Impact Assessment Study on a possible Revision of the Toy Safety Directive 2009/48/EC - Survey for SMEs

Introduction

Thank you for taking the time to participate in this survey for the 'Impact Assessment Study on a possible Revision of the Toy Safety Directive 2009/48/EC', commissioned by the Directorate-General for internal market, industry, entrepreneurship and SMEs.

The objective of the study is to understand the impacts of key options for a revision of the Directive, drawing from the experience deriving from the implementation and application of the Directive.

Through this survey, we seek to understand how the current Toy Safety Directive and a potential revision of it would impact your business.

All the information provided, including your personal details, will be treated confidentially, respecting the European Commission's standards on data protection. The information will be analysed in an aggregated manner together with data collected through other means, thereby ensuring full confidentiality.

The survey contains mostly questions with pre-defined answers and should not take longer than 15-20 minutes to complete.

1. In what State (or States, please select all that apply) are you based? *

2. In what State (or States, please select all that apply) do you operate? *

Background information on your company

3. What is your organisation's size? *

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)

4. Which type of products (toys) are you working with? *

5. How many toy models / products (Stock Keeping Unit (SKU)) are in your portfolio? *
Number:

6. Have some of the toys that you produce ever undergone an EU-type examination under the Toy Safety Directive? *

- Yes
- No

TIE : Hereunder is an extract of the TSD guidance document (brown text – direct extract from the TSD when bolded) that explains the two possible conformity assessment procedures (self-verification (testing to harmonised standards) or EC-Type examination (requires the involvement of a notified body for toys established in the EU)):

Article 19 The applicable conformity assessment procedures

4.2.1. Article 19 (1)

Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in paragraphs 2 and 3 to demonstrate that the toy complies with the requirements set out in Article 10 and Annex II.

Article 4 (2) of the Directive foresees an obligation for the manufacturer to carry or have carried out a conformity assessment procedure in accordance with Article 19. Article 19 (1) repeats this obligation which is carried out with a view of demonstrating that the toys comply with the essential safety requirements set out in the Directive. It has to be carried out before placing the toy on the market.

4.2.2. Article 19 (2)

If the manufacturer has applied harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the toy, it shall use the internal production control procedure set out in Module A of Annex II to Decision No 768/2008/EC.

Article 19 (2) foresees the conditions for the use of internal production control (Module A). It shall be used if the manufacturer has applied the harmonised standards the references of which have been published in the Official Journal of the European Union. These harmonised standards need to cover the relevant safety requirements for the toy, or in other words cover all the hazards that the toy may present. If such harmonised standards do not exist, or they do not cover all requirements of the TSD, the internal production control (module A) cannot be used.

The internal production control shall be carried out using the procedure set out in Module A of Annex II to Decision No 768/2008/EC. See also the 'Blue Guide' (http://ec.europa.eu/growth/single-market/goods/index_en.htm). It is important to note in this context that point 2 of the Module A includes a provision on the technical documentation when this module is applied. One of the points include “a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied.” However, since Module A for toys can only be used when harmonised standards have been applied, the last part of the sentence “descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied” is not applicable in case of toys, but the harmonised standards need to be included and applied fully.

In the following cases, the toy shall be submitted to EC-type examination, as referred to in Article 20, together with the conformity to type procedure set out in Module C of Annex II to Decision No 768/2008/EC:
(a) where harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering all relevant safety requirements for the toy, do not exist;
(b) where the harmonised standards referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;
(c) where one or more of the harmonised standards referred to in point (a) has been published with a restriction;
(d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

Article 19 (3) foresees in which cases the toy has to be submitted for a certification by a third party, which consists of EC-type examination combined with the conformity to type procedure. The first is the case when harmonised standards the references of which have been published in the Official Journal of the EU, covering all the safety requirements for the toy, do not exist. The second case is when such standards exist but the manufacturer has not applied them or has applied them only in part. The third case is when such standards or any of them have been published with restriction which applies to the toy in question. 54 Finally, the toy shall be submitted to the EC-type examination when the manufacturer considers that the nature, design, construction or purpose of the toy necessitates third party verification. This last case is a novelty, since under Directive 88/378/EEC this possibility did not exist. Under the new Directive, manufacturers have this obligation if they consider that the toy necessitates third party verification.

The EC-type examination shall be carried out using the procedures specified in Article 20. EC-type examination always needs to be combined with the conformity to type procedure which has to be carried out using the procedure set out in Module C of Annex II to the Decision No 768/2008/EC

In a very wide majority of the cases (more than 99.5%), and as a result of an appropriate safety assessment, compliance with toy safety harmonised standards, TSD Appendix C restrictions and other applicable pieces of EU legislation (such as REACH Annex XVII) is sufficient. EC type examination is not necessary. An example of when it could be required is for certain inflatable activity toys (such as a castle with a blower).

7. If Yes: Have any of the toys you produce ever be found to be non-compliant to the EU-type approval? What were the reasons? Please tick all the relevant boxes.

- No, all of the toys have been found compliant
- Risk of choking
- Risk of general injuries
- Risk of chemicals
- Risk of suffocation
- Risk of damage to hearingμ
- Risk of strangulation
- Risk of burns
- Missing/ wrong technical documentation
- Missing/ incorrect labelling

Current issues of the Toy Safety Directive

As you may be aware, the European Commission has undertaken an evaluation of the Toy Safety Directive (TSD) in 2020. The evaluation of the TSD identified a number of issues in the application of the Directive and two major problems to address.

8. On a scale of 1-5 (1 being not problematic at all, and 5 being very highly problematic) how important are the problems of the Toy Safety Directive cited below for your company?

	1 (not problematic at all)	2 (rather not problematic)	3 (problematic)	4 (rather problematic)	5 (very problematic)	I do not know – No opinion
Lack of safety of some toys for children *						
Lack of compliance of toys on the market with the Toy Safety Directive *						
Other options						

TIE : This question refers to 'problems of the Toy Safety Directive' (according to the consultant/European Commission) and lists 'Lack of safety of some toys for children'. We have asked the consultant what is meant with this and how does it differ from the next problem 'Lack of compliance of toys on the market with the Toy Safety Directive'.

'Lack of safety of some toys for children

This probably relates to the fact that the Commission and some stakeholders believe the current chemical limits are not strict enough. For example to protect child safety, it has been suggested to:

- Remove /change current derogations for CMRs would like
- Additional requirements in the TSD (such as generic restriction for chemical substances (e.g. endocrine disruptors) that have a different classification than CMR or the potential need of extending the current TSD Appendix C (restrictions of chemicals for toys for children below 3 years old) restrictions to all toys.

If companies believe toys currently compliant are safe, they should select answer 1 or 2. If they believe there is an issue withs safety of compliant toys, they should select 3, 4 or 5.

'Lack of compliance of toys on the market with the Toy Safety Directive'

This seems to refer to rogue traders/difficulties from market surveillance to control the EU market.

Other option

Companies can highlight other problems, some ideas: ineffective market surveillance, online sellers, chemical limits that are too strict and therefore punish compliant companies.

Current costs

9. Currently, what are the main causes of administrative burden, linked to the application of the Toy Safety Directive, in your company?

10. Currently, what could help you, as a SME, to lower the costs/ administrative burden linked to the application of the Toy Safety Directive?

11. Can you estimate the costs, per new Stock Keeping Unit (SKU), of specific actions potentially required by a revised Directive (in some cases already required for some products)?

	Staff costs (in number of working days per new SKU)	What type of staff is mainly responsible for this work	Outsourcing costs (in EUR per new SKU)	Equipment costs (in EUR per new SKU)	Total costs of process in % of total expected revenues
What are the costs for you of an EU type examination before introducing a new product (toy)?					
What are the costs for you of testing your products (toys) in general?					
What are the costs of replacing / redesigning a new product if the product is found to be not compliant (or not compliant any more due to new regulations)?					
What are the costs of adapting the labels indicating the chemical content of a product?					
What would be the costs of making available the declaration of conformity in your website (per toy model)?					
What would be the costs of registering the link to your website in a database?					
Other					

Kommentiert [LV-T1]: For example if certain substances are banned- - or have limit values divided by a factor of 10

TIE: we think it's important to show here what would it cost to have to submit certain toys (see Pre-market authorisation – question 17 below for details) to a mandatory third-party evaluation (EC type examination). This evaluation can only be performed by Notified Bodies

(NB) established in the EU (see Nando website). This means that toys will need to be sent to NB in the EU to be evaluated. The full details of the evaluation steps can be found in Module B of Annex II to Decision 768/2008/EC (see link).

NB will have to review the mandatory safety assessment carried out by the manufacturer and determine whether testing/evaluation may be necessary in addition to what the manufacturer has already done. NB may not accept test reports from other companies than theirs (e.g. Intertek may not accept test reports from TUV) to complete their evaluation, which means that new testing may be necessary.

We can also question the value of this Pre-market authorisation step if the role of NB here will be to review what has already been adequately done by reputable economic operators and is limited to review of compliance with harmonised standards and other applicable pieces of EU legislation.

The TSD also requires that:

The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.

12. If you selected "other", please explain your choice:

13. What is the number of new Stock Keeping Unit (SKU), per year, to which the administrative costs would apply?
Number:

Costs of the revision of the Toy Safety Directive (2)

Impacts of potential policy measures

The revision of the Toy Safety Directive is aiming to achieve the following two main objectives:

- The revision should make compliant toys even more secure for patients, and
- The revision should help reducing the number of non-compliant toys on the toy market in the EU.

Four specific measures considered in the policy options to achieve those objectives could be especially relevant:

- Introducing new limit values for toys or lowering the limit values (e.g., for nitrosamines) following the newest scientific evidence.
- Banning some chemicals from toys altogether (e.g., for endocrine disruptors).
- Extending pre-market authorisation (third party conformity assessment) to more type of toys.
- Introducing a digital passport for toys.

The survey will ask about all four potential changes in turn:

Limit values: Measures could include:

- Allowing setting, and easily amending, limit values for any chemicals and for toys for children of any age by introducing an additional Annex for toys that are not for young children or put into the mouth.

TIE: this suggests that a new Appendix would be created to restrict substances in toys not covered by Appendix C (under three toys and other toys intended to be placed in the mouth). This suggestion is in line with TIE proposals to cover certain substances in all toys (such as preservatives).

- Empower the Commission to introduce limit values for combination effects at a time when the reliable evidence for setting those values is available.

TIE: this "combination effect of chemicals" is something which is being discussed under the REACH revision and could lead to the setting of a generic "Mixture Assessment Factor" (MAF) for all hazardous chemicals. This MAF (value not yet agreed) could reduce by 2, 10 or even 100 the limits set in the TSD.

- Reduce limit values for nitrosamines and nitrosatable substances to align them with those in force in Germany (and in Standard DIN EN 71-12 Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances).

TIE: this should not be an issue since Germany is still allowed to apply their lower limits for certain toys.

14. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would these measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?
*

	1: Our competitiveness would strongly decrease	2: Our competitiveness would decrease	3: No change	4: Our competitiveness would increase	5: Our competitiveness would strongly increase	I do not know – No opinion
In comparison to imports from outside the EU *						
In comparison to large manufacturers *						

15. Please explain your choice:

Ban on specific substances: Based on the newest scientific evidence on chemical risks, some substances might be banned from toys altogether or only allowed using derogations. Those measures could include:

- Extend the existing general prohibition of CMR substances to endocrine disruptors.
- Extend the general approach to risk management to other most hazardous substances, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ (STOT RE + STOT SE).

TIE: this suggests that the current CMR rules (based on CLP thresholds) would be extended to other classified substances (as a result of the EU Chemical Strategy for Sustainability). The additional restrictions will likely lead to additional costs, especially for SMEs, to demonstrate compliance with the measure. They could also result in a need for additional testing, which also has an environmental impact. The full impact on economic operators will be strongly impacted by possible transition periods provided, derogations included and predictability of measures. Without sufficient possibilities to anticipate regulatory changes, reputable companies will suffer a real disadvantage compared to rogue traders.

- Revise derogations based on the 'relevant concentrations' of the CLP Regulation to reduce concentrations of CMRs in toy

TIE: We strongly disagree with the statement in the Inception Impact Assessment of the TSD that "while the Directive includes a generic CMR prohibition, it provides for derogations which appear to allow too much of a presence of CMRs in toys".

The current rules allow to set stricter limit values or migration limits when the need is identified (for example through Appendix C of the Directive, REACH or RoHS). The fact that such stricter limit values are set in certain instances should not be considered evidence that the current derogations are inadequate. The conclusion from the Evaluation of the Directive is seriously flawed in this instance.

No evidence is provided that children are currently at risk because of exposure to CMRs present in toys that are compliant with the current rules, nor that the current rules cannot address new scientific evidence.

A revision of the derogations of the general prohibitions of CMRs, to further lower the permissible limit values, risks to unintendedly ban toys that are perfectly safe. Such option should therefore not be considered lightly. Especially given the lack of evidence of any safety issue with toys that comply with the current rules and the flexibility of the current rules to adapt to new scientific evidence.

The additional restrictions will lead to many additional costs, especially for SMEs, to demonstrate compliance with the measure. This also means lot of additional testing, which will have an environmental impact.

If properly enforced, these stricter rules might also require additional resources of market surveillance authorities or lead to resources diverted from checking other issues.

This measure could lead to an increase of dangerous toys on the market as there would be a clear advantage for rogue traders due to the additional burden for compliant manufacturers and market surveillance authorities and a lack of enforceability.

In terms of compliance, this also means for SMEs: They need to be able to obtain information on presence of CMRs below the CLP threshold. This is currently not provided by most Safety Data Sheet/suppliers. This will therefore lead to more/excessive testing and also a big risk certain materials will no longer be available for them. It can be helpful if you can indicate these impacts in the questionnaire.

16. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would those measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?

	1: Our competitiveness would strongly decrease	2: Our competitiveness would decrease	3: No change	4: Our competitiveness would increase	5: Our competitiveness would strongly increase	I do not know – No opinion
In comparison to imports from outside the EU *						
In comparison to large manufacturers *						

17. Please explain your choice:

Pre-market authorisation: To reduce the number of non-compliant toys on the European market, pre-marketing conformity assessment (third-party conformity assessment) would be extended for certain toys. The conformity assessment could be extended to:

- New types of toys;
- Connected toys;
- Toys using certain chemical mixtures or substances;
- Toys marketed at children under the age of 36 months old or designed to be put in the mouth.

18. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would those measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers?*

	1: Our competitiveness would strongly decrease	2: Our competitiveness would decrease	3: No change	4: Our competitiveness would increase	5: Our competitiveness would strongly increase	I do not know – No opinion
In comparison to imports from outside the EU *						
In comparison to large manufacturers *						

19. Please explain your choice:

TIE: see comments on EC type examination below question 11

When responding, companies could consider for example additional costs, delay to the marketing of a toy, competition with rogue traders (who can produce cheaper and faster).

Companies can also highlight that so far the EU has not adequately tackled the issue of illegal imports through online marketplaces. Additional burden on manufacturers of safe toys will therefore be counterproductive.

Post market authorisation: Reduce the number of non-compliant toys on the European market option 2 could also include post-marketing facilitation of controls. With the introduction of a digital product passport containing the EU declaration of conformity which can be presented at customs and used by market surveillance authorities. This could be based on the Digital Product Passport under Sustainable Product Initiative.

	1: Our competitiveness would strongly decrease	2: Our competitiveness would decrease	3: No change	4: Our competitiveness would increase	5: Our competitiveness would strongly increase	I do not know – No opinion
In comparison to imports from outside the EU *						
In comparison to large manufacturers *						

20. On a scale of 1-5 (1 strong decrease, and 5 strong increase in competitiveness), how would those measures presented above make your products more or less competitive in comparison to imports and to larger manufacturers? *

21. Please explain your choice:

Concluding questions

22. In your opinion, what elements of your national laws transposing the Toy Safety Directive are working well?

23. In your opinion, what elements of your national laws transposing the Toy Safety Directive could be improved?

24. Would you have any documentation to share with us concerning the impact of the Toy Safety Directive on your company? If yes, please send the document(s) to m.goubet@vva.it.

25. Do you consent to being contacted for a follow-up interview to be held with VVA? If so, please provide your email address: