodies.

level, the Commission could **provide national competent authorities with soft regulation tools** – e.g. guidance on the minimum requirements to be assured when controlling toy compliance (**SR 11**).

Still with regard to market surveillance activities, as detailed in section 6.2.2, controls are focused on large and renowned toy manufacturers as they are easier to be checked. Market surveillance impact could be further improved by focusing controls on new and less known companies, while reducing the controls on firms having been compliant for many years. In this way, it would be possible to assure a more **widespread coverage of market surveillance** without increasing overall control costs (**SR 12**).

Furthermore, both Market Surveillance Authorities and economic operators are not always aware of specific provisions of the Directive, particularly as concerns the technical documentation to be provided by manufacturers. To overcome this problem, **training sessions and campaigns at EU level** could be organised, differentiating them based on the specific stakeholder category involved. Awareness would be raised among stakeholders as concerns the Directive's working mechanisms. Moreover, further harmonisation would be ensured, as stakeholders based in different Member States would be trained following the same approach (**SR 13**).

This evaluation also sheds light on several difficulties relating to the use of warnings, which are often written in a too small font size and not easily readable. In order to increase the impact of warnings on consumers, the possibility to **amend the warning provisions** could be assessed, increasing the use of pictograms instead of written words and modifying the font and language requirements so as to ensure that warnings are always clear, legible and written in all relevant languages. The use of **QR codes** could also be considered, as a smart tool to provide information while detailing warnings on the firms' websites (**SR 14**).

This evaluation further identified two main mechanisms having enhanced the overall effectiveness of the Directive. The first is the Rapid alert system for dangerous non-food products (RAPEX), which can be used as a monitoring tool as it contains exhaustive information on measures taken against dangerous products placed on the market. The second mechanism consists in the industry associations playing the role of advisors and information providers for economic operators, both at European and national level. As both these mechanisms deal with the provision of information, it is clear again that major limitations to the effectiveness of the Directive come from the capacity to properly disseminate information and raise awareness on legislative requirements in place. In this regard, it would be important to maximise the impacts of these policy mechanisms. Based on stakeholders' consultation **RAPEX should be systematically reviewed** at the EU level so as to assess whether it needs any change in terms of both contents and working procedures. This would allow enhancing its effectiveness by taking account of stakeholders' suggestions for the details to be provided on the types of risk associated with each notified toy. In this regard, a stakeholder's viewpoint is endorsed, based on which this would enable distributors to benchmark their own products with those that have been notified, and check whether the products they are selling also present the same safety risks (**SR 15**).

Furthermore, **industry associations should continue and intensify their information provision activities**, including horizontal information sharing among industry associations based in different Member States. This would integrate the top-down process – providing national toy industries with information on EU policy and legislative initiatives – with a

horizontal process consisting in the transfer of knowledge and information across Member States (**SR 16**).

Finally, the Directive's effectiveness could be enhanced by **broadening the scope of the safety assessment**. The safety assessment process seems to be often highly focused on chemical risks, without taking properly account of the multiple variables in the use of a toy, due to the children's largely unpredictable behaviour. Considering the high complexity of play value, it is important to **involve different categories of experts** – including psychologists - when drafting a safety assessment, as already experienced by some manufacturers reporting positive feedback. This would enhance the safety assessment procedure, taking into account also possible social developments such as the use of specific toys by children younger than in the past (**SR 17**).

Specific recommendations

- **SR 6**: to ensure the provision of exhaustive and up-to-date statistics on toy-related injuries, including details about the type of injury concerned so as to calculate the real observable damage to children. The system should be based on the regular monitoring and data collection of integrated data from different bodies – including emergency departments, schools, etc.
- **SR 7**: to establish incentive mechanisms - like for instance subsidies for research - for manufactures investing in toy innovation, particularly in toys for children under 36 months of age – so as to avoid that costs born to comply with the TSD hinder the innovation of toys.
- **SR 8**: to provide Notified Bodies with regular training sessions whenever a new Protocol/Recommendation is issued by NB-Toys so as to raise awareness on their contents, thus enhancing the harmonisation of testing methodologies used by Notified Bodies.
- **SR 9**: to provide national Notifying Authorities with common minimum requirements to select Notified Bodies – beyond the requirements set in article 26 of the TSD - in order to prevent major differentiation in the testing of toy compliance.
- **SR 10**: to regularly update guidelines on toy classification so as to take into account the difficulties experienced by economic operators in the identification of products as toys.
- **SR 11**: to provide enforcing authorities - and particularly Customs Authorities – with minimum voluntary standards, so as to enhance the harmonisation of national approaches to the toy compliance assessment.
- **SR 12**: to focus market surveillance activities on new and less renowned companies while reducing the controls on firms revealing to be compliant for many years, having therefore a very good reputation, so as to broaden the market surveillance scope without increasing overall costs.
- **SR 13**: to provide competent authorities and economic operators with guidance and regular EU training sessions so as to raise awareness on the Directive's working mechanisms, particularly in case legislative changes occur.
- **SR 14**: to discuss the feasibility of amending the warning provisions so as to increase their effectiveness. An option could be the use of QR codes while detailing warnings on the firms' websites.
- **SR 15**: based on the suggestions expressed by stakeholders, to systematically review RAPEX as regards the typology and details of information to be provided on the type of risks associated with each notified toy.
- **SR 16:** to continue and intensify the provision of information by industry associations', also through the establishment of horizontal information sharing mechanisms among industry associations based in different Member States in order to enhance the transfer of knowledge and information.
- **SR 17**: to enlarge the scope of the safety assessment, by involving different categories of experts – including psychologists - in order to fully take account of the complexity of play value.

7.3. Efficiency

The Directive has caused additional costs for economic operators. The most recurrent of these costs, although not the most substantive, are the **administrative costs** entailed by the procedures needed to comply with the Directive's safety and other requirements. While administrative costs continue to recur all along the toy supply chain, **compliance costs** concentrated in the initial implementation phase, when new requirements obliged companies to invest in technical resources (e.g. equipment to measure more chemical substances) and human resources (e.g. need for new professional roles such as chemists and persons in charge of quality controls).

Large economic operators vastly deem **costs as proportionate** to the objective of ensuring the safety of toys, without major duplications and unnecessary effort. Moreover, they appreciate the Directive as it ensures harmonisation and increases legal and procedural certainty, thus preventing information asymmetries between economic operators based in different Member States. In the economic operators' views, main inefficiencies are due to enforcement shortcomings. In particular, problems related to the technical documentation create obstacles to the effective and efficient implementation of the Directive and useless delays. As enforcing authorities often require test reports beyond the declaration of conformity, this causes a sort of chain reaction, with distributors requesting test reports from manufacturers. As already discussed for **SR 13**, these problems could be overcome by means of soft regulation tools - such as updated guidelines and regular training sessions – so to increase the awareness and skills of the enforcing authorities, particularly when dealing with changes caused by amendments to the Directive.

The requests for test reports represent a significant problem also due to the confidential information they contain, which makes manufacturers reluctant to provide them. In this regard, awareness could be raised among economic operators on the existence of **confidentiality agreements** so as to prevent the disclosure of sensitive production data (**SR 18**).

SMEs face major difficulties with the costs induced by the Directive. SMEs' production is indeed not large enough to reap economies of scale benefits and to compensate initial investments. Moreover, SMEs have limited staff, lacking specific skills like those of legal experts or chemists. Therefore, when faced with new legislative requirements, they turn to external consultants, significantly increasing overall costs. As it is not conceivable to establish different requirements according to the size of the firm, the only reasonable solution is to provide SMEs with very clear and updated guidance and supporting material - including **helpdesk and training** - so as to make them able to manage the Directive's requirements as much as possible by themselves, without turning to external consultants (**SR 19**).

Another efficiency issue raised during the study concerns the costs related to the harmonised standards. Economic operators ask to reduce the costs of harmonised standards when these are modified according to new mandates initiated by the Commission. Any time standards are modified to take account of scientific and technological developments, economic operators are obliged to buy them, thus facing costs for a limited counter value. As long as changes to standards concern delimited sections of the standard and do not modify it in its entirety, **the costs of the modified standard could be reduced** as compared to the cost of the original version (**SR 20**).

Moreover, economic operators claim that the development of standards is time-consuming and not always aligned with the transition period granted by the Directive, thus increasing overall compliance costs. As long as harmonised standards are not available, manufacturers are indeed forced to prove conformity through other means. In this view, a "grace period" could be introduced where toys compliant with previous safety requirements can be still sold under the old standards (**SR 21**).

Finally, as also suggested by two stakeholders, economic operators could benefit from a further reduction of costs if exemption from conformity assessment is provided in case toys are produced with the same materials already tested in the past, particularly when these materials are always provided by the same suppliers (**SR 22**).

Specific recommendations

- **SR 18**: to provide economic operators with guidance – e.g. through the Blue Guide - raising awareness on the existence of confidentiality agreements to avoid the disclosure of sensitive information along the supply chain.
- **SR 19**: to provide SMEs with clear and updated guidelines helping them to comply with the safety requirements without relying on external consultants.
- **SR 20**: to grant a significant discount percentage - compared with the original price - on harmonised standards to be re-purchased following amendment(s) to the standards.
- **SR 21**: to introduce a "grace period" where toys produced under the old safety requirements can be sold.
- **SR 22**: to establish a sort of "presumption of conformity mechanism" granting an exemption from conformity assessment for manufacturers who always rely on the same supplier and/or use the same raw materials already declared to be compliant in the past.

7.4. Coherence

There is no evidence of contradictions between the 2009 Directive and the other EU legislation relevant for toys, as concerns both limit values for chemicals and other provisions. However, confusion may arise when toys are "indirectly" regulated via legislation other than the TSD. In these cases, economic operators may find it difficult to identify the proper requirements to comply with.

To avoid confusion, **clear and updated guidance** on the links between the TSD and other relevant legislations should be provided, particularly if the same provision – e.g. the product testing – is applied in different sectoral legislations. This would save economic operators from the effort to check all these legislations looking for possible overlaps (**SR 23**). In any case, it is worth highlighting that stakeholders do not raise any major confusion or uncertainty. After all, the implementation of the Directive has been properly supported through several initiatives aimed at raising awareness on its provisions and working mechanisms, both at EU and national level.

Warnings represent the only provision raising issues of consistency. Some stakeholders deem indeed the warnings in EN 71 as not always consistent with Annex V of the Directive. This may represent a problem in terms of both safety and free market of toys as different interpretations of warnings may hinder and slow down business and market surveillance activities. To avoid the problem, **the warnings listed in Annex V of the Directive and the warnings listed in the EN 71 standards series could be aligned**, thus ensuring their consistency (**SR 24**).

Specific recommendations

- **SR 23**: to draft guidelines providing comparative overviews on the relationship between the TSD and the other main EU pieces of legislations relevant for toys so as to avoid any possible confusion for stakeholders dealing with more than one piece of legislation at the same time. They shall also include explanations on how the same provision – e.g. the product testing – is applied in different sectoral legislations.
- **SR 24**: to use the warnings listed in the EN 71 standard series in Annex V of the Directive in order to ensure consistency.

7.5. Added value

Notwithstanding the establishment of the TSD, there is one Member State that adopted chemical limit values different than those set at EU level. This makes it clear how national differences would increase and exacerbate in the absence of a common EU legislation.

The added value of the 2009 Directive is confirmed by all categories of stakeholders, leaving no doubt on the advantage to have a European Directive instead of 28 different Member State laws. Moreover, the Directive is vastly perceived as good legislative practice, with clear and focused provisions covering all major needs and ensuring common requirements and provisions across Europe. This enhances trust and transparent business deals, while ensuring a high level of safety of toys.

The overall added value is further increased by the TSD nature and structure, it being a New Approach Directive. As noted by economic operators, the New Approach requires legislative texts to rely on the same format and content structure, thus enhancing harmonisation and positive integration among different pieces of EU legislation. This prevents confusion, while highlighting possible synergies and complementarities among sectoral pieces of legislation.

Furthermore, as also reported by several economic operators, the EU added value of having common toy safety legislation could be increased by facilitating global – and not just European – convergence with regard to the requirements for toys, thus **aligning different legislations in place across international markets** (**SR 25**). In case this "optimum choice" would not be feasible, two further "second best" solutions could be carried out to **avoid any contradictions between European and international standards** (**SR 26**) and to implement bilateral agreements with important trade partners so as to **make toy imports into the EU increasingly compliant** (**SR 27**).

Finally, one stakeholder's suggestion to strengthen the EU added value of the TSD was to **incorporate the safety of products - including toys - in the concept of "corporate social responsibility"**. This would be appreciated by consumers, thus pushing manufacturers to invest on social compliance issues so as to further build their reputation (**SR 28**).

Specific recommendations

- **SR 25**: to align legislative requirements for toys across international markets so as to induce global – and not just European – added value.
- **SR 26**: to avoid any contradiction between European and international standards so as to enhance overall toy safety.
- **SR 27**: to implement bilateral agreements between the EU and important trade partners so as to make toy imports into the EU increasingly compliant.

- **SR 28**: to incorporate the safety of products – including toys – in the concept of corporate social responsibility so as to boost manufacturers' compliance attitude through proactive mechanisms (in addition to the legislative approach based on mandatory requirements).

8 RECOMMENDATIONS

This Chapter presents the general recommendations stemming from this evaluation.

As presented in Chapter 7, 28 specific recommendations emerged under the 5 evaluation criteria (relevance, effectiveness, efficiency, coherence, EU added value). Some of these recommendations were similar to each other although they had emerged under different criteria - and could be grouped into 7 general recommendations, which are presented in the table further below.

Each recommendation is addressed to several **stakeholders** and is given a certain level of **priority** (L= Low, M= Medium, H= High).

The priority level has been set according to three criteria:

i) The **impact** of the recommendation on the two strategic objectives of the Directive – i.e. ensure the safety of children and allow the cross-border movement of toys. The impact is high (H) when a recommendation concerns both objectives; it is low (L) when a recommendation concerns only one objective.

ii) The **feasibility** of implementing the recommendation, taking into account its acceptability by the different categories of stakeholders, the difficulties/risks for its technical implementation and the related costs. The higher the number of stakeholders involved, the lower the consensus expected, and consequently the lower the feasibility of implementing a recommendation. The analysis here takes into account six main categories of stakeholders concerned with the TSD: European Commission, economic operators - including both EU and national industry associations, consumer associations, Member States – including Custom and Market Surveillance Authorities, NB-toys and the European Standardisation Organisations. A recommendation scores as many points as the number of stakeholder categories concerned, thus the maximum score reachable by each recommendation is 6 points. The feasibility of the recommendation is valued as low if equal to 5 or 6; it is valued as medium if equal to 3 or 4; it is valued as high if equal to – or lower than – 2.

iii) The **relevance** of the recommendation, based on the number of stakeholder categories raising the same problem the recommendation is expected to address. The higher the number of stakeholder categories raising the same problem, the higher the relevance of the recommendation. The analysis here takes into account three main categories of stakeholders interviewed during the study: economic operators, consumer associations and Member States. Each stakeholder category raising a problem scores 1 point, thus the maximum score reachable by a problem is 3 points. The relevance of the recommendation is valued as high if a problem scores 3; it is valued as medium if a problem scores 2; it is valued as low if a problem scores 1. The other three stakeholder categories - European Commission, NB-Toys and the European Standardisation Organisations were not taken into account. While feasibility concerns all the stakeholder categories since it deals with a recommendation implementation, relevance relates to the importance of specific issues as perceived by stakeholders. In this view, although providing a significant contribution to the evaluation assignment, the European Commission, the European Standardisation Organisations and the NB-Toys did not raise major issues directly feeding the final recommendations. The European Commission has indeed been involved at the beginning of the study through

scoping interviews, which were aimed at enhancing the understanding of the context of reference and helped framing the whole analysis and related methodology. The European Standardisation Organisations and the NB-Toys provided useful insights to enhance the effectiveness of the Directive, with regard for instance to the need for reinforced cooperation between the ESOs and the European Commission, and the need to include "slings and catapults" into the scope of the Directive.

Table 12 – Relationship between general and specific recommendations

General recommendation	Stakeholders addressed	Priority	*Impact*	*Feasibility*	*Relevance*	Specific recommendations
1. To provide **effective communication and dissemination mechanisms** between all stakeholders concerned with the TSD	• EC • NB-Toys Technical Secretariat • Economic operators and their associations • MS • Consumers • ESOs	H	*H*	*M*	*H*	• **SR 3**: to establish a communication system aimed at timely disseminating information on amendments to the Directive to all stakeholders and institutions concerned, including guidelines to understand and manage the notified changes. • **SR 10**: to regularly update guidelines on toy classification so as to take into account the difficulties experienced by economic operators in the identification of products as toys. • **SR 13**: to provide competent authorities and economic operators with guidance and regular EU training sessions so as to raise awareness on the Directive's working mechanisms, particularly in case legislative changes occur. • **SR 15**: to systematically review RAPEX as regards the typology and details of information to be provided on the type of risks associated with each notified toy. • **SR 16:** to continue and intensify the provision of information by industry associations, also through the establishment of horizontal information sharing mechanisms among industry associations based in different Member States in order to enhance the transfer of knowledge and information across Member States. • **SR 18**: to provide economic operators with guidance – e.g. through the Blue Guide - raising awareness on the existence of confidentiality agreements to avoid the disclosure of sensitive information along the supply

General recommendation	Stakeholders addressed	Priority	*Impact*	*Feasibility*	*Relevance*	Specific recommendations
						chain. • **SR 19**: to provide SMEs with clear and updated guidelines helping them to comply with the safety requirements without relying on external consultants. • **SR 23**: to draft guidelines providing comparative overviews on the relationship between the TSD and the other main EU pieces of legislation relevant for toys so as to avoid any possible confusion for stakeholders dealing with more than one piece of legislation at the same time. They shall also include explanations on how the same provision – e.g. the product testing – is applied in different sectoral legislations.
2. To ensure a **common market surveillance framework**, including minimum standards on market controls and on the level of sanctions to be applied	• EC • MS	H	*H*	*M*	*H*	• **SR 4**: to establish communication and cooperation mechanisms among Customs and Market Surveillance Authorities to enhance the exchange of information and practices related to counterfeit toys. • **SR 5**: to provide stakeholders with non-legislative policy measures – e.g. guidelines and information material - to support enforcing authorities, economic operators and consumer associations in recognising, avoiding and contesting counterfeit toys. • **SR 11**: to provide enforcing authorities - and particularly Customs Authorities – with minimum voluntary standards, so as to enhance the harmonisation of national approaches to the toy compliance assessment.

General recommendation	Stakeholders addressed	Priority	*Impact*	*Feasibility*	*Relevance*	Specific recommendations
						• **SR 12**: to focus market surveillance activities on new and less renowned companies while reducing the controls on firms revealing to be compliant for many years - having therefore a very good reputation - so as to broaden the market surveillance scope without increasing overall costs. • **SR 21**: to introduce a "grace period" where toys produced under the old safety requirements can be sold. • **SR 22**: to establish a sort of "presumption of conformity" mechanism granting a reduction of the frequency of compliance tests on manufacturers who always rely on the same supplier and/or use the same raw materials already declared to be compliant in the past.
3. To ensure 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	• NB-toys Technical Secretariat • EC • MS	M	*H*	*M*	*M*	• **SR 8**: to provide Notified Bodies with regular training sessions whenever a new Protocol/Recommendation is issued by NB-toys so as to raise awareness on their contents, thus enhancing the harmonisation of testing methodologies used by Notified Bodies. • **SR 9**: to provide national Notifying Authorities with common minimum requirements to select Notified Bodies – beyond the requirements set in article 26 of the TSD - in order to prevent major differentiation in the testing of toy compliance.

General recommendation	Stakeholders addressed	Priority	*Impact*	*Feasibility*	*Relevance*	Specific recommendations
4. To consider measures aiming at **improving the Directive's provisions**	• EC • MS • Economic operators • Consumer associations • ESOs • Notified Bodies	M	*H*	*L*	*H*	• **SR 1**: to check the need for more stringent limits for values for chemicals in order to assess the appropriateness of current requirements. • **SR 14**: to discuss the feasibility of amending the warning provision so as to increase its effectiveness. An option could be the use of QR codes while detailing warnings on the firms' websites. • **SR 17**: to enlarge the scope of the safety assessment, by involving different categories of experts – including psychologists - in order to fully take account of the complexity of play value. • **SR 24**: to use the warnings listed in ENs into Annex V of the Directive in order to ensure consistency.
5. To consider measures aimed at **improving the Directive's working mechanisms**	• EC • Consumer associations • MS	H	*H*	*M*	*H*	• **SR 2**: to ensure participation of consumer associations and SMEs in each Directive's amending initiative, in order to ensure fair representativeness of different stakeholder categories. • **SR 6**: to ensure the provision of exhaustive and up-to-date statistics on toy-related injuries, including details about the types of injury concerned so as to calculate the real observable damage to children. The system should be based on the regular monitoring and data collection of integrated data from different bodies – including emergency departments, schools, etc.

General recommendation	Stakeholders addressed	Priority	*Impact*	*Feasibility*	*Relevance*	Specific recommendations
6. To provide **incentives to economic operators** to better comply with the Directive	• EC • MS • ESOs • Economic operators	M	*H*	*M*	*L*	• **SR 7**: to establish incentive mechanisms - for instance subsidies for research - for manufactures investing in toy innovation, particularly in toys for children under 36 months of age – so as to avoid that costs borne to comply with the TSD hinder the innovation of toys. • **SR 20**: to grant a significant discount percentage - compared with the original price - on harmonised standards to be re-purchased following amendment(s) to the standards. • **SR 28**: to incorporate the safety of products – including toys – in the concept of corporate social responsibility so as to boost manufacturers' compliance attitude through proactive mechanisms (in addition to the legislative approach based on mandatory requirements).
7. To improve **international alignment of toy safety**	• EC • MS • ESOs	M	*H*	*M*	*L*	• **SR 25**: to align legislative requirements for toys across international markets so as to induce global – and not just European – added value. • **SR 26**: to avoid any contradiction between European and international standards so as to enhance overall toy safety. • **SR 27**: to implement bilateral agreements between the EC and important trade partners so as to make toy imports into the EU increasingly compliant.

1) **To provide effective communication and information dissemination mechanisms between all stakeholders concerned with the TSD**

Issue

This evaluation raises the need for initiatives to increase the **awareness of different stakeholders of the TSD amendments and their implementation**, since both economic operators and Member State competent authorities often experience difficulties in adapting to new requirements.

The analysis thus reveals a lack of awareness of all the available policy tools, rather than the latter being ineffective.

Recommendation

A **communication system** should be established so as to ensure direct and effective information flows between the European Commission and the networks of all the other stakeholders.

The system could be organised in three sections with three different functions.

One section would aim at ensuring that legislative and non-legislative changes are timely and effectively communicated. To this purpose, a sort of alert mechanism specifically covering results stemming from the TSD adaptation mechanisms could be established. Alerts should include amendments to the Directive, modifications of harmonised standards and input from NB-Toys – including protocols and recommendations.

A second section would include an alert system covering guidelines and supporting material helping stakeholders to understand and manage the legislative and non-legislative changes. In this sense, the suggested system shall aim not only at communicating developments – through the first section - but also at disseminating information on how to properly face such developments – thanks to the second section.

These first two sections would significantly reduce informative and procedural costs for manufacturers (particularly SMEs), thus limiting the need for external consultancy and increasing overall stakeholders' awareness on the changes occurred.

The third section of the system would contain more general guidelines and supporting material concerning the safety and the sector of toys, beyond legislative changes. This section would be aimed at disseminating versions of previous guidelines updated according to external developments that might change the interpretation and management of specific issues - such as new technologies affecting the classification of products as toys - taking account of the main difficulties identified by different stakeholders. Furthermore, this section should include guidelines providing comparative overviews on the relationship between the TSD and the other EU and non-EU relevant pieces of legislation for toys. This would avoid any possible confusion as regards the implementation of provisions that apply also to other commercial products than toys.

Besides the three sections, the system could envisage the possibility to integrate an interactive platform, allowing direct exchanges of information among stakeholders experiencing similar difficulties. In this regard, an "*ad-hoc* queries system" could be established empowering stakeholders who face a specific issue to ask how other actors have managed it in the past or in other contexts.

Given that toy safety is under the responsibility of all stakeholders concerned with the TSD and that the Directive's strategic objectives can be better and more easily achieved with a combined effort, this interactive platform would be inclusive of all stakeholder categories. The system would be centrally managed by the European Commission, providing information to all stakeholders who have subscribed. Information could be spread through an automatic alert mechanism such as a newsletter.

Each section of the system would be freely accessible to anyone after subscription, so that any stakeholder concerned could also have access to the *ad hoc* queries platform. In order to improve its efficiency and impact, this area of the system would be similar to an open blog, completely interactive and directly involving all relevant actors.

In this context, ensuring that the website interface is as user-friendly as possible will be essential to increasing the system effectiveness. To this purpose, the stakeholder submitting an *ad hoc* query would have to specify in advance (using for instance a drop down menu) the addressee category(ies)[264] and nationality(ies). This information, together with the object of the query, will be publicly visible on the blog. This mechanism, without preventing the query to be answered by non-addressees, will strongly help to hold responsible all the actors directly concerned by the *ad hoc* query.

Furthermore, the European Commission and the representatives of the selected category (e.g. TIE and national industry association, NB-Toys and Member State Competent Authorities) would be notified every time a query is submitted. Each query would remain in the "active" status for 30 days until it is answered. The Commission and the stakeholder representatives will be notified 10 days before the query expires, so that they can solicit the addressee(s) of the query or alternatively decide to respond themselves.

Impact, feasibility and relevance of the recommendation

The recommendation has a **high priority** with a high score on all the three criteria taken into account – impact feasibility and relevance.

The knowledge, understanding and awareness of the Directive's working mechanisms and related amendments have been raised as main obstacles to the TSD effectiveness and efficiency. These obstacles affect the implementation (and the enforcement) of the Directive with direct negative effects on the achievement of its objectives. Implementation shortcomings may cause additional costs on economic operators, like information costs due to the effort and time needed to correctly understand new requirements entailed by amendments to the Directive. This justifies the high **impact** attributed to this recommendation.

The **feasibility** is high as all stakeholder categories would be granted open access to the implementation of the communication system, thus benefitting from it. The effort and the costs needed to implement the system are expected to be quite concentrated on the European Commission, which would be in charge of the development of the platform. These costs would be more than offset thanks to the enhanced implementation of the EU legislation due to better knowledge of - and communication among - stakeholders, including

[264] I.e. large or SME manufacturer, importer, distributor, Notified Body, Custom Authority, Market Surveillance Authority, National Competent Authority, standardisation organisation.

a reduced number of requests for clarification and support. In addition, the "*ad-hoc* query system" may have a positive impact on the overall EU cohesion regarding toy safety, facilitating the horizontal exchange of practices among Member States as well as other stakeholders. Moreover, also consumers would benefit from the system, since they would be granted access to the platform as well, being therefore systematically informed and updated on the policy debate on toys. As a result, consumers' monitoring role would be increased. Their involvement in this mechanism would grant consumers a 'gate-keeper' function in policy decisions relating to the TSD, given that the platform information sharing mechanisms would also be likely to advise and feed possible policy-making.

Finally, this recommendation has a high **relevance**, since requests for further communication and awareness raising around different issues related to the TSD came from all the stakeholder categories concerned with the Directive.

2) To ensure a common market surveillance framework, including minimum standards on market controls

Issue

The evaluation highlights how **the Directive's effectiveness is mainly hindered by difficulties related to its enforcement** - rather than to major legislative gaps or implementation issues. Enforcement shortcomings may be due both to an inadequate allocation of resources to Customs and Market Surveillance Authorities and to a limited coordination among Member States. In particular, there is a general slowness to adapt to new requirements stemming from the Directive's amendments, pointing to the need for public authorities to be provided with more resources and training.

Customs and Market Surveillance Authorities also need guidance on emerging issues that have a cross-border and inter-sectoral dimension – like counterfeit toys increasingly sold online - since they are common occurrences for different Member States and concern multiple industries and markets.

Such obstacles to effective enforcement raise the issue of having a proper balance between different levels of intervention, ensuring the full respect of the principles of subsidiarity and proportionality. Customs and market surveillance are regulated at national level. Furthermore, the effective enforcement of the EU legislation requires a coordinated approach among Member States as national shortcomings have impacts on the whole EU system.

In particular, since Member States have jurisdiction over surveillance activities - including the type and strictness of the sanctions applied - there is a significant fragmentation of market surveillance across Europe. Therefore, the same infringement may be differently punished in different Member States and what is considered as an infringement in one Member State may not be considered so in another Member State. This is also true for toy counterfeiting, since Member States have different approaches to control and punish counterfeiting-related infringements.

Overall, this fragmentation increases the risk of negative spill-overs, as the failure of one Member State in punishing counterfeiters may have side effects in all the other Member States, thus reducing the deterrent effect of controls and facilitating the circulation of unsafe toys across Europe. In this light, Member States' cooperation is very important, since it enhances alignment and consistency among national surveillance practices.

Recommendation

Even though common market surveillance legislation at EU level is not politically feasible since Member States have exclusive jurisdiction in this area, market surveillance could in any case be enhanced through soft regulation and other non-legislative policy tools.

In view of existing examples such as the ECHA Enforcement Forum,[265] the Platform of European Market Surveillance Authorities in Cosmetics (PEMSAC)[266] and the recent Single Digital Market initiative,[267] a **common market surveillance framework** could be introduced, ensuring strong coordination at EU level.

For instance, Customs and Market Surveillance Authorities could be provided with EU guidance on the type and frequency of controls to be carried out so as to increase harmonisation and integration of market surveillance strategies across Member States, particularly emphasizing the national practices related to counterfeit toys.

Guidelines would include minimum standards on market controls also to ensure a balanced approach between large and small firms as well as between renowned and emerging manufacturers. Furthermore, an incentive mechanism based on "past records" could be encouraged so as to reduce the number of controls performed on firms that have had a good compliance record in the past.

Minimum standards could also be suggested as regards sanctions to be applied for different types of infringements. Even though sanctions are regulated at national level, non-mandatory minimum standards of reference would support harmonisation among different national approaches, thus avoiding that the same infringement is differently punished in different Member States.

Cooperation is the prerequisite for information sharing and policy transfer across Member States. This would also be beneficial to find out solutions for new and emerging problems as the experience and background of one Member State may inspire the others.

For instance, as reported in section 5.1.3.2, there are significant differences in online toy sales across Member States. It is likely that Member States with higher shares of online sales have implemented innovative market surveillance systems aimed at well regulating online markets and related problems as compared with Member States with no or low experience of online sales. If this is the case, Member States with advanced online sales surveillance systems may communicate their practices to Member States where online sales are still at an infant stage, contributing to the exchange of good practices while triggering policy learning mechanisms across Europe.

Finally, sharing practices and viewpoints between Member States facing similar problems increases the chance to find out effective and innovative solutions beyond the toy market. Sectoral cooperation mechanisms – like those developed in the toy sector - may thus act as a springboard for policy cooperation in other sectors as policy problems are often horizontal to different areas of intervention.

[265] http://echa.europa.eu/about-us/who-we-are/enforcement-forum

[266] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1465

[267] http://ec.europa.eu/priorities/digital-single-market/

To conclude with an example, discussion on toy 3D printing may inspire regulative tools for 3D printing in general, since this is an emerging issue for market and commercial products that goes beyond toys.

Impact, feasibility and relevance of the recommendation

The recommendation has a **high priority**. The medium score on feasibility is counterbalanced by the high score obtained both in terms of impact and relevance.

The **impact** is high as shortcomings in market surveillance have negative effects on both objectives of the Directive. The unfair and disproportionate implementation of market controls may affect economic operators and their competitiveness, as economic operators will be differently controlled and punished according to the Member State they belong to. Different levels of control and punishment have also negative effects on the safety of children, since non-compliant toys could be made available on the market.

The political **feasibility** is expected to be medium. Member States have exclusive competencies on Custom and Market Surveillance Authorities and may therefore be hesitant, to some extent, to adopt the EU minimum standards, particularly as long as these diverge from current national practices. Such hesitancy could be further sharpened by the voluntary nature of the minimum standards, with Member States being free not to adopt them. Thus the negotiation process would be reasonably affected by the different balance among political interests, lobbying and trade union power at national level. In this view, the political feasibility of this recommendation would depend on the actual commitment of national competent authorities to adopt it. In this regard, Member States are expected to highly commit to the prevention and fight of toy-related crimes, such as counterfeiting. The benefits stemming from this recommendation – taking also account of the advantages for both economic operators and consumers – are indeed expected to balance out Member States' political conflict as regards the design and adoption of common minimum standards for enforcement and the costs to implement cross-border communication and cooperation mechanisms.

In any case, the problems behind this recommendation have a high intensity as they have been strongly pointed out by several stakeholders, confirming the high **relevance** of the recommendation.

3) To ensure 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

Issue

According to the New Approach, the TSD establishes essential safety requirements, leaving the technical details to European harmonised standards. In case no harmonised standard exists to assess specific risks, the conformity assessment shall be carried out by Notified Bodies, who apply their own technical parameters.

Therefore, **different testing methodologies are in place to assess the conformity of toys**, raising concerns for both the safety and the trade of toys. Depending on the Notified Body that performs the assessment, the same toy may indeed be considered compliant by one Notified Body and not by another, hence questioning the overall toy safety and hindering the toy free movement.

Recommendation

Notified Bodies could be provided with indications on **minimum common procedures** to be referred to when assessing the conformity of toys by means of the EC-type examination.

Furthermore, national Notifying Authorities could be provided with minimum requirements – beyond the requirements set in article 26 of the TSD – to select Notified Bodies.

These standards and requirements – although without regulatory power – would push harmonisation among the testing methodologies adopted by different Notified Bodies due to cost-opportunity reasons, thus avoiding the risk of market distortions and safety concerns.

Impact, feasibility and relevance of the recommendation

The recommendation has a **medium priority**. Despite the high impact, the political feasibility is medium and the relevance is even low.

The harmonisation of testing methodologies has effects on both the Directive's objective, thus the **impact** of the recommendation is valued as high. Differences among testing laboratories undermine the safety of toys across Europe as cost-opportunity and other reasons may make the same toy differently assessed according to the test laboratory concerned. At the same time, this poses issues of market competition among different testing laboratories and among economic operators who will be subject to different compliance costs depending on the laboratory they refer to.

With regard to the political **feasibility**, the same reasons discussed for Member States authorities concerned with the previous recommendation, also stand for Notified Bodies and Notifying Authorities. The greater the differences between the EU minimum standards and current practices and the greater the interest in maintaining the status quo, the higher the Notified Bodies' and Notifying Authorities' reluctance in adopting EU minimum standards.

Finally, it should be noticed that the issues behind this recommendation have been raised by economic operators and only three Member States, while they have not emerged from consumer associations. The problem has therefore a limited intensity, reducing the overall **relevance** of the recommendation.

4) To consider measures aiming at improving the Directive's provisions

Issue

The evaluation highlights some **provisions that turned out to be particularly problematic** for stakeholders. First of all, economic operators and consumers do not agree on the effectiveness of current **limits for chemicals** in toys. Furthermore, **warnings** requirements emerged as posing difficulties both in terms of effectiveness and consistency. More precisely, warnings are often written in a too small font size and are not easily readable. Finally, the **safety assessment** process seems to be often highly focused on chemical risks, without taking properly account of the multiple variables in the use of a toy, due to the children's largely unpredictable behaviour.

Recommendation

The problems that emerged with specific provisions would induce amendments to the Directive. Since legislative amendments always entail costs, policy recommendations in this regard should be supported by strong evidence. For instance, changes to current limits for chemical in toys should be justified by strong evidence on safety hazards caused by current

chemical requirements on children's health. Similarly, introducing requirements for the font and size of warnings should rely on a high level of consumers' consensus on this specific need.

By contrast, different stakeholders point to specific difficulties and requests, thus preventing any strong triangulation supporting the need for amending the Directive. As a result, the evidence collected during this study does not allow recommending any legislative intervention before proceeding with further scientific analysis and stakeholder consultation.

Nevertheless, the difficulties raised insofar, even though they are not confirmed by other stakeholder categories, are worth to be mentioned and taken into account in order to maximise the Directive's impacts. In this view, the study recommends to pay attention to these issues in order to further investigate the actual need to modify current legislation.

For example, both economic operators and consumers refer to different scientific opinions as concerns the appropriateness of current limits for chemicals in toys. Since the assessment of tolerable limits for hazardous substances is out of the scope of this study, it would be important to further investigate the validity of the requests for stricter requirements for chemicals as called for by consumer associations.

Furthermore, with respect to the difficulties related to warnings requirements, it would be important to assess the feasibility of using new technologies – like QR codes or other digital tools - in order to increase their clearness and readability.

Finally, the Directive's effectiveness could be enhanced by broadening the scope of the safety assessment in order to take account of the multiple variables in the use of a toy. To this purpose, as also suggested by some stakeholders already referring to this practice, different categories of experts – like psychologists – could be involved when drafting a safety assessment, in order to enhance the overall procedure.

Impact, feasibility and relevance of the recommendation

The recommendation has a **medium priority**. Despite the high impact and relevance, the political feasibility scores low.

The revision of current provisions would have effects on both the Directive's objectives, thus the **impact** of the recommendation is assessed as high. For instance, amendments to chemical limits would aim at increasing the level of toy safety while affecting economic operators who are required to adapt to new requirements. Similarly, new warnings requirements would enhance children's protection and affect manufacturers in charge of putting warnings on toys.

The political **feasibility** is expected to be low as several stakeholder categories would be affected, whose interests are very divergent. In particular, the need for amending current chemical limit values is one of the main issues emerged during the study, with economic operators and consumer associations having quite opposite viewpoints. As a consequence, the different stakeholder categories would play a crucial role in trying to demonstrate the validity of their respective opinions, thus supporting costs and investing time in order to reach their goals. The political consensus on the opportunity to modify the current legislation is expected to be very low, thus inducing a long and conflicting negotiation process.

In any case, since requests for amending current provisions have been raised by economic operators, Member States and consumer associations, the **relevance** of the recommendation is high.

5) To consider measures aiming at improving the Directive's working mechanisms

Issue

The evaluation highlights some **problems related to the context of reference for the Directive's implementation**. In particular, the effectiveness of the Directive turned out to be hindered by two main issues. Firstly, consumers and SMEs denounced an **unbalanced representation of the different stakeholder categories** concerned with the safety and trade of toys to the advantage of big toy manufacturers. Secondly, **the Directive lacks a proper monitoring system** based on up-to-date statistics on toy-related injuries.

Recommendation

Both the stakeholder involvement and the Directive's monitoring do not strictly represent issues of effectiveness as they do not depend on the Directive's design. Nonetheless, they may affect the Directive's performance in achieving its objectives.

A proper balance should be granted among representatives of all stakeholder categories concerned with the TSD, particularly between large manufacturers and SMEs, and between economic operators and consumers. Representatives of all these categories - especially consumers and SMEs - should be regularly involved in all the initiatives affecting the Directive's design and implementation.

The **proper involvement** of stakeholders allows taking account of specific requests and difficulties raised by different actors, thus acknowledging the dynamic and interactive role of the Directive. This is particularly true with regard to the Directive's adaptation mechanisms - including the amendments to the TSD, the standardisation process and the NB-toys initiatives.

By envisaging adaptation mechanisms aimed at aligning the TSD with social, scientific and technological developments, the legislator recognised the need to adapt the legislation to the external changes, without cutting off the surrounding context. However, social, technological and scientific developments differently affect stakeholders based on their specific interests and background. Consequently, the interpretation of context developments and of related legislative and policy initiatives should take account of diverging perspectives, ensuring effective coordination and negotiation mechanisms among different actors.

The importance of involving the organisations representing most affected, or most concerned stakeholders, with specific policy and legislative measures was already acknowledged by the 2011 "standardisation package"[268] that pointed to the stakeholders' involvement – including consumer associations, SMEs, environmental and social organisations - when drafting European standards.

[268] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0311:FIN:EN:PDF

Besides the existing Expert Group on Toy Safety - where all draft amendments of the TSD are discussed with active contributions from economic operators, consumer associations, Member States, the ESOs and Notified Bodies - legislative and policy initiatives should be based on – and take account of – open consultations with relevant stakeholders. The evaluation raises indeed the need for broadening and enhancing inter-actors negotiations on relevant issues.

In addition to a broader stakeholders' involvement, the **monitoring of injuries and accidents due to toys** is another factors increasing the TSD effectiveness, since it allows public authorities and other stakeholders to identify possible risks and to spot what types of products may pose a threat.

As reported in section 4.2.1, over the past years, there have been several projects supported by the European Commission to facilitate EU-level exchange of injury data. Among others, these projects include the establishment of databases providing comparable injury data across Member States and international-wide surveillance systems for specific typologies of risk.

These previous experiences may represent the starting point to finalise and implement a proper monitoring system based on exhaustive and up-to-date statistics relating injuries due to toys across Europe. The matching between what has been already done and current needs would allow identifying major shortcomings and maximise the performance of the new monitoring system.

Impact, feasibility and relevance of the recommendation

The recommendation has a **high priority**. The medium score in terms of political feasibility is counterbalanced by the high score obtained both in terms of impact and relevance.

The **impact** is expected to be high as both a balanced involvement of different stakeholders and the monitoring of toy related injuries would have an influence on both the Directive's objectives. In particular, the higher involvement of SMEs may affect the debate on the toy free movement and related barriers based on the new instances raised by small and micro manufacturers. At the same time, the voice of consumers is expected to nurture the discussion on the relevance and effectiveness of current safety requirements. Up-to-date statistics on toy-related injuries would allow a proper assessment of the Directive's performance in ensuring a high level of safety for toys and this may have also impact on the toy internal market. For instance, a systematic reduction of toy related injuries may induce Member States to decrease the intensity of market surveillance activities as expected by the 2008 Impact Assessment.

The higher the number of stakeholders involved in the policy debate, the higher the number of possible divergent opinions to be taken into account in the negotiation process. As a consequence, the level of consensus on relevant issues at stake may be significantly altered as long as new and different actors enter the policy arena, thus reducing the **feasibility** of this recommendation. However, the possible divergences expected to emerge in the short run may be balanced out in the long term as the stakeholders' involvement in the decision-making process may prevent possible political oppositions at a later stage. The political feasibility would be medium also as regards the establishment of a monitoring system as several stakeholders will be in charge of collecting data and entering them into the system.

In any case, the **relevance** of the recommendation is high as the problems behind it are perceived by multiple categories of stakeholders, including consumer associations, economic operators and Member States.

6) To provide incentives to economic operators to better comply with the Directive

Issue

Manufacturers claim that, since they bear most of the costs entailed by the TSD, some incentives should be provided so as to help them complying with the Directive. In particular, **the high costs needed for performing both safety and conformity assessments may reduce manufacturers' investment in toy innovation**. Further claims concern the **duplication of costs** borne by manufacturers for re-purchasing harmonised standards whenever revised standards apply.

Recommendation

This recommendation deals with non-legislative and proactive mechanisms that could be established in order to increase manufacturers' compliance with the Directive. Manufacturers are, indeed, the stakeholder category in charge of most of the requirements aimed at ensuring the safety of toys. As a result, they bear high compliance costs. This evaluation does not raise any issues relating to unaffordable costs preventing compliance with the Directive. However, the costs entailed by the TSD turned out to be counter-productive sometimes, inducing side effects that may hinder the Directive's overall impact.

In this view, proactive mechanisms may be established in order to overcome these difficulties. For instance, incentives – like subsidies for research activities - could be established in order to stimulate innovation that is currently hindered by the high costs needed for performing both safety and conformity assessments. Further cost reductions may come from discount mechanisms for revised harmonised standards. Finally, manufacturers' compliance may be supported through non-legislative mechanisms in order to increase manufacturers' commitment to toy safety beyond mandatory requirements. A good solution could be promoting the inclusion of the safety of toys into the concept of corporate social responsibility.

Stakeholders' commitment is crucial to enhance the Directive's sustainability. In this view, soft regulation mechanisms may help transform compliance in a social and cultural attitude rather than a simple legislative obligation. This means to create incentives for stakeholders to be compliant, thus facilitating their access to – and understanding of – legislation while making clear the advantages they may benefit from being compliant. Corporate social responsibility is a good example of non-regulatory mechanism focused on the relationship between producers and consumers: the higher consumers' trust in a product manufacturing process is, the higher their inclination to purchase that product.

In the long term, this would ensure a higher level of toy safety thanks to the match between – and mutual support of - legislative obligations and non-regulatory mechanisms. This is in line with EU better regulation principles aiming at ensuring the right balance between protecting people's rights - including safety - while freeing them from unnecessary bureaucracy. In this view, a better regulation consists in the design of policy and legislative measures whose objectives can be achieved at a minimum cost. Efficiency is expected to

come from high levels of clearness, transparency and participation of stakeholders when designing and implementing such measures.

Impact, feasibility and relevance of the recommendation

The recommendation has a **medium priority**. Despite the high impact, the political feasibility scores medium and the relevance is even low.

The suggested incentive mechanisms are expected to have an influence on both the Directive's objectives, thus the **impact** of the recommendation is valued as high. For instance, incentivising manufacturers' investments in research would increase the trade of high-tech and innovative toys while enhancing their safety.

The political **feasibility** is expected to be medium as suggested incentives would entail a redistribution of costs among stakeholders. For instance, in case of discount percentage - compared with the original price - on harmonised standards to be re-purchased following amendment(s) to current standards would imply a cost for the European Standardisation Organisations that would generate less profit. Similarly, the incentives for investments in toy innovation imply direct costs for stakeholders – like the European Commission and Member States – supporting the subsidies.

Finally, the **relevance** of the recommendation is low since the needs behind the suggested mechanisms have been raised only by manufacturers.

7) To improve international alignment of toy safety

Issue

This evaluation raises room for improvement as regards the consistency of the TSD with other relevant policy and legislative measures for toys. First of all, **European and international standards** for toys turned out to be sometimes written in a different way, thus raising possible confusion to stakeholders. In addition, a **better alignment of the requirements for toys across international markets** is crucial to enhance both the safety and trade of toys.

Recommendation

This recommendation is aiming to increase the impact of the Directive beyond the difficulties emerged during the study. In this view, it is not strictly related to specific problems. Rather, it relates to the room for improvement identified on the basis of the overall evaluation process, including the suggestions provided by stakeholders.

The study did not raise major contradictions or overlapping of the TSD with other pieces of legislation in place and both the coherence and the added value of the TSD have been positively assessed. However, some possible enhancements emerge that would be worth taking into account.

To this purpose, the alignment of the TSD with international requirements and standards for toys beyond Europe would be beneficial to both the objectives of the TSD.

The provision of a single and consistent framework of reference would ease stakeholders' understanding of the requirements they are subject to, thus enhancing their overall compliance. For instance, as far as international and European harmonised standards are fully aligned, referring to the former rather than to the latter would have the same effects in terms of toy safety.

Moreover, the harmonisation of the TSD provisions with legislative requirements in place outside Europe would ease the trade of toys as safety parameters are equal irrespective of the place where they are produced. Bearing in mind the complexity required to align legislation in place in different markets, a first step could be the establishment of bilateral agreements with trade partners. This is particularly important with regard to third country suppliers, as European manufacturers would be enabled to obtain materials and products with a guaranteed level of safety.

Toys placed on the EU market already have to comply with the Directive, either if produced in Europe or imported from third countries. Therefore, there is no need for additional requirements in this regard. The objective is not to add new rules, rather to make existing ones as clear as possible in order to maximise their impact. In this view, the highest the harmonisation among rules in place is, the easiest their understanding will be. Stakeholders would indeed subject to the same requirements irrespective of the specific context of reference, thus increasing their awareness of legislation in place and related procedures. The aim of this recommendation is thus to further enhance the compliance and safety of toys by taking a step forward towards the identification of a single legislative and policy framework of reference, thus reducing as far as possible any confusion, duplication and/or overlapping.

Impact, feasibility and relevance of the recommendation

The recommendation has a **medium priority**. Despite the high impact, the political feasibility is medium and the relevance is even low.

As discussed above in this section, the harmonisation of legislative requirements has effects on both the Directive's objective, thus the **impact** of the recommendation is valued as high.

With regard to the political **feasibility**, the reasoning is similar to that discussed in general recommendations 2 and 3. The greater the differences between the EU and other – national and international – requirements and procedures and the greater the interest in maintaining the status quo, the higher the reluctance expected in harmonising rules across different markets.

Finally, it should be noticed that the issues behind this recommendation respond to needs mainly raised by economic operators, thus limiting the overall relevance of the recommendation.

9 ANNEXES

9.1. List of findings

Key finding	Description
1.	Chemical exposure
2.	Choking hazard
3.	Toys in food related hazard
4.	Ingestion hazard
5.	Soft toy related hazard
6.	Noise-related hazard
7.	Scooter toy related hazard
8.	Electric hazard
9.	Flammability hazard
10.	Hygiene hazard
11.	Radiation hazard
12.	The German case
13.	Customs Authorities requesting tests reports instead of the EC DoC
14.	Distributors requesting technical documentation instead of the EC DoC
15.	Distributors and importers lacking awareness on the internal production control procedure
16.	"Grey area" issues
17.	Age classification issues
18.	Different testing methodologies in place
19.	Toy counterfeiting issues
20.	Online sales issues
21.	3D printing issues
22.	MS supporting economic operators with the TSD implementation
23.	MS participation in international standardisation activities
24.	Appropriateness of particular safety requirements
25.	Warnings issues
26.	CE marking issues
27.	Article 42 issues
28.	Specific problems faced by SMEs
29.	Needs for clarification
30.	Needs for unambiguous wording of the TSD
31.	Difficulties with the TSD amendments
32.	Existence of cooperation mechanisms
33.	Market Surveillance Authorities' participation in national standardisation bodies
34.	Communication channels between NB and Notifying Authorities/Market Surveillance Authorities

Key finding	Description
35.	Cooperation among Member States
36.	Cooperation with third countries
37.	Market Surveillance Authorities' strategies for dealing specifically with toy safety
38.	Higher controls faced by large manufacturers
39.	Problems with the technical documentation
40.	Difficulties with the definition of "*prior to placing on the market*"
41.	Problems with EC declaration of conformity
42.	Problems with safety assessments
43.	Sanction-related issues
44.	Member States' sanction levels
45.	Toys notifications in RAPEX
46.	High number of RAPEX notifications coming from China
47.	Frequency in the use of RAPEX information
48.	RAPEX notification lacking risk assessments

9.2. List of specific recommendations

SR	Description
1.	Check the need for more stringent limit values and ensure consumer associations' participation in each Directive's amending initiative.
2.	Ensure participation of consumer associations and SMEs in each Directive's amending initiative, in order to ensure fair representativeness of different stakeholder categories.
3.	Establish a communication system aimed at timely disseminating information on amendments to the Directive to all stakeholders and institutions concerned, including guidelines to understand and manage the notified changes.
4.	Establish communication and cooperation mechanisms among Customs and Market Surveillance Authorities to enhance the exchange of information and practices related to counterfeit toys.
5.	Provide stakeholders with non-legislative policy measures – e.g. guidelines and information material - to support enforcing authorities, economic operators and consumer associations in recognising, avoiding and contesting counterfeit toys.
6.	Ensure the provision of exhaustive and up-to-date statistics on toy-related injuries, including details about the type of injury concerned so as to calculate the real observable damage to children. The system should be based on the regular monitoring and data collection of integrated data from different bodies – including emergency departments, schools, etc.
7.	Establish incentive mechanisms – e.g. subsidies for research - for manufactures investing in toy innovation, particularly in toys for children under 36 months of age – so as to avoid that costs born to comply with the TSD hinder the innovation of toys.
8.	Provide NB with regular training sessions whenever a new Protocol/Recommendation is issued by NB-Toys so as to raise awareness on their contents, thus enhancing the harmonisation of testing methodologies used by NB.
9.	Provide national Notifying Authorities with common minimum requirements to select NB – beyond the requirements set in article 26 of the TSD - in order to prevent major differences in the testing of toy compliance.
10.	Regularly update guidelines on toy classification so as to take into account the difficulties experienced by economic operators in the identification of products as toys.
11.	Provide enforcing authorities - and particularly Customs– with minimum voluntary standards, so as to enhance the harmonisation of national approaches to the toy compliance assessment.
12.	Focus market surveillance activities on new and less renowned companies while reducing the controls on firms revealing to be compliant for many years, having therefore a very good reputation, so as to broaden the market surveillance scope without increasing overall costs.

SR	Description
13.	Provide competent authorities and economic operators with guidance and regular EU training sessions so as to raise awareness on the Directive's working mechanisms, particularly in case legislative changes occur.
14.	Discuss the feasibility of amending the warning provision so as to increase its effectiveness. An option could be the use of QR codes while detailing warnings on the firms' websites.
15.	Review RAPEX systematically, based on the suggestions expressed by stakeholders as well as on external developments like technological advancements.
16.	Continue and intensify the provision of information by industry associations', also through the establishment of horizontal information sharing mechanisms among industry associations based in different Member States in order to enhance the transfer of knowledge and information.
17.	Enlarge the scope of the safety assessment by involving different categories of experts – including psychologists, in order to fully take account of the complexity of play value.
18.	Provide economic operators with guidance – e.g. through the Blue Guide - raising awareness on the existence of confidentiality agreements to avoid the disclosure of sensitive information along the supply chain.
19.	Provide SMEs with clear and updated guidelines helping them to comply with the safety requirements without drawing upon external consultants.
20.	Grant a significant discount percentage - compared with the original price - on harmonised standards to be re-purchased following amendment(s) of the standards.
21.	Introduce a "grace period" in order to allow already produced toys to be still sold under the old safety requirements.
22.	Establish a sort of "presumption of conformity mechanism" granting a reduction of the frequency of compliance tests on manufacturers who always rely on the same supplier and/or use the same raw materials already declared to be compliant in the past.
23.	Draft guidelines providing comparative overviews on the relationship between the TSD and the other main EU pieces of legislations relevant for toys so as to avoid any possible confusion for stakeholders dealing with more than one piece of legislation at the same time. They shall also include explanations on how the same provision – e.g. the product testing – is applied in different sectoral legislations.
24.	Use the warnings listed in ENs into Annex V of the Directive in order to ensure consistency.
25.	Align legislative requirements for toys across international markets so as to induce global – and not just European – added value.
26.	Avoid any contradiction between European and international standards so as to enhance overall toy safety.

SR	Description
27.	Implement bilateral agreements between the EC and important trade partners so as to make toy imports into the EU increasingly compliant.
28.	Incorporate the safety of products – including toys – in the concept of corporate social responsibility so as to boost manufacturers' compliance attitude through proactive mechanisms (in addition to the legislative approach based on mandatory requirements).

9.3. Cross-referencing evidence table

The following cross-reference table displays the interrelations between the evaluation questions, the findings from both the desk and field research and related sources of information and suggested specific recommendations.

Evaluation question	Key findings	Evidence sources	Specific recommendations
RELEVANCE			
EQ1. To what extent do the objectives of the 2009 Directive (still) correspond to current needs/issues?	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 19, 20, 21, section 2.2.2.3	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: relevant literature on toy safety; ECSIP study on toy sector; scientific studies on chemical issues; 2008 IA; protocols and recommendations; RAPEX notifications.	From SR 1 to SR 5
EQ2. To what extent do the adaptation mechanisms of the 2009 Directive follow technological, scientific and social developments?	17 and section 2.2.2	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: relevant literature on toy safety; scientific studies on chemical issues; protocols and recommendations.	
EFFECTIVENESS			
EQ3. To what extent has the 2009 Directive contributed to the enhancing of the level of safety of toys while maintaining the smooth functioning of the internal market for toys?	12, 18, 25, 26, 28, 31, 39	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: relevant literature on toy safety; scientific studies on chemical issues; RAPEX notification.	From SR 6 to SR 17

Evaluation question	Key findings	Evidence sources	Specific recommendations
EQ4. What are the barriers to effective application and enforcement, in particular through surveillance of toys on the market, if any? How could any such barriers be overcome?	13, 16, 17, 18, 20, 25, 28, 38, 39, 40, 41, 43	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: relevant literature on toy safety.	
EQ5. Are there any aspects/means/actors that render the 2009 Directive more or less effective, and – if there are – what lessons can be drawn from this?	12, 13, 14, 15, 39, 45, 46, Figure 5 and Table 5	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: RAPEX notifications.	
EQ6. What, if anything (including non-legislative action), could be done to render the 2009 Directive more effective as a means to achieve its objectives?		Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: relevant literature on toy safety; scientific studies on chemical issues.	
EQ7. Does the legal form (Directive versus Regulation) have an influence on the effectiveness with which the objectives are reached?	16, 17, 31	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety.	
EFFICIENCY			
EQ8. Main efficient/inefficient Directive's provisions and related impacts in terms of administrative and reporting burdens on stakeholders.	18, 25, 28, 31,	Primary: Member States; economic operators; consumer associations; ESOs; expert on toy safety.	From SR 18 to SR 22
EQ9. Unnecessary costs and suggestions to reduce costs/ administrative burdens.	13, 14	Primary: Member States; economic operators; consumer associations; expert on toy safety.	

Evaluation question	Key findings	Evidence sources	Specific recommendations
COHERENCE			
EQ10. Are there overlaps/complementarities between the 2009 Directive and any pieces of EU legislation or Member State acts in the relevant areas, in particular with regard to the limit values for chemicals set out in the 2009 Directive? Are there contradictions?	22 and Box 10	Primary: Member States; economic operators; consumer associations; NBs; expert on toy safety. Secondary: scientific studies on chemical issues; EU relevant legislation for toys.	SR 23 and 24
EQ11. What can be done to optimise the relationship between them?	36 and Box 7	Primary: Member States; economic operators; consumer associations; expert on toy safety. Secondary: scientific studies on chemical issues; EU relevant legislation for toys.	
ADDED VALUE			
EQ12. Additional value resulting from the 2009 Directive.	12	Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: scientific studies on chemical issues; protocols and recommendations.	From SR 25 to SR 28
EQ13. The added value of the 2009 Directive for stakeholders.		Primary: Member States; economic operators, consumer associations, NBs, ESOs, expert on toy safety. Secondary: scientific studies on chemical issues.	

9.4. Interview guidelines

The aim of this evaluation exercise is to assess whether the 2009 Directive is effective in **ensuring a high level of safety of toys, while guaranteeing the functioning of the internal market**.

The evaluation framework is organised around five criteria, i.e. the Directive's **relevance** as concerns current needs, the **effectiveness** in relation to its objectives, the **coherence** with other legislative measures, the overall **efficiency**, and the **EU added value**.

Face-to-face and skype interviews with relevant stakeholders represent one of the main data collection tools for this evaluation. The table below presents the main issues discussed during the interviews.

Table 13 - Issues to be discussed and categories of stakeholders

Issues to be discussed	Industry associations	Manufacturers, importers and distributors	Consumers' associations	Notified Bodies	Standardisation Organisations
RELEVANCE					
Current **safety risks** and extent of the Directive in covering these risks.	X	X	X	X	X
Impact of **irregular toys** on both the safety of consumers and the competition in the Internal Market.	X	X	X	X	X
Perception of economic operators on the Directive's pertinence in ensuring a smooth functioning of the internal market for toys.	X	X	X	X	X
Safety risks and market concerns related to **toy internet purchases, 3D printing, counterfeiting,** and **second-hand toys sales**.	X	X	X	X	
Alignment of the Directive with current **scientific, technological and social progress**.	X	X	X	X	X
Clearness of the **definition of toys** and problems with the **"grey area",** including best practices to deal with borderline products.	X	X	X	X	X
Exceptions that should be added to or deleted from **Annex I** (products that are not considered to be toys) or in **Article 2(2)** (toys to which the TSD does not apply).	X	X	X	X	X
Need to adapt, complete or rephrase the particular safety requirements in Annex II.	X	X	X	X	X

Issues to be discussed	Industry associations	Manufacturers, importers and distributors	Consumers' associations	Notified Bodies	Standardisation Organisations
Main risks not covered by particular safety requirements and suggestions on how to deal with them.	X	X	X	X	X
EFFECTIVENESS					
Contribution of the Directive in reducing the **number of accidents/safety risks** related to toys.	X	X	X	X	X
Contribution of the Directive in facilitating the **trade of toys** among Member States and import from third countries. Any problems related to different levels of the Directive's harmonisation?	X	X		X	
Need for additional **guidance/interpretation** on specific points of the TSD.	X	X	X	X	
Need to introduce changes in the **conformity assessment** procedures.	X	X		X	
Clearness of the rules for affixing the **CE marking**, with a particular focus on SMEs.	X	X			
Problems to adapt to new requirements stemming from the **amendments** to the Directive.	X	X		X	
Best ways to deal with **hazardous chemicals** for which no regulatory provisions are in place.	X	X	X	X	X
Particular problems related to toy **warnings**.	X	X	X		
Appropriateness of **sanctions** in place.	X	X	X		

Issues to be discussed	Industry associations	Manufacturers, importers and distributors	Consumers' associations	Notified Bodies	Standardisation Organisations
Main obstacles to the effective (cross border) **enforcement** of the Directive.	X	X	X	X	X
Frequency in using information published on the **RAPEX website**.	X	X	X	X	
Reasons behind the high share of **RAPEX notifications** of unsafe toys.	X	X	X	X	
Official channels of **communication** with the Notifying Authority or the MSA to find solutions to practical problems.	X	X	X	X	
Are you aware of any **unintended consequences** related to the implementation of the Directive?	X	X	X	X	X
EFFICIENCY					
Costs and administrative burdens including procedural costs to comply with the Directive's provisions; informative/procedural costs to comply with other EU relevant legislations; informative costs to keep up with the Directive's amendments.	X	X		X	
Duplications of costs due to overlapping / contradiction between the TSD and other legislations.	X	X		X	
Duplications of costs due to differences among international and European standards.	X	X		X	
Specific costs faced by SMEs.	X	X			
Suggestions to reduce costs and administrative burdens.	X	X		X	

COHERENCE					
Contradictions/overlapping among the toy safety requirements set out in different pieces of legislation (EU and national level), including suggestions to harmonise them.	X	X	X	X	X
Need for aligning the **wording of European harmonised standards related to toys** to that used in the **Directive**.	X	X	X	X	X
Problems due to the existence of **different national requirements relating to chemicals**.	X	X	X	X	
Existence and **impact of national legislation** including toy safety requirements not foreseen by the Directive.	X	X	X	X	
Suggestions to optimise the relationship between the different pieces of legislation (EU and national level) and international standards in place.	X	X	X	X	
Specific problems with the documents required by different **national customs** to check toy compliance.	X	X			
ADDED VALUE					
Benefits stemming from an **EU Directive instead of national legislations,** in terms of toy safety and market (including the import of toys in the EU).	X	X	X	X	X
Benefits related to the establishment of **common methodologies for toy testing** at EU level.	X	X	X	X	X
International/European initiatives (e.g. WHO legislation) having influence/impact on toy safety standards.	X	X	X	X	X

GENERAL REMARKS					
Suggestions to increase the **impact of the Directive**.	X	X	X	X	X
Suggestions to further enhance the level of **toy safety**.	X	X	X	X	
Best practices to recommend.	X	X	X	X	X

9.5. List of involved stakeholders

The following table shows the complete list of all stakeholders involved in the interviews (F2F = Face-to-face interview).

N.	MS	Category	Type
1.	**AT**	Consumer association	Skype
2.	**EU**	Consumer association	Skype
3.	**EU**	Consumer association	F2F
4.	**BE**	Distributor/Manufacturer – Large	F2F
5.	**DE**	Distributor – Large	Skype
6.	**ES**	Distributor – Large	F2F
7.	**IT**	Distributor/Importer – SME	F2F
8.	**PL**	Distributor/Importer – SME	Skype
9.	**BG**	Industry association	Skype
10.	**DE**	Industry association	F2F
11.	**ES**	Industry association	F2F
12.	**EU**	Industry association	F2F
13.	**EU**	Industry association	F2F
14.	**FR**	Industry association	F2F
15.	**FR**	Industry association	F2F
16.	**FR**	Industry association	Skype
17.	**IT**	Industry association	F2F
18.	**IT**	Industry association	F2F
19.	**NL**	Industry association	F2F
20.	**PL**	Industry association	F2F
21.	**UK**	Industry association	F2F
22.	**UK**	Industry association	F2F
23.	**BE**	Manufacturer/Distributor/Importer – Large	F2F
24.	**BE**	Manufacturer – Large	F2F
25.	**DE**	Manufacturer – Large	F2F
26.	**DK**	Manufacturer – Large	Skype
27.	**FR**	Manufacturer - Large	F2F
28.	**IT**	Manufacturer – Large	F2F
29.	**IT**	Manufacturer/Distributor/Importer - Large	F2F
30.	**NL**	Manufacturer - Large	F2F
31.	**UK**	Manufacturer – Large	F2F
32.	**DE**	Manufacturer – SME	Skype
33.	**DE**	Manufacturer/Distributor – SME	Skype
34.	**ES**	Manufacturer/Distributor – SME	F2F
35.	**ES**	Manufacturer - SME	F2F
36.	**NL**	Manufacturer - SME	F2F
37.	**PL**	Manufacturer – SME	Skype
38.	**PL**	Manufacturer – SME	Skype
39.	**PL**	Manufacturer – SME	F2F
40.	**UK**	Manufacturer – SME	F2F
41.	**UK**	Manufacturer – SME	F2F

N.	MS	Category	Type
42.	**IT**	Manufacturer – Micro	F2F
43.	**CZ**	Notified Body	Skype
44.	**EU**	Notified Body	F2F
45.	**UK**	Expert on toy safety	Skype
46.	**EU**	Standardisation Organisation	F2F
47.	**EU**	Standardisation Organisation	F2F

9.6. List of RACER indicators

The table below outlines the indicators used for the evaluation and the related RACER assessment.

Relevance indicators	RACER evaluation
EU consumption[269] of toys in terms of volume and value	• **Relevant** → + market size affects the number of stakeholders affected • **Accepted** → + widely seen as a broad measure of market performance • **Credible** → + stakeholders understand key market data and the link to the objectives of the Directive • **Easy** → + market figures already exist or can be collected • **Robust** → + figures are widely used and scrutinised externally
Perceptions of EU consumers on toy safety	• **Relevant** → + perceptions of EU consumers are directly related to the objectives of the Directive • **Accepted** → + widely seen as a broad measure of market performance • **Credible** → + stakeholders understand the link between perceptions of EU consumers and relevance of the Directive • **Easy** → + stakeholder views can be collected through primary research • **Robust** → - understanding of investigated parameters might differ across EU consumers
Trends in accidents as gathered through desk research and reported by stakeholders	• **Relevant** → + safety and accidents are directly related to the objectives • **Accepted** → + widely accepted as relevant by all stakeholders • **Credible** → + stakeholders understand the link between the objectives of the Directive and accidents / threats • **Easy** → - injury figures (beyond RAPEX notifications) do not exist and are difficult to estimate at EU level • **Robust** → - due to lack of data directly related to toys this indicator can be misleading

[269] Including both production and import.

Number of health risks and issues emerged then being object of an adaptation mechanism	• **Relevant** → + safety and accidents are directly related to the objectives • **Accepted** → + widely accepted as relevant by all stakeholders • **Credible** → + stakeholders understand the link between the objectives of the Directive and accidents/threats • **Easy** → - injury figures do not exist and are difficult to estimate at EU level • **Robust** → - due to lack of data directly related to toys this indicator can be misleading
Number of complaints filed for non-compliant toys as reported by stakeholders	• **Relevant** → + safety and accidents are directly related to the objectives of the Directive • **Accepted** → + widely accepted as relevant by all stakeholders • **Credible** → + stakeholders understand the link between the objectives of the Directive and accidents / threats • **Easy** → - injury figures do not exist and are difficult to estimate at EU level • **Robust** → - due to lack of data directly related to toys this indicator can be misleading
Effectiveness indicators	**RACER evaluation**
Trends in the number of accidents related to toys before and after the implementation of the Directive as reported by stakeholders and qualitatively assessed in the literature	• **Relevant** → + before/after comparison of accidents is key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how accidents and complaints relate to safety and internal market • **Easy** → - injury figures do not exist and are difficult to estimate at EU level / - relevant accident data are difficult to obtain/ do not exist • **Robust** → - accidents data can be manipulated

Stakeholders' perception on the benefits resulting from a regulation	• **Relevant** → + stakeholder perceptions are key to assess the efficiency of the regulation / + Stakeholders' perception is key to assess the possible impact of different policy instruments • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how accidents and complaints relate to safety and internal market • **Easy** → + stakeholder perceptions can be assessed through primary data collection • **Robust** → - understanding of investigated parameters might differ across EU consumers
Number of infringement procedures against MS	• **Relevant** → + number of formal notice is key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how infringement procedures relate to safety and internal market • **Easy** → + data on infringements are available • **Robust** → + data available is generally not contested by stakeholders
Number of toys recalled/withdrawn from the market due to safety issues	• **Relevant** → + before/after comparison of RAPEX filings are key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how accidents and complaints relate to safety and internal market • **Easy** → + RAPEX data are available / - relevant accident data are difficult to obtain / do not exist • **Robust** → - accidents data can be manipulated
Number of accidents due to toys per Member State	• **Relevant** → + before/after comparison of accidents and RAPEX filings are key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how accidents and complaints relate to safety and internal market • **Easy** → - relevant accident data are difficult to obtain / do not exist • **Robust** → - accidents data can be manipulated (see also comment under "Relevance")

Number of RAPEX notifications and trends	• **Relevant** → + before/after comparison of RAPEX filings are key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how notifications relate to safety and internal market • **Easy** → + RAPEX data are available ◉ **Robust** → + RAPEX data are generally not contested by stakeholders
Number of notifications sent by the Member States to the EC	• **Relevant** → + number of notifications are key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how accidents and complaints relate to safety and internal market • **Easy** → + RAPEX data are available ◉ **Robust** → + stakeholders recognise the validity of RAPEX data
Percentage of requests for corrective measures due to not-compliant toys	• **Relevant** → + before/after comparison of requests are key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how the number of corrective measures relate to safety and internal market • **Easy** → + data is available ◉ **Robust** → + data available is generally not contested by stakeholders
Number of inspections carried out by market surveillance authorities	• **Relevant** → + before/after comparison of RAPEX filings are key to measuring effectiveness • **Accepted** → + clearly related to the achievements of the Directive in terms of single market and safety • **Credible** → + stakeholders understand how inspections and complaints relate to safety and internal market • **Easy** → + data is available ◉ **Robust** → + Data available is generally not contested by stakeholders

Efficiency indicators	RACER evaluation
Overall number of obligations that imply administrative and other compliance costs as reported by stakeholders	• **Relevant** → + cost estimates and number of obligations are key efficiency aspects • **Accepted** → + stakeholders agree that costs, time and number of obligations are key efficiency aspects • **Credible** → + all stakeholders understand the link between cost / obligations and efficiency / - cost figures from industry will be seen to be biased and may be contested by other stakeholders • **Easy** → - cost data need to be collected in primary research and there will be a high level of uncertainty around estimates / + legal obligations can be assessed through desk research • **Robust** → - costs will vary significantly over time and across stakeholder groups thus leading to different perspectives / - the number of obligations per se does not give an indication of costs (e.g. more different but clear obligations might lead to lower costs than broad, vague obligations with different interpretations at national level)
Cost impacts per each of the Directive's provision as reported by stakeholders	• **Relevant** → + cost estimates and number of obligations are key efficiency aspects • **Accepted** → + stakeholders agree that costs, time and number of obligations are key efficiency aspects • **Credible** → + all stakeholders understand the link between cost/obligations and efficiency / - cost figures from industry will be seen to be biased and may be contested by other stakeholders • **Easy** → - cost data need to be collected in primary research and there will be a high level of uncertainty around estimates / + legal obligations can be assessed through desk research • **Robust** → - costs will vary significantly over time and across stakeholder groups thus leading to different perspectives / - the number of obligations per se does not give an indication of costs (e.g. more different but clear obligations might lead to lower costs than broad, vague obligations with different interpretations at national level)
Qualitative assessment of the benefits achieved for citizens and European businesses (in terms of safety and internal market)	• **Relevant** → + understanding benefits is key to assess cost-benefit aspects of the Directive • **Accepted** → + stakeholders agree that benefits are key efficiency aspects • **Credible** → + all stakeholders understand the link between benefits/ obligations and efficiency • **Easy** → + qualitative assessment of benefits can easily be collected in primary research • **Robust** → - benefits will be difficult to monetise

Perception of economic operators on the costs faced to comply with the Directive	• **Relevant** → + cost estimates and number of obligations are key efficiency aspects • **Accepted** → + stakeholders agree that costs, time and number of obligations are key efficiency aspects • **Credible** → + all stakeholders understand the link between cost/obligations and efficiency / - cost figures from industry will be seen to be biased and may be contested by other stakeholders • **Easy** → - cost data need to be collected in primary research and there will be a high level of uncertainty around estimates / + legal obligations can be assessed through desk research • **Robust** → - costs will vary significantly over time and across stakeholder groups thus leading to different perspectives / - the number of obligations per se does not give an indication of costs (e.g. more different but clear obligations might lead to lower costs than broad, vague obligations with different interpretations at national level)
Number of cost/burden duplications as reported by stakeholders	• **Relevant** → + cost estimates and number of obligations are key efficiency aspects • **Accepted** → + stakeholders agree that costs, time and number of obligations are key efficiency aspects • **Credible** → + all stakeholders understand the link between cost / obligations and efficiency / - cost figures from industry will be seen to be biased and may be contested by other stakeholders • **Easy** → - cost data need to be collected in primary research and there will be a high level of uncertainty around estimates / + legal obligations can be assessed through desk research • **Robust** → - costs will vary significantly over time and across stakeholder groups thus leading to different perspectives / - the number of obligations per se does not give an indication of costs (e.g. more different but clear obligations might lead to lower costs than broad, vague obligations with different interpretations at national level)

Perception of stakeholders on the time needed to comply with the Directive's requirements	• **Relevant** → + cost estimates and number of obligations are key efficiency aspects • **Accepted** → + stakeholders agree that costs, time and number of obligations are key efficiency aspects • **Credible** → + all stakeholders understand the link between cost/obligations and efficiency / - cost figures from industry will be seen to be biased and may be contested by other stakeholders • **Easy** → - cost data need to be collected in primary research and there will be a high level of uncertainty around estimates / + legal obligations can be assessed through desk research • **Robust** → - costs will vary significantly over time and across stakeholder groups thus leading to different perspectives / - the number of obligations per se does not give an indication of costs (e.g. more different but clear obligations might lead to lower costs than broad, vague obligations with different interpretations at national level)
Coherence indicators	**RACER evaluation**
Number of overlapping elements and contradictions between the TSD on the one hand, and the EU and national legislation in the scope of the analysis on the other hand	• **Relevant** → - the number of provisions does not indicate the extent of the burden of each provision • **Accepted** → + all stakeholders accept that conflicting obligations are a coherence issue • **Credible** → - there will be different perspectives on what is conflicting among stakeholders • **Easy** → + can be done through legal desk research / + information can be found in the national reports • **Robust** → + the number of obligations is a factual indicator / - the number of provisions does not say much about the burden of each / - there will be differences in opinion about whether two provisions are conflicting
Possible options identified to optimise the EU and national legislations/Proposals put forward in the EU or at Member State level	• **Relevant** → - the number of provisions does not indicate the extent of the burden of each provision • **Accepted** → + all stakeholders accept that conflicting obligations are a coherence issue • **Credible** → - there will be different perspectives on what is conflicting among stakeholders • **Easy** → + can be done through legal desk research / + information can be found in the national reports • **Robust** → + the number of obligations is a factual indicator / - the number of provisions does not say much about the burden of each / - there will be differences in opinion about whether two provisions are conflicting

EU added value indicators	RACER evaluation
Number of products recalled from all EU markets as a result of a violation of the Directive	• **Relevant** → + trade related indicators directly link to single market objectives and injury indicators relate to EU level safety objectives • **Accepted** → + stakeholders agree that there is a close link between EU added value and reduction of differences across Member States • **Credible** → + stakeholders understand the link between EU intervention and reduction of differences in accidents and market access • **Easy** → + market related indicators exist and can be measured / - injury related indicators need to be collected • **Robust** → + market data come from reputable sources that are not generally contested / - injury related indicators need to be estimated, leading to less robustness
Reduction in toy-related injuries rates at EU level as reported by stakeholders	• **Relevant** → + trade related indicators directly link to single market objectives and injury indicators relate to EU level safety objectives • **Accepted** → + stakeholders agree that there is a close link between EU added value and reduction of differences across Member States • **Credible** → + stakeholders understand the link between EU intervention and reduction of differences in accidents and market access • **Easy** → + market related indicators exist and can be measured / - injury related indicators need to be collected • **Robust** → - injury related indicators need to be estimated, leading to less robustness

Reduction in differences in toy-related injury rates across Europe based on data provided in the national reports	• **Relevant** → + trade related indicators directly link to single market objectives and injury indicators relate to EU level safety objectives • **Accepted** → + stakeholders agree that there is a close link between EU added value and reduction of differences across Member States • **Credible** → + stakeholders understand the link between EU intervention and reduction of differences in accidents and market access • **Easy** → + market related indicators exist and can be measured / - injury related indicators need to be collected • **Robust** → + market data come from reputable sources that are not generally contested / - injury related indicators need to be estimated, leading to less robustness
Stakeholders' perception on the benefits resulting from a common regulation	• **Relevant** → + trade related indicators directly link to single market objectives and injury indicators relate to EU level safety objectives • **Accepted** → + stakeholders agree that there is a close link between EU added value and reduction of differences across Member States • **Credible** → + stakeholders understand the link between EU intervention and reduction of differences in accidents and market access • **Easy** → + market related indicators exist and can be measured / - injury related indicators need to be collected • **Robust** → + market data come from reputable sources that are not generally contested / - injury related indicators need to be estimated, leading to less robustness

9.7. List of information sources

9.7.1. Information sources mentioned in the report

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