

<b>Title:</b> <b>Impact Assessment of Proposals to Revise the Toys (Safety) Regulations 1995</b> <b>Lead department or agency:</b> BIS <b>Other departments or agencies:</b> None	<b>Impact Assessment (IA)</b>
	<b>IA No:</b> BIS0016
	<b>Date:</b> June 2011
	<b>Stage:</b> Final
	<b>Source of intervention:</b> EU
	<b>Type of measure:</b> Secondary legislation
	<b>Contact for enquiries:</b> Tony Eden-Brown

## Summary: Intervention and Options

### What is the problem under consideration? Why is government intervention necessary?

The market failure rationale behind the revision of the 1995 Toy Safety Directive (TSD) is asymmetric information: (i) children/parents are not necessarily able to accurately judge the toy's appropriateness prior to purchase; (ii) there is insufficient provision of information for manufacturers or importers to display/document the products characteristics and surveillance authorities lack enough information on the toy's safety, and (iii) the existing TSD lacks clarity on the scope. As EU Member States considered an update necessary in the light of experience of its operation, developments in scientific knowledge in respect of the long term effects of chemicals. Without government intervention UK manufacturers would be left with considerable uncertainty as exporters would need to comply with UK regulations and European Law.

### What are the policy objectives and the intended effects?

The objectives that the revision of the Directive tries to fulfil are to improve the functioning of the internal market for toys, in part by incorporating the New Legislative Framework and ensuring there is a 'level playing field' between manufacturers of toys in the EU, while ensuring an improved level of safety, enforcement and clarification of scope and concepts. This is in line with BIS's departmental priority number 3: Stimulate exports and inward investment by promoting open and fair global markets. The new Directive should reduce the effects of toy related injuries as well as reduce the long term health costs on consumers by substantively improving toy safety levels above those of the current regulations.

### What policy options have been considered? Please justify preferred option (further details in Evidence Base)

The following options have been considered:

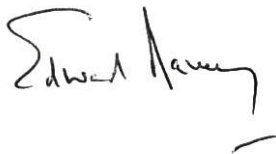
- (0) do nothing, whereby the level of safety in toys would not change and the Department risks infraction proceedings and an uneven playing field between Member States and third countries;
- (1) modification of the UK legislation to conform to the renegotiated Directive (the Government's preferred option that is being taken forward because it has already been agreed at EU level in Council), which will ensure an improved level of safety, enforcement and clarification of scope and concepts.

Alternative to regulation is also discussed on page 11.

<b>When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?</b>	It will be reviewed 2015
<b>Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?</b>	Yes

**SELECT SIGNATORY Sign-off** For final proposal stage Impact Assessments:

***I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs. Signed by the responsible Minister***

A handwritten signature in black ink, appearing to read "Edward Harvey". The signature is written in a cursive style with a horizontal line underneath.

:

Date: 11 July 2011

**Description:**

Modification of UK regulations in line with the EU Directive

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: -210	High: -133	Best Estimate: -190
Year	2011	10			

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition)	Total Cost (Present Value)
Low	32	2	9	136
High	107		13	320
Best Estimate	66		11	221

**Description and scale of key monetised costs by ‘main affected groups’**

Reoccurring costs: testing and certification increases, delays to production schedules, technical file and documentation control and safety assessments.

Transition Cost: Product redesign and manufacturing costs, warning labels, training, update of procedures, technical file work, upgrade of data and scrapping materials.

**Other key non-monetised costs by ‘main affected groups’**

Enforcement costs and CE requirements are not expected to have an impact on costs (see para 95-96 respectively). Some cost to manufacturers of addressing the new requirements is likely to be partly passed on in the form of higher prices.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition)	Total Benefit (Present Value)
Low	0		0.4	3
High	0		13	110
Best Estimate	0		4	32

**Description and scale of key monetised benefits by ‘main affected groups’**

Health Benefits:

Disability Adjusted Life years due to chemical requirements

Reduction in rate of injuries due to greater information provision and safety enhancements. Hence, avoided human cost, lost output and resource cost avoided from reduced rate of mild injuries is estimated.

**Other key non-monetised benefits by ‘main affected groups’**

Benefits to industry from reduced legal uncertainty.

**Key assumptions/sensitivities/risks**

Discount rate 3.5

Transition costs and reoccurring costs are derived from EU IA estimates and industry estimates (para 68/69, 85). Benefits from avoided Disability Adjusted Life Years derived from EU IA apportioned for UK based on population weighting. Human cost, lost output, resource cost from avoiding mild injury equates to £350 per person (HSE). Toy related injuries toys from the RoSPA database of which 3% is assumed to be relevant to injuries under the auspices of this directive. Rate of reduction in injuries is estimated at 5-35%.

<b>Direct Impact on business (equivalent annual)</b>	<b>Impact on policy cost savings</b>	<b>In</b>
Costs : 10	Policy cost savings:	No
Benefits: 0		
Net : 10		

## Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options UK wide		
From what date will the policy be implemented?			20/06/2011		
Which organisation(s) will enforce the policy?			Trading Standards		
What is the annual change in enforcement cost (£m)?			minimal		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b> N/a	<b>Non-traded:</b> N/a	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			<b>Costs:</b> n/a	<b>Benefits:</b> n/a	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	<b>Micro</b>	<b>&lt; 20</b>	<b>Small</b>	<b>Medium</b>	<b>Large</b>
Are any of these organisations exempt?	No	No	No	No	n/a

### Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on...?	Impact	Page ref within IA
<b>Statutory equality duties</b> <sup>1</sup> <a href="#">Statutory Equality Duties Impact Test guidance</a>	No	23
<b>Economic impacts</b>		
Competition <a href="#">Competition Assessment Impact Test guidance</a>	Yes	20
Small firms <a href="#">Small Firms Impact Test guidance</a>	Yes	20
<b>Environmental impacts</b>		
Greenhouse gas assessment	No	22
Wider environmental issues	No	22
<b>Social impacts</b>		
Health and well-being <a href="#">Health and Well-being Impact Test guidance</a>	Yes	22
Human rights <a href="#">Human Rights Impact Test guidance</a>	No	22
Justice system <a href="#">Justice Impact Test guidance</a>	No	22
Rural proofing <a href="#">Rural Proofing Impact Test guidance</a>	No	23
<b>Sustainable development</b> <a href="#">Sustainable Development Impact Test guidance</a>	No	23

<sup>1</sup> Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

## Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

### References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	European Commission Impact Assessment <a href="http://ec.europa.eu/enterprise/sectors/toys/files/toys_final_report_without_annexes_en.pdf">http://ec.europa.eu/enterprise/sectors/toys/files/toys_final_report_without_annexes_en.pdf</a>
2	RoSPA data: <a href="http://www.hassandlass.org.uk/query/MainSelector.aspx">http://www.hassandlass.org.uk/query/MainSelector.aspx</a>
3	HSE health impact – appraisal guidance <a href="http://www.hse.gov.uk/economics/eauappraisal.htm">http://www.hse.gov.uk/economics/eauappraisal.htm</a>
4	

+ Add another row

## Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

### Annual profile of monetised costs and benefits\* - (£m) constant prices

	Y <sub>0</sub>	Y <sub>1</sub>	Y <sub>2</sub>	Y <sub>3</sub>	Y <sub>4</sub>	Y <sub>5</sub>	Y <sub>6</sub>	Y <sub>7</sub>	Y <sub>8</sub>	Y <sub>9</sub>
<b>Transition costs</b>	67	65								
<b>Annual recurring cost</b>	0.04	12	12	12	12	12	12	12	12	12
<b>Total annual costs</b>	67	77	12	12	12	12	12	12	12	12
<b>Transition benefits</b>										
<b>Annual recurring</b>	0.1	0.1	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7
<b>Total annual benefits</b>	0.1	0.1	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7

\* For non-monetised benefits please see summary pages and main evidence base section



Microsoft Office  
Excel Worksheet

## Evidence Base (for summary sheets)

## Overview

1. The draft revision of Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (TSD) was published on 25 January 2008. The Department regularly consulted stakeholders on the negotiations within Council and Parliament. Agreement was reached and the Directive published on 18 June 2009 as Directive 2009/48EC.
2. On balance the final result is close in substance to the original Commission proposal on which the European Union (EU) Impact Assessment (IA) referred to below is based.
3. Directive 2009/48 achieves the overall objective of enhancing the level of safety of toys while maintaining the smooth functioning of the Internal Market. Three specific objectives identified.
  - Strengthening, clarifying, modernising and completing the essential safety requirements for toys, in response to market developments and scientific progress, and to deal with an increased awareness of health and safety issues by consumers and enforcers.
  - Improving the understanding, implementation and enforcement of the Directive within Member States.
  - Providing clarity and updating the scope, concepts and definitions of the Directive, ensuring that it is in line with the general legislative framework for marketing products within the EU.
4. The Directive enters into force on 20 July 2011, except in respect of restrictions on levels of substances which are or may be carcinogenic, mutagenic or toxic to reproduction, which come into force in July 2013. Whilst the Directive sets content limits, migration levels (the amount of a substance released) which are the more toxicologically valid measurement have not been decided, and therefore the costs of this to industry cannot be estimated with any accuracy. This has been confirmed by the responses to the public consultation and informal discussions with the British Toy and Hobby Manufacturers Association and other industry and importers produced no further information on the likely costs of the long term chemical restrictions, the main area of uncertainty. Similarly the potential benefits over the next 10 years are based on limited evidence especially as many health benefits are expected to occur after the given time frame assessed in this IA.

## Background

5. The requirements of the TSD were implemented into UK Law by the Toys (Safety) Regulations 1995 (SI 1995 No. 204), (the Regulations.) The TSD was one of the first “New Approach” Directives, whereby the Directive sets the basic requirements and harmonised standards set the detail. The revised Directive 2009/48/EC also needs to be implemented into our domestic legislation, as the UK assented in Council in January 2009.
6. The Directive which enters into force on 20 July 2011 offers a two-year transitional period for toys already complying with 88/378/EEC, and which were placed on the market before entry into force of the revised Directive. Importantly it offers a further 2 year grace period in respect of the chemical restrictions of Directive 2009/48 in order to

reduce the impact on industry and to allow the development of new harmonised standards for those chemicals. The exact requirements have not yet been agreed (they will be agreed between now and 2013) therefore costs associated with this aspect cannot be easily estimated.

7. This first deposited text on 25 January 2008 reflected the informal discussions from 2003 in Commission working groups. The Directive had a difficult passage in formal Council Working Groups as some Member States wished to make the Directive over-precautionary in respect of the limits applied to chemicals and by banning all fragrances in toys, a position reflected in the European Parliament. A number of high-profile recalls of toys because of safety concerns in the summer of 2007 led a number of Member States to call for further restrictive measures, which would in effect ban the possibility of certain types of toy, and potentially lead to manufacturers and importers withdrawing from the market. The 2007 recalls were high-profile because they involved a leading manufacturer, but stricter legal safety assessment requirements would not have prevented these recalls. Under normal circumstances most recalls on the EU RAPEX (Rapid Alert System for Non-Food Products) system involve low-priced/low-quality or counterfeit toys which basically make no attempt to pass the existing standards in any case.
8. The UK has consistently promoted an appropriate and proportionate level of revision. The final Directive better reflects this position.

### **Rationale for Government Intervention**

9. The market failure to be addressed through the revision of the Toy Safety Directive (TSD) is that of asymmetric information, whereby children are a particularly vulnerable group of people who lack the ability to take decisions. As a consequence of this fact, it is their parents who have to take decisions on their behalf. Similarly parents are not always in a position to judge the toy's safety, in relation to the age and ability of their child, and in particular regarding substances that are not visible (harmfulness of chemicals, noise emissions levels and dangers of laser components). Moreover, the Directive as it stands at present does not always follow technical progress, cannot respond fully to recently identified hazards, needs to clarify general safety requirements and could provide more adequate warning requirements.
10. The enforcement of the Directive is based on the manufacturer's responsibility for the safety of the product; market surveillance is carried out ex-post by public authorities – generally Trading Standards in the UK. The existing TSD does not contain any explicit requirement for manufacturers to carry out, document or make available for inspection the hazard/risk analysis. The revised Directive requires the hazard/risk analysis to be available to enforcement authorities. This improves on the current requirement which simply is a requirement to test against standards – although in practice most manufacturers would conduct a risk assessment. The rules on the information provided, through CE marking (European Conformity), are also outdated due to Regulation (EC) No.765/2008 and EC Decision No 768/2008/EC, which further complicates the task of the surveillance authorities. Regulation in this area will help the surveillance authorities more easily ensure that toys produced or entering the EU market are hazard-free, therefore reducing the information asymmetry that exists at the moment.
11. Moreover it has been acknowledged that there is a lack of clarity on the scope of the TSD, particularly in respect of the definitions surrounding how the use of toys is specified and toys for particular age groups.

## Problem Definition and Background

12. The Directive was reviewed in 2003 as it had not been reviewed during its existence and subsequently after informal discussion in Commission Working Groups the European Commission published a revised Directive in 2008.
13. The main areas the draft identified where improvement was needed related to:
- labelling and warnings surrounding the use of toys,
  - chemical substances contained in toys which were potentially dangerous and about which more had been learnt in the intervening period
  - the need to take into account Directives which had effects on certain toys (eg Low Voltage Directive) and a lack of clarity on the scope of the TSD, in terms of risk assessment of a particular toy and its foreseeable use/misuse.

Details on the directive are provided below:

14. **New provisions on chemical requirements:** Directive 2009/48 maintains the safety requirements existing in the TSD with regard to the use of chemicals in toys, and is enhanced by banning certain allergenic fragrances and requiring the labelling of others. The revision also bans all substances categorised as Carcinogens, Mutagens and substances toxic to Reproduction (CMRs) in accessible parts of toys unless authorised by comitology procedure, in order to reduce preventable illnesses being caused in later life by negative effects inflicted in childhood. There is however a derogation allowing the use of these substances within safe limits, which are noted in the Directive as Category 1A, 1B (0.1%) and Category II (1.0%). These limits will have to be amended in terms of specific chemicals either before the chemical aspects of the Directive enter into force in 2013 or during its lifetime. This will add costs in terms of testing of limits, but as the methodology is not yet complete, let alone individual limits for all substances costs are difficult to accurately estimate. As stated previously this area is complicated as a number of these substances already have limits under the standards set under the existing Directive.
15. **New provisions on warnings:** The current Directive covers some warnings on toys. The new measures are designed to improve their effectiveness in preventing accidents. They provide for the mandatory display of minimum/maximum age for users at point of sale and specific warnings will be required on age or ability, as well as the minimum/maximum user weight and the need for the relevant toys to be used under adult supervision. The additional cost impact is unclear one noted that there would be no costs associated with this (and stated the clearer warnings would help consumers select more appropriately select toys for an age group). The second stated they would be hiring an additional member of staff to look at this and the more general area of safety assessment.
16. **New provisions on choking and suffocation risks:** The Directive currently covers the risk of inhalation of small parts from toys intended for children under 36 months. It has been decided that this provision needs to be extended to any toys intended to be put in the mouth, regardless of age. The Directive currently covers the risk of *external* airway obstruction of the mouth and nose. The proposal is to extend this definition to *internal* airway obstruction to deal with the risk presented by new toys such as those with suction cups. The new draft also covers risks of strangulation and asphyxiation. This has largely been covered by standards, but has never been specified as an essential safety requirement in the legislation.



17. **New provisions on airway obstruction as a result of the association of toys and food items:** The current Directive contains no specific provisions for toys in food. The revision addresses this problem with a new requirement that i) toys should be marketed in a package separating them from the food items they are attached to; ii) the packaging itself should not present a choking hazard, and iii) there will be a ban on toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy. There have been deaths in the EU and the UK because of this type of toy; an accidental death of a child is estimated to have associated costs of around £1.5 million.
18. **New provisions on reinforcement of Market Surveillance measures:** The revision reinforces the Directive's relationship with the Regulation on Accreditation and Market Surveillance and General Product Safety Directive, particularly in relation to specific powers for market surveillance authorities and enforcement cooperation between Member States.
19. **New provisions on information on chemicals in the technical files:** The revision will require further information on the chemical composition of certain components and materials used in toys.
20. **Provision on CE Marking:** The revision extends the CE Marking requirements of the Directive, requiring the marking to be affixed to the packaging of the toy if the marking on the toy is not visible through the packaging. This incorporates the requirements of Regulation (EC) No. 765/2008 and EC Decision No 768/2008/EC – therefore the impact of this provision is not considered, as it's not a new requirement.
21. **New provision on the Safety Assessment:** Manufacturers and importers etc. will in future be required to perform an analysis of the hazards that the toy may present and make it available as part of the toy's technical file to market surveillance authorities for inspection, although many manufacturers will have been undertaking this as a matter of course.
22. **Alignment of the Directive with the provisions of the Council and Parliament Decision on the marketing of goods:** The revision of the TSD is aligned to the Common Framework on the Marketing of Goods Decision 768/2008/EC. This ensures consistency between all New Approach Directives, particularly in areas such as conformity assessment bodies, definitions, routes to conformity and rules for CE Marking.
23. **Clarification of the scope of the Directive:** The revision will aim to complete the list of products which are not within its scope with regards to new products such as videogames and their peripherals. The new Directive will also include further definitions specific to the toys sector such as activity toys etc. More widely it requires more consideration of the risks, requiring thought be given to the use of toys used in a foreseeable way as in the existing Directive, but adding "bearing in mind the behaviour of children" – in other words foreseeable misuse.

## Interaction with other Legislation

24. Two legislative provisions are relevant:
25. The General Product Safety Regulations 2005 (GPSR) set the general safety requirement of a product by requiring that no producer may place, offer to place on the market, supply, agree to supply, expose or possess a product for supply if the product is intended for use by consumers unless the product is safe in normal and foreseeable

use. Specifically, the GPSR place certain obligations on producers and distributors, including a requirement to provide adequate warnings and instructions for use, and to notify local authorities when they become aware that a product placed on the market/supplied presents a risk to consumers.

26. The Consumer Protection Act 1987 (CPA): This provides the legal basis for much of the consumer safety legislation introduced in the UK, including the Regulations. Infringement of the Toys Regulations is an offence under the CPA.
27. The draft Regulations also vary from the previous UK Regulations in that they take account of 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 which is complementary to 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 which came into force on 1 January 2010.

### Identifying the unique aspects of the Regulations

28. The 1995 Regulations set out the essential safety requirements for toys and specifically limits the amounts of dangerous substances which may be used in toys, mostly harmonised standards developed by the European Committee for Standardization (CEN). Toys that meet these standards benefit from a presumption of conformity with the essential safety requirements, as long as all the safety features of the toy are covered by the standards.
29. The new Directive specifies more chemicals and their limits– it also bans or introduces requirements for certain allergenic fragrances. The requirements for many of the chemical aspects are yet to be refined by CEN.
30. The existing Regulations set out the specific steps and requirements manufacturers and importers must meet to place products on the market, which in terms of the new Directive are in part replaced by the horizontal New Legislative Framework legislation particularly in respect of obligations of economic operators, conformity assessment procedures and market surveillance.

### **Scale and Scope**

31. Gross value added of the toy manufacturing industry<sup>2</sup> in the UK was approximately £233 million in 2009, which amounted to 0.17% of total UK manufacturing GVA. In addition, the UK toy manufacturing industry has a total turnover<sup>3</sup> of £550 million (0.1% of total manufacturing turnover). This comprises of approximately 565 businesses which employ roughly 6,000 people. The market structure of the UK toy manufacturing industry is almost entirely made up of Small Medium Sized Enterprise (SMEs)<sup>4</sup> with 86% of its enterprises having fewer than 9 employees.
32. In terms of trade of toys, the UK imported £1.5 billion worth of toys in 2006, 70% of which came from outside the European Union. According to the Commission, at EU level a large majority of the toys sold are imported and the greatest proportion (up to 90%) comes from China. In addition, industry has estimated that sales were about £2.7bn in 2009.

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<sup>2</sup> SIC 32.4 which includes: manufacture of games and toys, manufacture of professional and arcade games and toys and manufacture of other games and toys not elsewhere classified

<sup>3</sup> Excluding VAT

<sup>4</sup> Following the European Commission definition

33. These calculations have been made on a wider level of aggregation than the products the Directive specifically considers. Disclosure problems were encountered with Office of National Statistics (ONS) data when trying to drill the data down to a more detailed analysis of this specific market under consideration. It is therefore the case that the calculations undertaken (in terms of costs for this impact assessment) may be an overestimation since the fragment of the market analysed is wider than that considered in the Directive. The industry association best estimate of size comes to around 400 companies – the wider product coverage ONS figure is 640. Because of this, we have included some industry estimates of the size of the market, although these are estimates.

## **IDENTIFICATION OF OPTIONS**

34. There are two main options under consideration in this Impact Assessment:

### **Option (i) Do nothing**

### **Option (ii) Modifications to the directive (as detailed above)**

35. In addition an **alternative to regulation** was considered at an early stage i.e. voluntary standards or guidelines, but it was rejected. If the UK did not comply the UK would risk incurring EU infraction proceedings. The rationale behind rejecting alternative to regulation is noted below:

36. Unsafe toys present a serious risk to vulnerable citizens. The externalities are borne by the children who are never the customers of the companies. The production is mainly based off-shore and even the tightest of business systems can lead to supply problems (e.g. the mass Mattel recall of 2008). Products are heterogeneous and complex and can be part of short term trends which make this sector less ideal for self regulation. In addition, the market is fragmented with responsible businesses at the high-street retail end (traditional toy suppliers) and non-specialist toy suppliers selling in street markets or over the internet where the quality and safety of goods can differ significantly from those on the high street.

37. The Directive itself places a prohibition on supply of non compliant goods which has to be put into place. Member States also have to provide dissuasive penalties including criminal sanctions for those that breach the legislation and endanger vulnerable consumers. Given that the New Agreement/New Legislative Framework model is considered to be business-friendly with a great deal of emphasis on the supplier making decision on conformity, this needs to be balanced by an enforcement regime to ensure that business will act responsibly to safeguard the health and safety of children. The New Legislative framework is the closest regulatory model to the co-regulation because of the reliance on and use of standards and conformity assessment e.g. those businesses that use standards as most businesses will do (which gives their products a presumption of conformity with the safety requirements), do not require 3rd party intervention of a notified body and can self declare conformity.

### **Option (i) – Do nothing**

38. The first option to consider is to do nothing, which would mean that the UK would not transpose the revision of the Directive and would therefore be (i) almost certainly liable to EU infraction, (ii) contravening EU internal market rules and (iii) breaching Article 10 of the EC Treaty, the duty of loyal co-operation. This approach leads to both internal market problems for UK exporters whose goods would have to meet the new requirements and safety issues. To do nothing would also mean that problems such as safety requirements, enforcement and clarification of scope and concepts would not be dealt with; as a consequence the risk of health incidents related to toys would persist.

The do nothing approach is used in this Impact Assessment (as is common practice) as the baseline to our analysis.

## **Option (ii) – Regulatory Approach through Modifications to the UK Regulations**

### **BENEFITS**

39. These are considered to improve the Directive's efficiency, functioning, reliability and transparency. The relevant authorities in Member States will in theory benefit from a clarification of responsibilities and information, and from the enhanced accessibility of the data. The revision of the Directive would make these authorities' duties easier and reduce costs. Manufacturers would in theory benefit from the clarification of definitions and responsibility. Other benefits claimed by the Commission's impact assessment which would accrue to manufacturers would be the reduction of the level of counterfeiting that currently takes place in the EU market. However the main benefits from the revision of the Directive would benefit consumers as stated below.

### **Health Benefits**

40. The main social benefits of the Directive's revision would be to consumers, in particular children. The revision of the Directive would have benefits through reductions in the number of toy-related incidents. In particular, the most significant benefits would arise from modifications to the chemical safety requirements which would help reduce the number of children developing diseases and other chemical-related harmful medium and long-term effects.

41. A World Health Organisation (WHO) report in 2007<sup>5</sup> states that the current main threats to children's health were increasingly connected to the environment, including chemicals in the environment (air, food, water) and from proximity to individual exposures. Chronic illnesses – including asthma, paediatric cancer, developmental and behavioural disorders and congenital defects – are becoming an increasing burden to society. Noise can induce hearing impairment. Moreover, the human body is vulnerable to the output of certain lasers and under some circumstances exposure can result in damage to the eye and skin. These items are covered by harmonised standards, but not included in the essential safety requirements of toys. Market surveillance surveys carried out in Member States have highlighted the presence of dangerous chemicals in toys, some of which are not currently regulated at Community level, such as allergens and nitrosamines.

42. The current TSD maintains that toys cannot contain dangerous substances within 67/548/EEC and 88/379/EEC in amounts which might harm the health of children. The new Directive extends the provisions on the use of certain dangerous substances in toys, such as CMRs (substances which are or may be carcinogenic, mutagenic or toxic to reproduction) or allergenic fragrances and takes account of Regulation (EC) No 1272/2008 of 16 December 2008 which provides for the harmonisation of the classification and labelling of substances and mixtures by aligning existing EU legislation with the United Nations Globally Harmonised System (GHS) and contributes to the GHS aim that the same hazards will be described and labelled in the same way all around the world. It substantively changes hazard descriptions and classes from the previous EU legislation covering dangerous substances: Council Directive 67/548/EEC.

43. Therefore, it is important to prevent these negative health effects associated with exposure to chemicals from toys from affecting children, as they are more sensitive

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<sup>5</sup> 'Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals'

than adults to the effects of certain chemicals and have also different behaviour patterns, such as being more likely to mouth objects which result in greater intake of migratable substances

### **Monetisation of benefits**

#### **DALYs:**

44. Health benefits were quantified in the Commission's Impact Assessment in terms of Disability Adjusted Life Years (DALYs) for the EU as a whole.<sup>6</sup> Those results are not easily translated into quantifiable benefits for the UK. The benefits accrued by the different EU options range from €1.2 billion present value (for low ingestion and low damages) to €50.9 billion present value (PV) on a high-ingestion/high-damages scenario to 2051. Previous IA for TSD based these benefits on estimates in the EU IA for approach 1 in which assumes the "status quo + ban of allergenic fragrances". However, approach 2 in the EU's IA which assumes "Status quo + ban of allergenic fragrances and ban of all CMR's Cat.1 & 2 unless authorised under REACH" (REACH: Registration, Evaluation, Authorisation and Restriction of Chemical substances i.e. European Community Regulation on chemicals and their safe use) is closer to the new directive and is used in this IA to estimate DALY benefits to the UK. The EU level benefits are weighted by UK population and adjusted to remove the 4% discount rate applied. Total DALY benefits are therefore estimated to range from £3m - £130m for the UK (constant prices) over 8 years.

#### **Illustration of Disability Adjusted Life Years (DALYs) Calculation:**

EU middle scenario for "approach 2" is estimated at €340m PV from 2007 to 2051 discounted at 4%. UK IA 'best' scenario is derived in the following way: €340m (as noted above) adjusted for inflation factor to remove discount rate = €1910m i.e. £1648m. To get a UK level estimate this is weighted by 12% (which is the % of UK to EU population) = £202m benefits for the UK to 2051. An annual impact of ~£5m is estimated by dividing by 44 (i.e. no of years used in EU IA time frame; 2007 to 2051). The impact is estimated from 2013 onwards when the chemicals requirement is implemented, the total impact (best scenario) equating to £37m over 8 years.

#### **Injury Reduction:**

45. The age warnings and the ban on toys attached to food should also have a positive effect where the toy is responsible for a serious incident principally by making parents more aware of the risks involved. The reduced risk of injury will also reduce burden on health services. The home and leisure accident surveillance system database (RoSPA) contains data on accidents and injuries – it notes there were 51537 accidents in 2002 with the following objects involved: construction kits, soft toys, marbles, other game, other plaything, other toy, other toy to enter, other toy weapon, small game or toy part, small toy vehicle, toy to ride on, trampoline, unspecified toy, unspecified plaything. The vast majority of cases do not involve a hazard intrinsic in the toy, but that simply a toy has been involved e.g. someone trips over one left on the floor or children falling off roller skates, bicycles etc, or very young children swallowing parts of toys intended for

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<sup>6</sup> One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population, or the burden of disease, can be thought of as a measurement of the gap between current health status and an ideal health situation where the entire population lives to an advanced age, free of disease and disability. DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for incident cases of the health condition:

older children. Approximately, 0.4% of which were because of suspected poisoning or due to chemical effects. However the directive could potentially prevent a broader range of injuries. Having discussed with parts of the industry we estimate the figure of accidents involving toys themselves, where a child is cut or swallows a part which breaks off a toy or similar, is probably around 1000 - 2000 per year at the most – i.e. 2-4% of the recorded incidents. It is assumed that the injuries could fall from 5% to 35% through implementation of the directive and that all injuries are moderate in severity (requiring some medical attention). This is a simplifying assumption due to lack of evidence, in practice injuries may vary from mild to fatal. The estimated cost incurred of the injury per person based on HSE appraisal guidance is £350 based on these assumptions, the health costs avoided over the 10 year period considered are £1.3m

46. It should be noted that this is likely to underestimate savings as the severity of the accident could vary considerably. A child's accidental death is estimated to cost £1,500,000 in total costs (Treasury Green Book), so even a small reduction would be significant

## **COSTS**

47. Two companies, both relatively large SMEs responding to the consultation, commented on the immediate physical cost aspects of labelling reflecting the impacts. One suggested the clearer warnings would help consumer's select appropriate toys for an age group and that there would be no costs associated with this. The second stated they would be hiring an additional member of staff to deal with the administrative aspects of updating technical files. Both also stated they could not currently estimate costs of the chemical aspects.
48. In addition industry estimate of a global multinational company were provided and have been scaled up to generate estimates for the UK toy industry.
49. Although consumers are likely to be the main beneficiaries of the revision of the Directive, it is unclear to what extent the increase in costs will be passed on to them. Manufacturers pointed to the fact that retailers have target price ranges and toys which do not fall within the price range would not be stocked, or the manufacturer would have to accept a cut in their margin. Alternatively, retailers may have to adjust their target price ranges due to the increased costs, which would then mean consumers would bear the costs of the Directive. The Commission estimate the degree of pass-through to result in SMEs increasing their prices by 5%.
50. There is a possibility that future cost estimates have been overestimated by stakeholders, as well as an assumption that additional manufacturing costs are incurred every year, implying that manufacturers would not adjust their processes over time.

## **Description of costs**

51. **Chemical requirements:** The Commission's impact assessment considers three different approaches when considering the revision of the provisions on chemicals requirements in relation to REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals). The chosen approach for cost estimates would be the most stringent one, whereby there would be a ban on allergenic substances and on all CMRs in Category 1a, 1b (proven and evidenced CMRs) and II (suspected CMRs), unless authorised by dedicated comitology procedure.

52. The original approach to CMRs banned them in toy parts that are accessible. This approach will lead to some substitution of chemicals or in some cases possibly the withdrawal of certain toys from the market.
53. The UK was instrumental in obtaining derogation to this blanket ban and the final Directive specifies that CMRs in accessible parts should be cleared on a positive basis by the Scientific Committee on Consumer Products, where the CMR exceeds 0.1% for CMR category 1 and 1% for CMR category II content limit. These will need to be refined by reference to migration limits (the amount of a substance released). The stricter approach would have involved substantial extra costs to manufacturers in presentation of scientific evidence that a wide range of products are safe. The rationale behind choosing a strict approach is that children are particularly vulnerable consumers. It is difficult to detangle the costs of this approach to reflect costs in the UK toy market. The Commission's estimates are believed to be an indication and are caveated in a number of ways.
54. The **implementation** of the Directive's chemical requirements revision is not likely to happen before **2013** due to the complexity of the issues under consideration. The rest of the issues raised by the Directive will most likely be implemented in 2011.
55. **More stringent requirements on warnings:** minimum and maximum age would be displayed at the point of sale, since this is considered the most important information for the consumer to ensure the toy is used under safe conditions.
56. **Changes on requirements of choking risk:** It has been considered disproportionate to raise the age limit from 36 months in respect of choking etc hazards in respect of all toys. However, it is proportionate for the Directive to extend choking risks requirements to toys which are intended to be put in the mouth (i.e. toy instruments). The EU IA notes that in the public consultation, most respondents felt that this kind of requirement in the Directive would not be necessary because harmonised standards already cover such a risk. However it was considered important in view of the future development of standards to ensure a legal base for guaranteeing a high level of safety also in the future. The suggestion here is that this requirement will not impose any additional costs to the industry at this stage, since the risk of choking for these kinds of toys needs already to be covered in accordance with the harmonised standard standards.
57. **Clarifying the suffocation risk:** The Commission's chosen regulatory approach covers the risk of internal airway obstruction for the toy only. Standards already cover the risk of internal airway obstruction but including it in the Directive will ensure a legal base for guaranteeing a high level of safety in the future. The requirement will not impose any additional cost. These standards were harmonised standards that are listed in the OJEU to support the Directive. Standards are not mandatory but the use of them provides a presumption of conformity with the essential safety requirements of the Directive
58. **Clarifying the general requirement for safety:** A clear general safety definition is essential since it is the only legal basis for taking dangerous toys out of the market. The new wording in this revised provision referring to the 'behaviour of children' as opposed to the 'normal behaviour' of children is unlikely to create major new costs for industry, although it may require some design changes for some toys. The option to clarify the definition does not seem to affect procedures for assessing safety.
59. **Special requirements for toys in food:** These new provisions ban toys sold directly attached to food, and recognises that current standards for toy/food products, (e.g. Kinder eggs) should prevent further suffocation incidents. Specific warnings for products where a toy is combined with food are likely to reduce risk levels. According to the Commission, these measures appear consistent with the main precautionary principles approach of proportionality and non-discrimination. Costs of regulatory action

to industry are likely to be minimal as there are few of these toys in the UK. The new requirements for the minimum size of general packaging may have some negative impact on part of the range of vending machines.

60. **Information on chemicals in the technical profile:** Industry will face some administrative costs associated with redrafting their technical files that include information and data on safety assessments but it is not envisaged that these will be high in the longer term. There will be some additional permanent costs arising from the extended requirements on testing. Companies will have to record more information in their safety assessments.
61. **Affixing of CE-marking:** The Commission considered the costs of affixing the amended rules on CE marking which would involve the modification of existing moulds and designs (for plastic toys) and text on labels and packaging in plush toys. The extension of the Directive in this specific instance would involve the requirement that the CE marking be affixed to the toy or the packaging and (if not visible from outside) the (transparent) packaging, it should always be affixed at least to the packaging. This would facilitate the surveillance authority's task with minimal costs to industry. However these requirements would have to be met anyway as they result from Regulation (EC) No. 765/2008 and EC Decision No 768/2008/EC. Therefore this is not considered an additional impact here.
62. **Conformity assessment procedures:** Mandatory third-party verification was considered disproportionately costly to industry in view of the expected benefits. However, harmonised standards covering all safety aspects of all toys do not exist, EC type approval is deemed necessary. The estimated compliance costs of such an approach will be minimal since the large majority of toys are subject to harmonised standards. Therefore this is not monetised.

### ***Monetisation of transitional costs***

63. **Review of existing product lines:** The first transitional impact will be the need of manufacturers and importers to review their existing product lines. This will involve removing some product lines that will not meet the requirements or where it is not deemed cost beneficial to redesign. In addition, due to the change in definitions, some products that were not previously classified as toys will now need to be assessed as toys, such as musical instruments and crayons.
64. It is uncertain at this stage what impact this will have on these industries, especially without the chemical requirements not being announced. Estimate of the cost of scrapping materials and products were provided by industry, costs included:
- a. Semi finished materials (cannot be economically changed to comply)
  - b. Finished goods in inventory (goods that do not comply with new marking requirements)
65. Industry provided total costs estimate of a to b above, for an illustrative large multinational toy manufacturer at £0.08m at firm level. Assuming all firms incur these costs total cost to industry is estimated at £32m which is assumed to be divided over years 1 and 2. This figure may be an over-estimate depending on how successful firms are in managing inventories and re-using semi-finished goods.
66. **Toys Redesign:** In discussion with industry, they considered that they potentially may have two different sets of costs, once for July 2011 and again for 2013 when the chemical requirements come in to force. The first set of costs will be to include warnings and address details of the manufacturers on the toys themselves.



67. The need to review the warning labels on packaging may also lead to additional costs. This will involve expanding the **warning labels and increasing the packaging** used so the directives' requirements are complied with. For warning labels the EU IA notes industry has indicated that much of the information is already present on toys so the impact would be minimal especially because of the short lifecycle for toys. However, some companies noted a need to spend additional time working out an appropriate age grade for the toy and other administrative tasks. An illustrative example is taken from a case study company response in the EU IA. The additional work is estimated to amount to two working hours per day within a timeframe of 9 months. It's evident from the consultation and that not all companies will incur costs (para 47) – therefore it is assumed that 50% of companies incur costs (best) with a range of 20% to 70%. This would amount to costs of £0.5m (2hrs/day x 195 working day for 9 months x £5.93 wage per working hour x 200 toy companies). As far as the requirement to display minimum and maximum ages displayed at the point of sale is concerned, some companies have indicated that the cost is minimal (since age grading is normally already visible on the packaging of the toy). However, on the basis of input of three producers industry have indicated that this could amount to 3 working hours per day for one year, again these costs are assumed to apply to 50% of companies. This could amount to a total of £0.9m (3hrs/day x 260 working days x £5.93 wage/hrs x 200 companies) spread over 2 years.

68. The transitional cost due to change in chemical requirements and consequent **product re-design** is uncertain as they have not been announced. Therefore estimates are based on a case study for an SME from the Commissions IA, (ref EU IA; page 81) to illustrate costs to the UK. Based on information provided for one SME it is assumed that companies on average to produce 75 different product types, 10% of which are assumed to require replacement and 90% require altering an old mould, in order to meet new chemical requirements. The estimated cost of which based is noted below:

Table 1: cost of product redesign:

<b>Scenario</b>	<b>Low</b>	<b>High</b>	<b>Best</b>
<i>Cost of altering mould (£)</i>	<i>£431</i>	<i>£836</i>	<i>£647</i>
<i>Cost of replacing mould (£)</i>	<i>£4314</i>	<i>£43,140</i>	<i>£21,570</i>

69. These assumptions as noted are illustrative and may not be fully representative of a typical toy company in the UK. In practice costs will vary from zero to hundreds of thousands of pounds for individual firms depending on firm specific characteristics. Costs in table 1 may underestimate that for larger firms and over estimate for smaller firms, in order to get a sense of total costs a simplifying assumption is applied whereby all toy manufacturers incur these costs. Based on these assumptions total re-design cost which is split between 2011 and 2012 is estimated at £82m (best scenario).

70. Estimates of product re-design (para 69) and labelling costs (para 67) presented in this IA can be validated to some extent by estimates provided by industry on the cost of changes to product and packaging, these include:

- a. Tooling changes (i.e. mould replacing / altering)
- b. Packaging film changes
- c. Delays to production schedules
- d. Increased product testing costs (year 1)

71. Industry provided total costs estimate of a to d above, for an illustrative large multinational toy manufacturer at £0.36m per firm. They noted that small firms may incur

less/no direct cost from toy redesign relative to a larger firm that would bear a greater cost burden. Based on this evidence if we presume that 90% of these costs (ie. 0.32m) can be attributed to a and b and that ~60% of toy manufacturers incur costs of £0.32m, costs are approximately the same as that estimated for toy redesign and packaging using assumptions derived from the EU IA i.e. costs are approximately £84m.

72. Other monetised transitional costs, based on estimates provided by industry includes personnel time and effort:

- a. Training of various staff
- b. Training of vendors
- c. Update of procedures and workflows to align with new TSD
- d. Technical file work and upgrade of data

73. Industry provided total costs estimate of a to d above, for an illustrative large multinational toy manufacturer at £0.04m per firm. Assuming all firms incur these cost total cost to industry is £16m. These costs are assumed to be split over years 1 and 2.

74. It should be noted that not all redesign costs can be accounted for by the directive for two reasons. First, some toys are periodically redesigned during normal course of business so as they are redesigned, they can incorporate the new requirements without any additional cost to business. Second, some toys have a short product lifecycle and thus would not be renewed and new toys being designed could already incorporate the requirements of the directive. Therefore any cost estimates may be an overestimate.

### *Recurring costs*

75. **Enhancement of safety requirements including testing requirements:** This includes, new provisions on chemical requirements, more stringent requirements on warnings, changes to requirements around the choking risk, clarification of suffocation risk, and general requirement of safety, and special requirements for toys in food.

76. As a result of the directive and particularly the chemical requirements, most toys will need to be tested to ensure that they comply with the requirements and to provide reassurance to retailers.

77. Industry representatives estimated that this could increase the amount of testing by a scale of four (this is a preliminary worst case estimate as the methodology for testing, let alone limits for individual substances is not yet agreed) compared to current practice because of expected more stringent testing limits and the need for more refined testing equipment if this is the case. This will clearly have implications on both the cost to businesses and resource requirements for testing houses. There have been concerns that the testing industry is not yet ready for the additional demand on its services and this is likely to lead to an increase in the cost of each individual test. There may also be a likely increase in safety assessments for toys and product risk assessments.

78. There are circumstances under which testing may not be required, for example if all the inputs are known to the manufacturer. However, if this is not the case, testing is likely to be required.

79. **Additional administrative cost to companies:** One of the major impacts of the directive will be the additional compliance requirements for toys. It is believed that this will mean that there may be a 30-40% increase in the amount of quality assurance work required, especially with the increased testing. Industry representatives estimated that a great deal of SME's will either need to employ one more person to do this work or

outsource the work. However, there are not thought to be a large number of companies with the capacity to outsource this work to.

80. **Costs of enforcement on industry:** due to changes in technical files in information on chemicals, CE marking and traceability information and conformity assessment procedures. It is currently very difficult to assess whether enforcement costs will increase or decrease.

81. On the one hand the enforcement agency responsible the Trading Standards Institute (TSI) suggested there would be extra costs associated with more time taken to look at paperwork and additional testing costs and on the other there is recognition that more paper based evidence could reduce the testing/time required as those toys for which the necessary procedures had not been carried out would be exposed by the lack of paperwork. This IA therefore assumes that there is no overall impact.

82. TSI suggested SMEs would require more advice on compliance issues. However, we believe it will be negated by the fact there is already very substantial and accurate guidance, (developed jointly with industry and Member States), publicly available on the European Commission web-site and the BTHA web-sites. BIS will also provide its own guidance.

### ***Monetisation of Reoccurring Costs:***

83. Industry provided BIS with estimates of reoccurring cost, this included:

- a. Testing and certification increases
- b. Delays to production schedules (more raw material rejections etc)
- c. Technical file/ Documentation control (greater burden)
- d. Safety assessments (new obligation)

84. Industry provided total costs estimate of a to d above, for an illustrative large multinational toy manufacturer at £0.3m per firm. Assuming all firms incur a cost the total cost to UK firms would be estimated at £109m spread over 9 years. This is equivalent to 3% of production costs for the toy industry per annum which is roughly in line with EU IA estimates which suggest that such (including product re-design and transition costs related to chemical requirements) will equate to approximately 7.6% of production costs. It therefore seems reasonable that the proportion of reoccurring costs sits well within this estimate. For 2011 0.01% of turnover is assumed to estimate costs associated a-d. Total reoccurring costs to business are estimated at £109m over 10 years, or £11 per annum.

Table 2: Summary table of costs (illustrative)

	Para reference	Total over 10 years (£/m)
<b>Transitional costs</b>		
Toys Redesign – manufacturing/re-design costs	69	82
Warning labels	67	1.4
Training and updating	73	16
Scrapping/ reviewing	65	32
<b>Total transition costs</b>		132
<b>Recurring costs</b>		
Admin costs of enhancement of safety requirements	84	109
Additional Costs of enforcement	81	Nil
<b>Total reoccurring cost</b>		109
<b>Total</b>		240

\*totals may not all add up to the same number on front sheet due to rounding

## Competition Assessment

85. The Directive will apply to all Member States of the EU. It is unlikely that the proposals will directly limit the range of suppliers, their ability or incentives to compete. However it may well indirectly affect the range or products, as discussed above, because of the additional testing requirements. However it is believed that is unlikely to have the effect of distorting or removing competition in the market. The Commission's Impact Assessment thinks it plausible that overall market competitiveness will not be affected since EU and non-EU manufacturers would need to adhere to the same standards if they wish to sell their products in the EU. However those manufacturers exporting outside the EU might have some contained cost increase exporting to non-EU markets as they will not be likely to develop two different production chains.

## Small Firms Impact test

86. According to the Commission's Impact Assessment (specifically in terms of the revision of chemical requirements) the burden of costs associated with the proposed TSD could fall disproportionately on smaller companies. For instance, the EU IA estimates which are based on industry survey responses from European firms, estimates that cost of more stringent requirements on warnings will hit SME's harder with costs approximately 27 times higher. Further investigation has suggested this is not likely to be the case for the UK. The market structure of the UK toy manufacturing industry is almost entirely made up of SMEs<sup>7</sup> with 86% of the 450 enterprises having fewer than 9 employees.

87. Consultation with industry has suggested that overall there will not be a disproportionate impact on SME's. In terms of training, updated procedures and workflows, technical filing and upgrade of data it is expected that SME's will incur less training cost. It's possible however that resource costs will increase by relatively more as a proportion of their total costs due to the cost of employing an additional person (£30 - £60k). In terms of costs associated with changes to products and packaging industry have indicated that SME's are likely to have fewer (or no) moulds that need to be altered suggesting they incur lower costs. However, SME's will buy from factories that have already made these changes and the cost of moulds may rise to reflect higher production costs. The cost associated with the scrapping of materials and products for

<sup>7</sup> Following the European Commission definition

SME's are likely to be lower by approximately 25% to 50%. However, industry flagged that they are more likely to lack technical resource which may result in poorer control and could increase costs associated with withdrawals or recalls. Testing and quality assurance costs will also rise disproportionately for manufacturers whose toys are complex and involve a wide range of materials, these are more likely to be larger firms. However, large companies are more likely to already have the technical infrastructure whereas a SME may have to employ someone for the first time or pay a third person to provide the expertise. Overall, taking this assessment on board, SME's are not expected to bear a disproportionate cost burden.

88. Other factors aside from size of business will also determine the level of cost burden, this includes, range of materials used, complexity of toys designed and number of product lines – these are more likely to feature in larger firms. Therefore exemptions for SME's, where costs may be higher (e.g. testing), was not considered an option because overall costs are not expected to be disproportionately imposed on SME's. Also, as noted virtually all the manufacturers in this industry are SMEs, 5 or 6 companies employ more than 50 people. In order for the risks associated with less stringent testing to be mitigated these businesses could not be exempt. Exemption would in addition disadvantage SME exporters to the EU27 who would have to comply with legislation in order to sell products to EU member states.
89. Microbusiness Exemption Rule: Under the microbusiness exemption rule whereby regulation exempts organisations of 10 or fewer employees and start-ups, this measure is out of scope because it relates to the EU.

#### **Direct costs and benefits to business calculations (OIOO)**

90. Under the One In, One Out rule whereby a measure of net cost to business (a One In) cannot be implemented unless an equivalent regulation of net cost is removed or simplified (a One Out), the preferred government option in this IA is not adding any additional layer of legislation as it uses existing legislation to address the identified market failures. This cannot be banked as a One IN because EU measures are currently exempt from OIOO.
91. The proposed legislation does not gold plate because it does not go over the minimum EU requirements. The TSD is a directly applicable EU measure. It must be transposed within 18 months of publication (est. July 2011). Therefore, the legislation is being implemented at the latest possible transposition date.
92. Direct cost to business includes the additional costs to transitional cost of redesign and R&D as well as ongoing cost from compliance on enforcement and is estimated at £10m equalised annual cost over 10 years from 2011.

#### **Impact on the Public Sector – Enforcement and Sanctions**

93. The Toys (Safety) Regulations 1995 are enforced by local authorities' trading standards departments. It is the responsibility of the manufacturers of toys made in the EU or importers of finished products to ensure that products comply with the Regulations.
94. The obligation to prove a toy is unsafe lies with Trading Standards. On the one hand the Trading Standards Institute (TSI) suggested there would be extra costs associated with more time taken to look at paperwork and additional testing costs and on the other there is recognition that more paper based evidence could reduce the testing required as those toys for which the necessary procedures had not been carried out would be exposed by the lack of paperwork. It is there considered that there is no overall impact.

#### **Health Impact Assessment**

95. The proposed revision of the Directive will benefit health of consumers, in particular children. The extension of the Directive would have health benefits through reductions in the number of toy-related injury related incidents. As noted in para 45 it is estimated that benefits from reduced rate of injuries will amount to £1.3m over 10 years. This is based on the assumption that the directive will reduce injuries by approximately 20%. There is a great deal of uncertainty from industry on the extent to which the directive will reduce injuries, but as noted in the EU IA it is presumed there will be some reduction due to more stringent requirements on for instance food and toys and greater information provision to consumers via labelling.

96. The most significant benefits would arise from modifications to the chemical safety requirements which would help reduce the number of children developing diseases and other chemical-related harmful medium and long-term effects. Results from the Disability adjusted life years (DALYs) analysis conducted for the EU IA is used to derive UK level benefits. DALYs reflect benefits of any reduction in disease caused by the removal of any chemical hazards in toys. The basis is that scientific knowledge of hazards has identified a number of substances which are potentially carcinogenic, mutagenic or toxic to reproduction – the effects of these restrictions in toys may be minimal, but equally may catch something very harmful: e.g. an asbestos equivalent. However the effects of any particular restriction were not measureable partly because the level of chemical requirements have not been agreed. It is estimated that benefits from DALYs will range from £3m to £130m (see para 44)

### **Environmental Impact Test**

97. Consideration of the effect of the revision of the Directive in the environment has been considered. Environmental protection is not within the objectives of the Directive therefore no direct environmental impacts are expected from this proposal. The only modifications which could potentially result in (indirect) environmental impacts are the proposed restrictions of the use of chemicals in toys. The forthcoming limits/ban on certain dangerous chemicals would limit the amount of these chemicals which could potentially enter the environment. Therefore an impact has not been quantified.

### **Greenhouse Gas Assessment**

98. The regulations are not expected to have any significant impact on Greenhouse gas levels

### **Human Rights**

99. The Regulations are not expected to have an impact on the rights and freedoms of individuals as set out in the Human Rights Act 1998

### **Justice System**

100. The regulations are not expected to have any material effect on the criminal or civil liberty of those who it affects, and so should not have impact on the justice system in the UK

### **Rural Proofing**

101. The regulations are not expected to have significant impacts on rural areas or circumstances

## **Sustainable Development**

102. The regulations are not expected to have significant impacts on sustainable development.

## **Statutory Equality Duties**

103. After an initial screening as to the potential impact of this regulation on race, disability and gender equality it has been decided that there will not be a major impact upon minority groups in terms of numbers affected or the seriousness of the likely impact, or both.

## Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

### Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

<p><b>Basis of the review:</b> [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];</p> <p>The Commission intends for Member States to report on the application of the Directive 3 years after it is implemented and every 5 years thereafter. A summary of Member States' reports will be published by the Commission.</p>
<p><b>Review objective:</b> [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]</p> <p>The objective of the PIR will be to assess whether the policy has had the intended effects, in particular reducing the number and effect of toy-related incidents.</p>
<p><b>Review approach and rationale:</b> [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]</p> <p>The PIR will be based on a mix of qualitative and quantitative evidence, gathered from enforcement teams (in this case, Trading Standards) and industry participants, hopefully supported by evidence from accident-related statistics.</p>
<p><b>Baseline:</b> [The current (baseline) position against which the change introduced by the legislation can be measured]</p> <p>The current number and effect of toy-related incidents provides the baseline against which the effect of the policy can be judged.</p>
<p><b>Success criteria:</b> [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]</p> <p>Success of the policy will be evident from a reduction in the number and effects of toy-related incidents. However, it is important to note that other factors may be involved, such as increased consumer awareness leading to increased reporting of incidents.</p>
<p><b>Monitoring information arrangements:</b> [Provide further details of the planned/existing arrangements in place that will allow a systematic collection of monitoring information for future policy review]</p> <p>Market surveillance activities are required under EC Regulations. In the UK market surveillance activities generally undertaken by Trading Standards, will allow a systematic collection of relevant information.</p>
<p><b>Reasons for not planning a PIR:</b> [If there is no plan to do a PIR please provide reasons here]</p> <p>N/A</p>