

THE SAFETY OF TOYS

Government response document
to the Department for Business,
Innovation and Skills' public
consultation on the transposition
of European Directive on the
Safety of Toys 2009/48/EC

JULY 2011

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1. Executive Summary

This document is in response to the Department for Business, Innovation and Skills' public consultation document issued on 4 February 2011 for the transposition of the European Directive on the safety of toys (2009/48/EC). The proposed UK legislation should have been implemented on 20 January 2011 for application on 20 July 2011.

The objective of the Directive is to enhance the level of safety of toys while maintaining the smooth functioning of the Internal Market for toys. To achieve this overall objective three specific objectives were identified.

- Strengthen and modernise the essential safety requirement for toys.
- Improve the understanding and enforcement of the Directive within Member States.
- Improve clarity of the scope and definitions of the Directive.

Our proposal is to implement new Regulations, the Toys (Safety) Regulations 2011, which will repeal the existing Toys Safety Regulations 1995 (SI 1995/204) and have been designed to ensure that only safe toys are made available on the EU market. These new regulations have been designed to transpose the Directive of the European Parliament and the Council on the safety of toys (2009/48/EC) of 18 June 2009.

2. Background

The purpose of the February consultation was to gauge views and information on the likely effects of UK implementation of the proposals on the toy manufacturing industry, importing and distribution industries, regulatory bodies and local authorities, conformity assessment bodies and consumer organisations.

Further details of the EU Directive and the detailed guidance developed by the European toys industry is available on the European Commission website at:

http://ec.europa.eu/enterprise/sectors/toys/documents/directives/index_en.htm

Our draft Regulations have been designed to implement the European Directive into UK law by following the wording of the Directive as closely as possible and by putting in place the

necessary market surveillance provisions covering enforcement of the legislation and the requirements for UK Notified Bodies. Separate Guidelines (available on the BIS website) have been developed for the assessment of those conformity assessment bodies that wish to be notified under the new Directive.

Directive 2009/48/EC replaces the existing Directive 88/378, revising and enhancing it. The existing Directive follows the New Approach model of European harmonisation legislation by detailing the essential safety requirements on the face of the Directive and delineating the specifics to the harmonised standards. The revision closely follows Decision 768/2008/EC which creates the New Legislative Framework for goods (negotiated and adopted as part of the Goods Package in 2008). This specifies more detail, particularly on the obligations of economic operators and the notification process, on the face of the Directive, although much of the detail relating to the essential safety requirements will still have to be clarified in the harmonised standards. This is particularly true in relation to the chemical restrictions which will come into force in 2013.

In regard to the use of chemicals in toys, certain allergenic fragrances are prohibited and the labelling of 26 other fragrance allergens is required in certain circumstances. The revision also prohibits substances that are categorised as carcinogens, mutagens and substances that are toxic to reproduction (CMRs) in accessible parts of toys unless authorised in comitology procedures under the Directive or within the derogation limits of the Directive.

New provisions are included to improve the effectiveness of warning 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 user weight and the need for the relevant toys to be used under adult supervision.

The Directive extends the safety requirement relating to the risk of inhalation of small parts from toys so that it covers those toys intended for children under 36 months but also any toys or packaging intended to be put into the mouth regardless of age. The Directive also extends the safety requirements so that they cover not only the risk of external airway obstruction of the mouth and the nose but also internal airway obstruction. The Directive bans 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.

The revision reinforces the relationship with the EU Regulation on Accreditation and Market Surveillance (Regulation (EC) No 765/2008) particularly in relation to the specific powers and sanctions available to the market surveillance authorities (in the UK these are the Local Authority enforcement authorities).

Manufacturers, or importers where they take on the responsibility of a manufacturer, will be required to perform a more detailed analysis of the risks presented by a toy via safety

assessments which will include more detailed analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards.

We carried out a detailed analysis of the relevant national legislation to assess whether it already met the objectives of the new Directive. Given that the new Directive was a fundamental recast of the Toys Directive (1988/378/EEC), the existing UK legislation also needed to be updated in line with the new requirements. The current 1995 Regulations are to be repealed when the new Regulations come into force.

We also looked at the enforcement provisions within the Consumer Protection Act 1987 (CPA) to assess whether they fully addressed the requirements of the Directive. We found that the CPA does not fully cover the requirements of the EU Regulation on Accreditation and Market Surveillance (RAMS, No. 765/2008) and that certain enforcement provisions of the General Product Safety Regulations (SI 2005/1803) (GPSR) were necessary to supplement the provisions of the CPA in order to fully implement the requirements of the new Directive.

10 responses were received to the consultation and were from trade associations representing the toy sector, individual businesses and from the enforcement community.

We gave very careful consideration to the arguments put forward and in conjunction with BIS legal analysis, we have concluded that the information provided was very helpful in updating and revising the Impact Assessment (particularly the new costs to businesses) and also for amendments to the draft regulations. In a number of areas the draft regulations have been clarified and simplified.

Better Regulation Principles

Our legislative proposals are in line with the Government's Regulatory principles. The UK is required to implement Directive 2009/48/EC into UK law. We propose to do so using powers under s2(2) of the European Communities Act 1972 and section II of the Consumer Protection Act 1987. We considered other non-regulatory forms of implementation but concluded that the reliance on the use of standards and self declaration was already a business-friendly method of regulation. We also considered that because the legislation is aimed at protecting children under the age of 14 from unsafe toys it was necessary to ensure that the regulations would be proportionately enforced with appropriate sanctions (including criminal sanctions) for those who endanger children.

We have ensured that our draft regulations to the extent that it is possible to do so "copy-out" the Directive and do not go beyond the Directive's minimum requirements ("gold-plating"). The

essential safety requirements are taken directly from the Directive and there are ambulatory provisions to account for any changes agreed by the regulatory committee (by the way of the comitology procedure). The proposed legislation only brings in measures which we consider to be necessary for legislative implementation so it omits any provisions that are directed at the UK competent authority.

Under the Government's new "One In One Out" rule, which took effect from 1 September 2010, when Government Departments seek to introduce new regulations which impose costs on business, they will have to identify current regulations with an equivalent value that can be removed. However, transposition of European Directive on the safety of toys 2009/48/EC does not apply because EU measures are exempt for the foreseeable future. The Toys (Safety) Regulations 1995 are to be revoked when the new regulations apply.

3. Responses Received

The consultation process, which took the form of a consultation document was made available through the BIS website.

The consultation posed questions about the transposition of the Directive on the safety of toys, including the Impact Assessment. A total of responses were received (see Annex A for details of the respondents) and they are broken down as follows:-

Large Business	2
Small to Medium Enterprise	3
Professional Body	1
Trade Associations	3
Test House	0
Enforcement Authority	1

As part of our consultation process, we also held meetings with stakeholders representing the toys industrial sector, the Notified Bodies, and with the co-ordinating body responsible for the enforcement authorities.

4. Summary of Responses

The following analysis of the responses received to the consultation is focused on the questions posed in the consultation document. The Government responses to the points raised are set out following each question. It is worth noting that there were a number of responses which were not in direct response to the Consultation but were more focused on the policy on the implementation of the Directive. We have not responded directly to those questions as they do not directly effect the UK regulations.

Question 1 - Can you provide any evidence to help inform the Impact Assessment?

In particular:

- any observations on the potential immediate benefits from clearer labelling and warnings
- any observations on the potential long term benefits from the additional chemical restrictions
- any clarifications on the costs
 - a) of the immediate new labelling/warning requirements
 - b) of the longer terms chemical restrictions

and any views of the observations on costs relationships with SMEs?

Recap of the Consultation Stage Impact Assessment:

The Consultation Stage Impact Assessment covered 2 possible options, do nothing or modification of the UK regulation in line with the Directive. Only the latter was fully analysed because of the legal obligation on the UK to bring national regulations in line with the Directive. Costs to business were estimated on a best case scenario to be £45.4m per annum. The benefits were difficult to assess given that the sector was already subject to safety regulations and the main benefits from harmonisation of the single market has been largely accounted for by the 1988 Directive. However, using the EU Impact Assessment as the basis of the analysis it was considered that the range of benefits could be from £4.6m to £198.5m per annum. These were mainly as a result of the health benefits although we accepted that a best estimate was highly uncertain and may well be at the lower end of the spectrum.

Analysis of responses

There were 4 responses to this question. One large business thought that there would be few new benefits from clearer labelling and warnings on the grounds that these have always been part of the safety requirements for toys. Another thought that there were benefits to the consumer to better choose toys for specific age groups.

On the potential long term benefits of the new chemical requirements, two large businesses considered that these would be unclear.

On costs, one large business considered that there could be costs associated with retooling to mark products with information, additional processes to capture warning information from suppliers and to manage the presentation of the information, and costs associated with ensuring their supply base was aware of the legislative changes. One trade association made the point that SMEs will be disproportionately impacted by the costs of compliance especially the costs of testing for compliance which may dissuade them from bringing new products to market. Another large company did not think that there would be additional costs from labelling.

The costs of the chemical changes would have a profound effect on a large business from reviews of the chemical constitution of products and to implement a testing regime. Another large company agreed but was unable to quantify the costs. One SME was very concerned at the potential costs for testing for chemicals. It felt that the testing should be carried out upstream by the chemical suppliers rather than by the manufacturers of the products. Testing (for chemicals) to comply with US toy safety legislation (for phthalates alone) cost 55k HKD.

A professional body took the view that the costs of enforcement will not be minimal on the grounds that the Regulations are complex and SMEs will need extensive advice and that the costs of enforcement will increase substantially because of the greater number of processes to examine and increased costs of testing for compliance. One large business thought that the safety assessment would also bring additional costs. About £10k had already been spent on training and a new person would be recruited to lead on this work at the cost of £35k PA.

Government Conclusions

We thank those who responded to these questions and have amended the Impact Assessment accordingly and by taking into account new information that has been made available outside of the consultation. The final Impact Assessment is at Annex B. It concludes that the average annual cost will be £11m pa with best estimate transitional costs of £66m. The average benefits are estimated to be £4m pa. We have not altered the enforcement costs because we believe that the enforcement authorities will focus less on expensive testing than on the assessment of

the documentation including the technical files. Enhanced traceability of those in the supply chain will also assist the enforcement authorities.

Question 2- Do you believe the enforcement provisions are effective, proportional and enforceable?

Recap of the draft Regulations

The draft Regulations build upon existing provisions for enforcement in the Consumer Protection Act 1987 (CPA) and utilises certain sanctions available under the GPSR where there is an explicit requirement in the Directive for non-compliant products to be withdrawn or recalled.

The current Directive has no explicit market surveillance provisions but the new Directive is markedly different in this respect. We have attempted to maintain the existing regime i.e. CPA powers remain available to the enforcement authorities and the sanctions and the use of the GPSR powers are available where additional powers are necessary.

Analysis of responses

There were 4 responses to this question. A representative body was concerned at the distinction made between the provisions for manufacturers and importers where it was considered that an element of *mens rea* was introduced for importers which would make enforcement against importers problematic in a way which had not been intended.

An enforcement authority agreed and considered that there was no sanction for an importer supplying an unsafe toy. It also thought that economic operators should be required to present information rather than just identify a supplier.

There were also concerns about the perceived lack of offence for breaching the regulations by “placing on the market” as opposed to supplying an unsafe toy, which is the language used in the CPA.

One large business thought that the enforcement provisions were effective, proportional and enforceable. Another thought that the draft regulations appeared to facilitate a more objective enforcement approach by differentiating between the responsibilities of the economic operators.

However, it thought that it would be inappropriate to serve a compliance notice on a distributor for a failure (by the manufacturer) to draw up a declaration of conformity.

Government Conclusions

We concluded that the draft regulations would benefit from having simpler enforcement provisions to aid clarity for both businesses and the enforcement authorities. These provisions have therefore been streamlined whilst effectively maintaining the original policy objective. We agree that the provisions regarding the prohibition on an importer placing a product on the market needed to be stronger and we have amended the duty on importers to match the duty on manufacturers, in that they must not place a non-compliant toy on the market.

We note the comments about the need for a business to “present information”, however, we consider that the current draft will already achieve the underlying objective of these provisions because the powers to require information in s29 of the CPA can be used in addition to the provisions in Regulation 38.

In respect of a specific offence of “placing on the market” we do not believe that this is necessary. “Placing on the market” and “making available on the market” are synonymous with “supply” in the CPA because of the definition in Regulation 3 which links them to “supply” under the CPA. Legally, the actions of “making available on the market” and “placing on the market” under these regulations includes the action of “supply” under the CPA, so that the offence of “supplying” under s12 of the CPA is triggered by placing on or making available on the market.

We believe that the latest version of the Regulations in respect of the enforcement provisions are more fit for purpose and clearer for both enforcement authorities and businesses.

Question 3 - Do you agree that we should bring the Notified Body notifications into force as soon as possible?

Recap of the draft Regulations

We had hoped that the draft Regulations would be made in advance of the date from when they would apply and by bringing the notified body provisions in at an earlier date this would help those bodies gear themselves up for when business had to comply.

Analysis of responses

There was just one response to this question from a large business who agreed that prior notification in other Member States would put the UK Notified Bodies at a disadvantage..

Government Conclusions

Unfortunately because of the delay in the making the Regulations, this provision is now redundant and has been removed from the Regulations.

Question 4 - Do you agree with the proposal to deal with some of the Annexes to the Directive, by reference; i.e. referring to them in the Regulations rather than reproducing the Annexes in the body of the Regulations? The advantage of this is that as and when the Directive is updated, the Regulations do not need to be updated and the information can be made available to interested parties by publication on the BIS web-site and notification through Businesslink. This type of reference in legislation is called an ambulatory reference.

For example; at regulation 4(3)(f), listing products to which the regulations do not apply, at regulation 5(1)(b) listing essential safety requirements and regulation 6, particular safety requirements.

Recap of the draft Regulations

See the explanation above in the question for a detailed description of the intention of the policy of using ambulatory references.

Analysis of responses

There were 2 responses to this question. One large business agreed with the use of ambulatory references. One professional body thought that for clarity, transparency and understanding, all of the annexes should be in one document.

Government Conclusions

Clarity, transparency and understanding are vitally important for legislation. However, we expect the annexes to the Directive to be amended on a regular basis and if the Directive annexes were subsumed within the draft regulations then these would have to be amended legislatively at regular intervals. We do not believe that such amendments would add to clarity for business. We therefore propose to proceed as proposed and to use ambulatory references in the Regulations but we will ensure that our website and that of the European Commission is continually up to date.

Question 5 - Do you have additional observations on the detailed drafting?

Analysis of responses and Government Conclusions

There were 10 responses to this question.

Regulation 2: A trade association was concerned at the impact of returns on its SMEs when the new Regulations comes into effect because of the long shelf-life of their members' products. Regulation 2 makes clear that the 1995 Regulations continue to apply to any toy that has been placed on the market before the new Regulations come into effect. This should alleviate the need for returned products.

Regulation 3: A trade association thought that risk should be defined. The term "consumer" should be used instead of "end-user" and "natural or legal person" should be used instead of "person". We agree that it would be helpful to transpose the definition of risk from the Directive but disagree on the other two points as we believe that the current drafting is clearer.

Regulation 3: A large business thought that the use of "placing on the market" and "making available" could cause problems for Trading Standards. We believe that this is covered by the definitions which link the concepts into the CPA definition of supply.

Regulation 4: A Trade Association thought that there should be a distinction made here between sporting slings and catapults and toy versions. Since these products are not to be considered within the scope, this is unnecessary.

Regulation 4(3): A small and medium enterprise commented that this regulation did not include the word toys in the references to those categories of products that are excluded from the scope of the regulations. We consider that the use of the term “toys” is unnecessary in this context especially as regulation 4(3)(f) includes products in Annex I that may have some play value but are not toys within the meaning of the Directive.

Regulation 8: A trade association was concerned that these provisions added nothing. This is a provision of the Directive that is required to be implemented.

Regulation 8: Another trade association thought the policy behind the regulation was impractical and commercially counterproductive and that dummy products were not intended to replicate the finished in its specific sector. This is a provision of the Directive that is required to be implemented.

Regulation 10(1): A trade association thought that this was identical to Regulation 10(2) and Regulation 11. We consider that Regulation 10(2) is effectively the prohibition whilst Regulation 11 is a Directive requirement which must be implemented.

Regulation 13: A trade association stated that in theory all toys are required to be type examined but are not and is thought to be a defect in the Directive. We do not believe that it is the intention of the Directive for all toys to be type examined and that the current drafting addresses the issue appropriately for businesses to be able to determine what their legal obligations are.

Regulation 16(1) and (2): A trade association thought that Regulation 16(1) has the same effect as Regulation 16 (3)(a) and (b), and that Regulation 16(2) has the same effect 16(3)(c). In response, the regulations deal with the Declaration of Conformity requirements before and after 2013.

Regulation 16: A large business thought that the reference made to the chemical requirements for Directive 88/378/EC differed from the requirements in the Directive for a Declaration of Conformity and from the technical guidelines and would require additional information just for the UK market. We have removed the need to make reference to the pre or post July 2013 chemical requirements in the Declaration of Conformity.

Regulation 16(7): A trade association questioned why the Declaration of Conformity was required to be in English when Article 21(2) and (3) covering technical documentation states that the latter can be in any EU language and translated on request. We believe that the requirements for the Declaration of Conformity are quite specific in Article 15(2) and in the Guidance material produced by the European Commission.

Regulation 17(6): A trade association suggested that the phrase “upon a reasoned request” be added. We believe that this is what Regulation 17(7) means.

Regulation 18(7): A trade association considered this to be redundant. However, we consider that this requirement is in the Directive and therefore should be implemented.

Regulation 18(9): A trade association wondered under what conditions the presumption in Regulation 18(8) is rebuttable. This presumption is rebuttable in any circumstances where a presumption of conformity does not in fact equate to compliance with the legislation.

Regulation 19: A small and medium enterprise asked for greater clarity on when a toy is too small to be marked with information about the product and the manufacturer. We believe that where the other options in the Directive and in Regulation 19 do not suffice, any further should be provided for in the guidance to the Directive.

Regulation 19(2)(c): A trade association and a large business thought that there may be more than one address but that this would be acceptable where the main contact address is highlighted. We agree but do not believe that it is necessary to make any drafting changes because a single contact address is necessary even if other addresses are shown as well.

Regulation 20(5): A trade association thought “intended use” should be replaced with “commonplace use” instead. We disagree and believe that the wording of the Directive should be used since commonplace use would require clarification.

Regulation 20(7)(b): A trade association thought that the requirement to affix permanently went further than the Directive. We agree and have removed this.

Regulation 20(9): Two trade associations thought that “on-line” needed to be defined and the responsibility placed on the person responsible for maintaining a website or a catalogue. Since

the legislation is consumer law the provision applies to consumer sales only and as such “on-line” sales do not need to be defined. We do not think that the provision requires amendment.

Regulation 21(1): A trade association considered that series production is not a clear term. Another argued for rewording. We considered re-drafting but concluded that as the term series production was that used in the Directive we should follow this approach under the principle of copy-out. However, we have amended the heading of the Regulation to “Compliance procedures for series production” to make this easier to understand.

Regulation 23(1): A trade association wished to see this provision prefaced by “when deemed appropriate with regard to the risks presented by the toy”. We have considered this carefully but believe that the regulation already uses this language since the manufacturer must only take action as he “considers appropriate...”

Regulation 23(1): An enforcement authority considered that the phrase “the manufacturer considers” be removed and replaced by the word “are” or “are deemed”. We believe that our drafting is better aligned to the Directive.

Regulation 24(1) and (2): A trade association wondered whether the word “consider” should be used with “and has reason to believe”. We do not believe that there is a difference in meaning between consider and having reason to believe.

Regulation 24(3) and (4): A trade association considered that a requirement for the request to be “reasoned” needed to be added. We agree and have made the amendment.

Regulation 26: A trade association disagreed with the policy that an importer has only to ensure that the manufacturer has undertaken its responsibilities. We have strengthened the prohibition in Regulation 26(1) which should alleviate these concerns.

Regulation 29(1): A trade association considered that this needed to be prefaced by the Directive wording “when deemed appropriate with regard to the risks presented by the toy”. We believe that the current draft has the same effect because the provision applies “as the importer considers appropriate” taking into account any “risk” presented by a toy.

Regulation 29(1): An enforcement authority thought the phrase “the importer considers” should be removed and replaced by the word “are” or “are deemed”. We believe that our drafting is better aligned to the Directive.

Regulation 29(2): A trade association thought that keeping a register of complaints needed to be prefaced by “if necessary”. We believe that the current drafting has the same effect as if there are no complaints, there will be no such register.

Regulation 30(1) and (2) and Regulation 35(1) and (2): A trade association considers that this goes beyond the Directive because “intending to place on the market” capture more than the Directives wording “before placing on the market”. We believe that the wording of the Directive “before placing” has the same effect as the word “intending” and is clearer.

Regulation 30(3) and (4) and Regulation 35(1) and (3): A trade association thought that the word “consider” should be used as well as “reason to believe”. We consider that these words do not add anything to the meaning of the existing wording.

Regulation 33: A trade association felt that requiring that an importer to comply with the storage and transportation requirements went further than the Directive. We disagree and think we have almost exactly replicated the Directive’s requirements on this point.

Regulation 33(1) A large business thought that this drafting is inconsistent with the Directive in that it could be interpreted that the Regulations offer a broader interpretation of the duty of care potentially expanding into areas not intended by the Directive. We disagree and think that the Directive’s requirements that distributors act with due care in relation to the “applicable requirements” is implemented precisely in this Regulation.

Regulation 35(1): A trade association believed that this could add an additional risk assessment role for distributors. We believe that this is in line with Article 7(2) of the Directive.

Regulation 35(5) and (6): A trade association thought that the request would have to be reasoned. We agree and have amended this with a new Regulation 35(6).

Regulation 36: A trade association thought that this gives the impression that distributors were required to have documents in their possession. We believe that it only requires those that already have the documents in their possession to provide them rather than requiring them to keep any documents.

Regulation 38: A trade association felt that a one-up, one-down identification of the economic operators is easier to understand. We have amended to drafting to simplify this.

Regulation 38(1): An enforcement authority asked for the words “present information” to be inserted before the word “identify” in order to better trace suppliers on non-compliant products. We believe that powers to require information are already available under the CPA and that the current drafting is sufficiently aligned to the Directive.

Regulation 39: A trade association said that Regulation (EC) 765/2008 allows other markings to be used. We agree and will incorporate within the guidance material.

Regulation 39(1)(b) and Regulation 47(4): A large business queried the use of the phrase “foreseeable and normal period of use” and how this can be demonstrated by using the various modules. The use of the phrase is taken directly from Article 10(3) covering the essential safety requirements which the UK is obliged to implement into law.

Regulation 45: A trade association asked if there was an appeal process in Regulation 44(6). We think that there is a form of appeal in that the Notified Body must invite the manufacturer to respond to its conclusions before making a decision.

Regulation 47: A trade association thought that since enforcement authorities will be able to insist on sight of EC Type examination certificates and other information from NBs it is even more important that those certificates are not the norm for mainstream toys. This is a comment not a drafting suggestion. We propose to maintain the drafting.

Regulation 50: A trade association thought that charging requirements do not include Regulations 44 and 45. We think that the drafting is correct.

Regulation 51: A trade association wondered whether there should be similar controls to those under the RAPEX notifications. We agree to consider adding this in the guidance.

Regulation 53 and 54: A professional body thought that these were unnecessary as the General Product Safety powers were already available. We do not agree that these powers will be available because of the way these powers work with the sectoral legislation that is more specific, but we have redrafted in order to make the GPSR powers available.

Government Conclusions

We would like to thank all those who responded to the consultation whether in writing or during the course of meetings. We have taken on board a number of the comments and have redrafted the Regulations accordingly (an amended draft is at Annex C). The biggest changes are in the enforcement provisions which have been simplified and shortened. We have also made changes to ensure that the Regulations are more closely aligned to the requirements of the Directive.

5. Next Steps

We have carefully considered all the responses to the questions. As a result of our considerations, and as explained earlier in this consultation, we have revised our draft regulation on the safety of toys to take account of certain points which were raised during the consultation process.

The draft regulations will be laid in Parliament shortly and will take effect 21 days from the date of the regulations being laid.

In terms of guidance, at the same time as publishing this Government Response Document, we will issue a one page information note on the BIS website which gives an overview of our proposals and provides a link to the very detailed guidance developed by industry and the European Commission.

We will be issuing more detailed guidance on our UK legislation in due course. The guidance will be aimed at enforcement authorities, businesses and others who will have responsibility for taking forward or are affected by the provisions in the draft Regulations.

Contact details for further information on the Toys (Safety) Regulations 2011:

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6. Annexes

Annex A - List of Respondents

Scan Design Ltd

PMS Ltd

British Toy and Hobby Association

Ferrero UK Ltd

Logiblocs Ltd

The Publishers Association

Home Retail Group Plc

Trading Standards Institute

EQUITOY

London Trading Standards Authorities

Annex B – Final Stage Impact Assessment

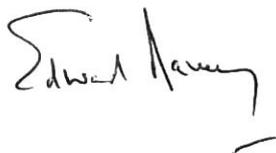
Title: Impact Assessment of Proposals to Revise the Toys (Safety) Regulations 1995 Lead department or agency: BIS Other departments or agencies: None	Impact Assessment (IA)
	IA No: BIS0016
	Date: June 2011
	Stage: Final
	Source of intervention: EU
	Type of measure: Secondary legislation
Contact for enquiries: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

Summary: Intervention and Options

<p>What is the problem under consideration? Why is government intervention necessary?</p> <p>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.</p>	
<p>What are the policy objectives and the intended effects?</p> <p>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.</p>	
<p>What policy options have been considered? Please justify preferred option (further details in Evidence Base)</p> <p>The following options have been considered:</p> <p>(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;</p> <p>(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.</p> <p>Alternative to regulation is also discussed on page 11.</p>	
<p>When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?</p>	<p>It will be reviewed 2015</p>
<p>Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?</p>	<p>Yes</p>

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 long horizontal stroke at the end.

:

Date: 11 July 2011

Summary: Analysis and Evidence Policy Option 1

Description:

Modification of UK regulations in line with the EU Directive

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

COSTS (£m)	Total Transition (Constant Price) Year	Average Annual (excl. Transition)	Total Cost (Present Value)
Low	32	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) Year	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%.

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

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 ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/a	Non-traded: 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?			Costs: n/a	Benefits: n/a	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large
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
Statutory equality duties ¹ Statutory Equality Duties Impact Test guidance	No	23
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	20
Small firms Small Firms Impact Test guidance	Yes	20
Environmental impacts		
Greenhouse gas assessment	No	22
Wider environmental issues	No	22
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	22
Human rights Human Rights Impact Test guidance	No	22
Justice system Justice Impact Test guidance	No	22
Rural proofing Rural Proofing Impact Test guidance	No	23

¹ 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.

Sustainable development Sustainable Development Impact Test guidance	No	23
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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	<u>European Commission Impact Assessment</u> http://ec.europa.eu/enterprise/sectors/toys/files/toys_final_report_without_annexes_en.pdf
2	RoSPA data: http://www.hassandlass.org.uk/query/MainSelector.aspx
3	HSE health impact – appraisal guidance http://www.hse.gov.uk/economics/eauappraisal.htm
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 ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs	67	65								
Annual recurring cost	0.04	12	12	12	12	12	12	12	12	12
Total annual costs	67	77	12	12	12	12	12	12	12	12
Transition benefits										
Annual recurring	0.1	0.1	4.7	4.7	4.7	4.7	4.7	4.7	4.7	4.7
Total annual benefits	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

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 industry² 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 turnover³ 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)⁴ 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.
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.

² 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

³ Excluding VAT

⁴ Following the European Commission definition

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 2007⁵ 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

⁵ 'Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals'

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 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.⁶ 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.

⁶ 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:

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 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 plus h toys. The extension of the Directive in this specific instance would involve the requirement that the CE marking be affixed to the toy or to 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:
- Semi finished materials (cannot be economically changed to comply)
 - 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 redesign** 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:

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

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 manufactures 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)
Transitional costs		
Toys Redesign – manufacturing/re-design costs	69	82
Warning labels	67	1.4
Training and updating	73	16
Scrapping/ reviewing	65	32
Total transition costs		132
Recurring costs		
Admin c osts of enhanc ement of safety requirements	84	109
Additional Costs of enforcement	81	Nil
Total reoccurring cost		109
Total		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 SMEs⁷ 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 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.

⁷ Following the European Commission definition

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 measurable 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.

Basis of the review: [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];

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.

Review objective: [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?]

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.

Review approach and rationale: [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]

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.

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

The current number and effect of toy-related incidents provides the baseline against which the effect of the policy can be judged.

Success criteria: [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]

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.

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

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.

Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]

N/A

Annex C – The Amended Toys (Safety) Regulations 2011

DRAFT STATUTORY INSTRUMENTS

2011 No. XXXX

CONSUMER PROTECTION

<i>Made</i>	- - - -	***
Laid before Parliament		***
<i>Coming into force</i>	- -	***

The Secretary of State is a Minister designated⁽⁸⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽⁹⁾ in relation to measures relating to consumer protection.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of an EU instrument to be construed as a reference to those provisions as amended from time to time.

In accordance with section 11(5) of the Consumer Protection Act 1987⁽¹⁰⁾ the Secretary of State has consulted such organisations as appear to him to be representative of interests substantially affected by the proposal to make these Regulations and such other persons as he considers appropriate.

The Secretary of State makes regulations 1 to 7, 10 to 12 and 14 to 38 in exercise of his powers conferred by section 11 of the Consumer Protection Act 1987⁽¹¹⁾, and paragraph 1A of Schedule 2 to the European Communities Act 1972⁽¹²⁾, and all other regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972.

⁽⁸⁾ S.I. 1993/2661.

⁽⁹⁾ 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1)(a) and by the European Union (Amendment) Act 2008 (c.7), section 3(3) and Schedule, Part 1.

⁽¹⁰⁾ 1987 c.43.

⁽¹¹⁾ Section 11(1) was amended by S.I. 2005/1803.

⁽¹²⁾ 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51) and was amended by the European Union (Amendment) Act 2008 (c.7), section 3(3) and Schedule, Part 1.

PART 1

Preliminary

Citation and commencement

- 1.—(1) These Regulations may be cited as the Toys (Safety) Regulations 2011.
- (2) These Regulations come into force on [XXth July]2011.

Revocation, saving and amendment

- 2.—(1) The Toys (Safety) Regulations 1995⁽¹³⁾ (“the 1995 Regulations”) and the Toys (Safety) (Amendment) Regulations 2010⁽¹⁴⁾ are revoked.
- (2) The 1995 Regulations, as amended, continue to apply, as if they had not been revoked, to a toy placed on the market before 20th July 2011.
- (3) The Pencils and Graphic Instruments (Safety) Regulations 1998⁽¹⁵⁾ are amended as follows.
- (4) In regulation 1, insert after paragraph (2)—
 - “(3) These Regulations do not apply to any article to which the Toys (Safety) Regulations 2011 apply.”

Interpretation

3. In these Regulations—
 - “the 1987 Act” means the Consumer Protection Act 1987;
 - “the Directive” means Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys⁽¹⁶⁾;
 - “the GPSR” means the General Product Safety Regulations 2005⁽¹⁷⁾;
 - “authorised representative” means a person who has been appointed in accordance with regulation 25(1);
 - “CE marking” means a marking—
 - (a) by which a manufacturer indicates that a toy will comply with the essential safety requirements during its foreseeable and normal period of use; and
 - (b) which takes the form set out in Annex II of Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁽¹⁸⁾;
 - “conformity assessment” means the process demonstrating whether specified requirements relating to a toy have been fulfilled;
 - “conformity assessment activities” means activities relating to conformity assessment, including calibration, testing, certification and inspection;
 - “distributor” means any person who—
 - (a) is in the supply chain for a toy, other than the manufacturer or the importer; and
 - (b) makes the toy available on the market;

⁽¹³⁾ S.I. 1995/204, amended by S.I. 2004/1769, S.I. 2005/1082 and S.I. 2010/1928.

⁽¹⁴⁾ S.I. 2010/1928

⁽¹⁵⁾ S.I. 1998/2406. (S.I. 1998/2406 does not apply, by virtue of regulation 2(3) of S.I. 1995/204, to articles which are toys to which S.I. 1995/204 applies.)

⁽¹⁶⁾ OJ No L 170, 30.6.2009, p1.

⁽¹⁷⁾ S.I. 2005/1803.

⁽¹⁸⁾ OJ No L 218, 13.8.2008, p30.

“economic operator” means a manufacturer, an authorised representative, an importer or a distributor;

“enforcement authority” has the same meaning as in section 45(1) of the 1987 Act;

“essential safety requirements” has the meaning given in regulation 5;

“harm” means physical injury or any other damage to health, including long-term health effects;

“harmonised standard” means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations⁽¹⁹⁾ on the basis of a request made by the European Commission in accordance with Article 6 of that Directive, the reference of which standard has been published in the Official Journal of the European Union;

“hazard” means a potential source of harm;

“importer” means any person who—

- (a) is established within the EU; and
- (b) places a toy from a third country on the EU market;

“intended for use by” means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group;

“make available on the market” means supply in the course of a commercial activity (whether in return for payment or free of charge) for distribution, consumption or use on the EU market, and related expressions shall be construed accordingly;

“manufacturer” means a person who—

- (a) manufactures a toy or has a toy designed or manufactured; and
- (b) markets that toy under that person’s name or trademark;

“Member State” means a member State of the EU;

“Module” means a Module of Annex II to Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC⁽²⁰⁾ and Module A, B or C shall be construed accordingly;

“Notified body designation” has the meaning given in regulation 40;

“place on the market” means make a toy available on the EU market for the first time, and related expressions shall be construed accordingly;

“recall” means take any measure aimed at achieving the return of a toy that has already been made available to the end user;

“risk” means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply;

“toy” has the meaning given in regulation 4;

“UK notified body” has the meaning given in regulation 40;

“withdraw” means take any measure aimed at preventing a toy in the supply chain from being made available on the market.

Toys to which these Regulations apply

4.—(1) These Regulations apply to toys placed on the market on or after XXth xxx 2011.

(2) Toys are products designed or intended (whether or not exclusively) for use in play by children under 14 years old.

(3) These Regulations do not apply to—

- (a) playground equipment intended for public use;

⁽¹⁹⁾ OJ No L 204, 21.7.1998, p37, to which there are amendments not relevant to these Regulations.

⁽²⁰⁾ OJ No L 218, 13.8.2008, p82.

- (b) automatic playing machines intended for public use, whether coin operated or not;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines;
- (e) slings and catapults;
- (f) products listed in Annex I to the Directive, as amended from time to time.

Essential safety requirements

5.—(1) The essential safety requirements in respect of a toy are—

- (a) the general safety requirement set out in paragraphs (2) to (5); and
- (b) the particular safety requirements set out in Annex II to the Directive (as amended from time to time), so far as relevant.

(2) Toys, including the chemicals they contain, must not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

(3) The ability of the users and, where appropriate, their supervisors must be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.

(4) Information as to the matters mentioned in paragraph (5), aimed at users of the toy or their supervisors, must be preceded by the word “Warning” or “Warnings” and must be marked in English in a clearly visible, easily legible, understandable and accurate manner on—

- (a) the toy, a label affixed to the toy, or the toy’s packaging; and
- (b) any instructions for use which accompany the toy.

(5) The matters are—

- (a) the inherent hazards and risks of harm involved in using the toy; and
- (b) the ways of avoiding such hazards and risks.

Particular safety requirements for toys placed on the market before 20th July 2013

6. Where a toy is placed on the market before 20 July 2013, the particular safety requirements in respect of chemical properties are those in paragraph 3 of Part II of Annex II to Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys⁽²¹⁾, and not those in Part III of Annex II to the Directive.

Presumption of conformity

7.—(1) A toy which conforms with harmonised standards shall be presumed to comply with the essential safety requirements to the extent that those requirements are covered by those standards.

(2) The presumption set out in paragraph (1) is rebuttable.

Exception for trade fairs or exhibitions

8.—(1) A toy which does not bear the CE marking, or in relation to which any other requirement of these Regulations is not complied with, may be shown or used at a trade fair or exhibition.

(2) Such a toy must be accompanied by a sign which indicates clearly that—

- (a) the toy does not comply with the Directive; and
- (b) the toy will not be made available in the EU before being brought into conformity with the Directive.

⁽²¹⁾ OJ No L 187, 16.7.1988, p1, amended by Directive 2008/112/EC of the European Parliament and of the Council in order to adapt Council Directive 88/378/EEC to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ No L 345, 23.12.2008, p68); there are other amending instruments to Council Directive 88/378/EEC but none is relevant.

Regulations to be treated as safety regulations within the meaning of the 1987 Act

9. Parts 1 and 2 of these Regulations are to be treated for all purposes as if they were safety regulations within the meaning of the 1987 Act.

PART 2

Prohibitions and Obligations on Economic Operators

Manufacturers and their authorised representatives

Prohibitions on placing toys on the market

10.—(1) A manufacturer must not place a toy on the market unless it will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) A manufacturer must not place a toy on the market without having complied with—

- (a) regulation 11 (design and manufacture of toys in accordance with essential safety requirements);
- (b) regulation 12 (safety assessment);
- (c) regulation 13 (applicable conformity assessment procedures);
- (d) regulations 15 (EC declaration of conformity and CE marking);
- (e) regulation 17(1) to (3) (drawing up of technical documentation);
- (f) regulation 19 (information identifying toy and manufacturer);
- (g) regulation 20 (instructions for use, safety information and warnings); and
- (h) regulation 21 (compliance procedures for series production).

Design and manufacture of toys in accordance with essential safety requirements

11. The manufacturer must ensure that the toy has been designed and manufactured to comply with the essential safety requirements during its foreseeable and normal period of use.

Safety assessment

12. The manufacturer must carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

Applicable conformity assessment procedures

13.—(1) The manufacturer must follow the applicable conformity assessment procedure to demonstrate that the toy will comply with the essential safety requirements during the toy's foreseeable and normal period of use.

(2) If the manufacturer has applied harmonised standards covering all the essential safety requirements, the manufacturer must use the internal production control procedure set out in Module A.

(3) In each of the following cases, the toy must be submitted to EC-type examination in accordance with the following provisions of these Regulations, together with the conformity to type procedure set out in Module C—

- (a) where harmonised standards covering all the essential safety requirements for the toy do not exist;
- (b) where the harmonised standards referred to in sub-paragraph (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 sub-paragraph (a) has been published with a restriction;
- (d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitates third party verification.

Application for EC-type examination

14. An application for EC-type examination to be performed in relation to a toy must—
- (a) be made to a notified body;
 - (b) be made in accordance with Module B;
 - (c) include a description of the toy;
 - (d) indicate the address at which the toy has been or will be manufactured; and
 - (e) if the application is made to a UK notified body, be accompanied by such fee as may be required by the body in accordance with regulation 50 (charging of fees by UK notified body).

EC declaration of conformity and CE marking

15. Where it has been demonstrated by performance of the applicable conformity assessment procedure that a toy will comply with the essential safety requirements during its foreseeable and normal period of use, the manufacturer must—

- (a) draw up an EC declaration of conformity in accordance with regulation 16(1) to (4); and
- (b) affix a CE marking in relation to the toy in accordance with regulation 18.

16.—(1) The EC declaration of conformity must state that it has been demonstrated that the essential safety requirements have been satisfied in relation to the toy.

(2) The EC declaration of conformity must also—

- (a) include the information, and follow the structure, set out in Annex III to the Directive; and
- (b) include any information required to be included by any Module which was followed in relation to the toy.

(3) The EC declaration of conformity may contain further information.

(4) The manufacturer must keep up to date the EC declaration of conformity drawn up in relation to a toy.

(5) Where the EC declaration of conformity drawn up in relation to a toy which is made available on the market in the United Kingdom was drawn up in a language other than English, the manufacturer must translate the EC declaration of conformity into English.

(6) By drawing up the EC declaration of conformity, the manufacturer assumes responsibility for the compliance of the toy.

Technical documentation and correspondence relating to EC-type examination

17.—(1) The manufacturer must draw up technical documentation which contains all relevant information about the means used by the manufacturer to ensure that a toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) The technical documentation must be drawn up—

- (a) in so far as it relates to EC-type examination of the toy, in an official language of the Member State in which the notified body which performed that examination is established or in a language acceptable to that body;
- (b) in so far as it does not relate to such examination, in one of the official languages of the EU.

(3) The technical documentation must include the information and documents listed in Annex IV of the Directive (technical documentation).

(4) Any correspondence relating to the EC-type examination of a toy must be drawn up in the official language of the Member State in which the notified body is established or in a language acceptable to that body.

(5) The manufacturer must keep the technical documentation for a toy (including the EC declaration of conformity) for a period of 10 years after the day on which the toy was placed on the market.

(6) An enforcement authority may, during the 10 year period, request a manufacturer to provide to it, within a specified period—

- (a) a copy of all or part of the technical documentation drawn up in relation to a toy; and
- (b) a translation into English of all or part of the technical documentation.

(7) A request must be accompanied by the reasons for making the request.

(8) The specified period must be 30 days beginning with the day on which the request was received by the manufacturer, unless a shorter period is justified in the case of serious and immediate risk.

(9) The manufacturer must comply with the request.

(10) If a manufacturer fails to comply with any of the manufacturer's obligations under paragraphs (1), (2), (3) or (9), an enforcement authority may request the manufacturer to ensure that a notified body performs such tests as the notified body identifies, within such period as the notified body may specify, to verify that the toy will comply with the essential safety requirements during its foreseeable and normal period of use, and that the toy complies with any harmonised standard applicable to the toy.

(11) The manufacturer must comply with the request (at the manufacturer's own expense).

Toys to bear CE marking

18.—(1) The manufacturer must affix a CE marking in relation to a toy.

(2) The CE marking must be affixed visibly, legibly and indelibly.

(3) The CE marking must be affixed to—

- (a) the toy;
- (b) a label affixed to the toy; or
- (c) the toy's packaging.

(4) Where the toy is small or consists of small parts, the manufacturer may, in place of affixing the CE marking in accordance with paragraph (3), affix the CE marking to—

- (a) a label which is not affixed to the toy; or
- (b) a leaflet which accompanies the toy.

(5) The manufacturer may (in place of affixing the CE marking in accordance with paragraphs (3) or (4)) affix the CE marking to a counter display where —

- (a) the toy is sold in the counter display;
- (b) it is not possible to affix the CE marking in accordance with paragraph (3) or (4); and
- (c) the counter display was originally used as packaging for the toy.

(6) Where the toy is inside packaging the CE marking must—

- (a) be affixed to the packaging (whether or not it is also affixed elsewhere); or
- (b) be otherwise visible from outside the packaging.

(7) The CE marking may be followed by a pictogram or by any other mark indicating a special risk or use.

(8) Any toy which bears the CE marking shall be presumed to comply with all the provisions of these Regulations.

(9) The presumption set out in paragraph (8) is rebuttable.

Information identifying toy and manufacturer

19.—(1) The manufacturer must ensure that the required information is marked—

- (a) on the toy; or
- (b) where the size or nature of the toy precludes the information from being marked on the toy—
 - (i) on the toy's packaging; or
 - (ii) in a document accompanying the toy.

(2) The required information is—

- (a) a type, batch, serial or model number or other information enabling the toy to be identified;
- (b) the manufacturer's name, registered trade name or registered trademark; and
- (c) a single address at which the manufacturer can be contacted.

Instructions for use, safety information and warnings

20.—(1) The manufacturer must ensure that a toy is accompanied by such instructions for use and safety information as is appropriate.

(2) In particular, the manufacturer must ensure that the following provisions of this regulation are complied with.

(3) Where it is appropriate in order to ensure the safe use of a toy, any information provided as to hazards and risks and avoiding them required by regulation 5(5) must include the specification of appropriate user limitations in accordance with Part A of Annex V to the Directive (general warnings).

(4) Where a toy falls within a category listed in Part B of Annex V to the Directive, the toy must be accompanied by any warning and other information which is required to accompany that category of toy.

(5) But a toy must not be accompanied by a warning set out in Part B where that warning would conflict with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

(6) The wording of a warning which is required by any of points 2 to 10 of Part B to accompany a category of toy must be replicated without alteration.

(7) A warning, instructions or other information required to accompany a toy must be marked in English in a clearly visible, easily legible, understandable and accurate manner on—

- (a) the toy;
- (b) a label affixed to the toy; or
- (c) the toy's packaging and, if appropriate, on any instructions for use which accompany the toy.

(8) Any warning or warnings accompanying a toy in accordance with this regulation must be preceded by the word "Warning" or "Warnings".

(9) A warning which determines the decision to purchase a toy (such as a warning specifying the minimum or maximum age for users) must also be clearly visible to the consumer before the purchase (whether by appearing on the consumer packaging for the toy or elsewhere), including in cases where the purchase is made on-line.

(10) In this regulation a reference to Part A or Part B of Annex V to the Directive, or to any provision of either of those Parts, is a reference to that Part or to that provision as amended from time to time.

Compliance procedures for series production

21.—(1) A manufacturer of toys which are manufactured by means of series production must ensure that procedures are in place to ensure that any toy so manufactured will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) In doing so, the manufacturer must take into account—

- (a) any change in the design or characteristics of the toy; and
- (b) any change which has been made to any of the harmonised standards referred to in the EC declaration of conformity drawn up in relation to the toy.

Submission of EC-type examination certificate for review

22. An EC-type examination certificate issued in relation to a toy must be submitted by the manufacturer to a notified body for review if—

- (a) any change is made to—
 - (i) the manufacturing process for the toy;
 - (ii) any raw material used in the toy; or
 - (iii) any component of the toy;
 - (b) 5 years have elapsed since the certificate was issued without it having being reviewed by a notified body;
 - (c) 5 years have elapsed since the certificate was last reviewed by a notified body without it having being reviewed again by a notified body; or
- the manufacturer is of the view that a review of the certificate is necessary for any other reason.

Monitoring of toys

23.—(1) The manufacturer must take such of the actions following in relation to a toy as the manufacturer considers appropriate for the purpose of protecting the health and safety of consumers, taking into account any risk presented by the toy.

(2) The actions are—

- (a) carrying out sample testing of marketed toys;
- (b) investigating any complaint made in relation to the toy;
- (c) keeping a register of—
 - (i) any such complaints;
 - (ii) any toy in relation to which any provision of these Regulations has not been complied with; and
 - (iii) any toy which has been recalled; and
- (d) keeping distributors informed of any action taken by the manufacturer in accordance with sub-paragraph (a), (b) or (c).

Non-compliant toys and toys presenting a risk

24.—(1) Where a manufacturer has placed a toy on the market and has reason to believe that any provision of these Regulations has not in fact been complied with by the manufacturer in relation to the toy, the manufacturer must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the toy, or withdraw or recall the toy, if appropriate; and
- (b) where the toy presents a risk, provide the relevant enforcement authority with information about the following matters.

(2) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any corrective measures taken in accordance with paragraph (1)(a).

(3) An enforcement authority may request a manufacturer who has placed a toy on the market to cooperate with it in relation to any action taken or to be taken to eliminate any risk posed by the toy.

(4) A request must be accompanied by the reasons for making the request

(5) The manufacturer must comply with the request.

Manufacturer's authorised representative

25.—(1) A manufacturer may, by a written mandate, appoint a person established within the EU as the manufacturer's authorised representative to act on the manufacturer's behalf in relation to specified tasks in relation to a toy.

(2) The mandate must allow the authorised representative to do at least the following-

- (a) perform the manufacturer's obligations under regulations 17(5) and (9) (duties to keep technical documentation and comply with a request by an enforcement authority for a copy or translation of technical documentation); and
- (b) perform the manufacturer's obligations under regulation 24(5) (duty to comply with a request in relation to action taken to eliminate risks posed by a toy).

(3) An authorised representative may not be appointed to perform the manufacturer's obligations under regulation 11 (duty to design and manufacture toy in accordance with essential safety requirements) or regulation 17(1) (duty to draw up technical documentation).

(4) An authorised representative must perform each obligation under these Regulations that the representative is appointed by the mandate to perform.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

Importers

Prohibitions on placing toys on the market

26.—(1) An importer must not place a toy on the market unless it will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) An importer must not place a toy on the market unless—

- (a) the importer has ensured that the manufacturer has done all of the following in relation to the toy—
 - (i) followed the applicable conformity assessment procedure in accordance with regulation 13;
 - (ii) drawn up the technical documentation in accordance with regulation 17;
 - (iii) affixed the CE marking in accordance with regulation 18;
 - (iv) complied with regulation 19 (information identifying toy and manufacturer);
 - (v) complied with regulation 20 (instructions for use, safety information and warnings); and
- (b) the importer has complied with both of the following—
 - (i) regulation 27 (information identifying importer);
 - (ii) regulation 28 (storage or transport of toys).

Information identifying importer

27.—(1) An importer must ensure that the following information is marked on the toy—

- (a) the importer's name, registered trade name or registered trade mark; and
- (b) the address at which the importer can be contacted.

(2) The information may instead be marked on the toy's packaging or on a document accompanying the toy where—

- (a) the size or nature of the toy precludes the information from being marked on the toy; or
- (b) the importer would have to open the toy's packaging in order to mark the information on the toy.

Storage or transport of toys

28. An importer must ensure that, while a toy is under the importer's responsibility, the conditions in which it is stored or transported will not jeopardise the toy's compliance with the essential safety requirements during its foreseeable and normal period of use.

Monitoring of toys

29.—(1) An importer must take such of the following actions in relation to a toy as the importer considers appropriate for the purpose of protecting the health and safety of consumers, taking into account any risk presented by the toy.

(2) The actions are—

- (a) carrying out sample testing of marketed toys;
- (b) investigating any complaint made in relation to the toy;
- (c) keeping a register of—
 - (i) any such complaints;
 - (ii) any toy in relation to which any provision of these Regulations has not been complied with; and
 - (iii) any toy which has been recalled; and
- (d) keeping distributors informed of any action taken by the importer in accordance with sub-paragraph (a), (b) or (c).

Non-compliant toys and toys presenting a risk

30.—(1) Paragraph (2) applies if an importer has reason to believe that a toy which the importer was intending to place on the market—

- (a) will not comply with the essential safety requirements during its foreseeable and normal period of use; and
- (b) presents a risk.

(2) The importer must inform the manufacturer and the relevant enforcement authority of the risk presented by the toy.

(3) An importer who has placed a toy on the market and has reason to believe that any provision of these Regulations has not been complied with in relation to the toy must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the toy, or withdraw or recall the toy, if appropriate; and
- (b) where the toy presents a risk, provide the relevant enforcement authority with information about the following matters.

(4) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any corrective measures taken in accordance with paragraph (1)(a).

(5) An enforcement authority may request an importer who has placed a toy on the market to cooperate with it in relation to any action taken or to be taken to eliminate any risk posed by the toy.

(6) The importer must comply with the request.

Duties to retain and provide information

31.—(1) An importer must, for a period of 10 years after the day on which the toy is placed on the market—

- (a) keep a copy of the EC declaration of conformity; and
- (b) ensure that the technical documentation can be made available to an enforcement authority on request by the authority.

(2) An enforcement authority may, during the 10 year period, request an importer to provide, within such period as the authority may specify, a copy of all or part of the technical documentation (including the EC declaration of conformity), or a translation of it into English.

(3) A request must be accompanied by the reasons for making the request.

(4) The importer must comply with the request.

Duty in certain circumstances to comply with manufacturers' duties in place of importers' duties

32.—(1) This regulation applies where an importer—

- (a) places a toy on the market under the importer's name or trademark; or
- (b) modifies a toy already placed on the market in such a way that compliance with the essential safety requirements may be affected.

(2) An importer must comply with all of the duties imposed by these Regulations on a manufacturer and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the importer.

(3) Such an importer is not required to comply with the duties imposed by these Regulations on importers.

Distributors

Duty to act with due care and prohibitions on making toys available on the market

33.—(1) A distributor must act with due care in relation to the compliance of a toy which the distributor intends to make available on the market with the provisions of these Regulations.

(2) A distributor must not make a toy available on the market if the distributor has reason to believe that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use.

(3) A distributor must not make a toy available on the market unless the distributor has—

- (a) verified that the manufacturer has done all of the following things in relation to the toy—
 - (i) affixed the CE marking in accordance with regulation 18;
 - (ii) complied with regulation 19 (information identifying toy and manufacturer); and
 - (iii) complied with regulation 20 (instructions for use, safety information and warnings);
- (b) verified that any importer has complied with regulation 27 (information identifying importer) in relation to the toy; and
- (c) complied with regulation 34 (storage or transport of toys) in relation to the toy.

Storage or transport of toys under distributor's responsibility

34. A distributor must ensure that, while a toy is under the distributor's responsibility, the conditions in which it is stored or transported will not jeopardise the toy's compliance with the essential safety requirements during its foreseeable and normal period of use.

Non-compliant toys and toys presenting a risk

35.—(1) Paragraph (2) applies if a distributor has reason to believe that a toy which the distributor was intending to make available on the market—

- (a) will not comply with the essential safety requirements during its foreseeable and normal period of use; and
- (b) presents a risk.

(2) The distributor must inform the following of the risk presented by the toy-

- (a) the importer (if there is one);
- (b) the manufacturer (if there is no importer); and
- (c) the relevant enforcement authority.

(3) A distributor who has made a toy available on the market and has reason to believe that any provision of these Regulations has not been complied with in relation to the toy must immediately—

- (a) take the corrective measures which are necessary to ensure that the provision is complied with in relation to the toy, or withdraw or recall the toy, if appropriate; and
- (b) where the toy presents a risk, provide the relevant enforcement authority with information about the following matters.

(4) The matters are—

- (a) the risk presented by the toy;
- (b) the non-compliance in question; and
- (c) any corrective measures taken in relation to the toy in accordance with paragraph (3)(a).

(5) An enforcement authority may request a distributor who has made a toy available on the market to cooperate with it in relation to any action taken or to be taken to eliminate any risk posed by the toy.

(6) A request must be accompanied by the reasons for making the request

(7) The distributor must comply with the request.

Duty to provide information

36.—(1) An enforcement authority may request a distributor to provide, within such period as the authority may specify, any information or documents within the distributor's knowledge or possession which demonstrate that the toy will satisfy the essential safety requirements during its foreseeable and normal period of use.

(2) A request must be accompanied by the reasons for making the request.

(3) A distributor must comply with a request.

(4) A request for information or documents may not be made more than 10 years after the day on which the toy is placed on the market.

Duty in certain circumstances to comply with manufacturers' duties in place of distributors' duties

37.—(1) This regulation applies where a distributor—

- (a) places a toy on the market under the distributor's name or trademark; or
- (b) modifies a toy already placed on the market in such a way that compliance with the essential safety requirements may be affected,

(2) The distributor must comply with all of the duties imposed by these Regulations on a manufacturer, and in such a case, a reference to the manufacturer in these Regulations is to be taken as being a reference to the distributor.

(3) Such a distributor is not required to comply with the duties imposed by these Regulations on distributors.

All economic operators

Identification of economic operators to enforcement authorities

38.—(1) An enforcement authority may, before the end of the period specified in paragraph (3), request an economic operator to identify to the authority, within such period as the authority may specify—

- (a) any other economic operator who has supplied it with a toy; and
- (b) any other economic operator to whom it has supplied a toy.

(2) The economic operator must comply with the request.

(3) The period is—

- (a) where the request is made to a manufacturer, 10 years after the day on which the toy was placed on the market;
- (b) where the request is made to any other economic operator, 10 years after the day on which the economic operator was supplied with the toy.

Protection of CE marking

39.—(1) A person must not affix a CE marking in relation to a toy unless—

- (a) the person is—
 - (i) the manufacturer; or
 - (ii) an authorised representative of the manufacturer who has been appointed by the manufacturer in accordance with regulation 25(1) to affix the CE marking on the manufacturer's behalf; and
- (b) it has been demonstrated by performance of the applicable conformity assessment procedure that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) A person must not affix any marking in relation to a toy which—

- (a) is not a CE marking; but
- (b) purports to attest that the toy satisfies the essential safety requirements.

(3) A person must not affix in relation to a toy any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking affixed in relation to the toy.

(4) Any other marking may be affixed in relation to a toy provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

PART 3

Designation of Notified Bodies

Designation of UK notified bodies

40.—(1) The Secretary of State may designate a person to carry out conformity assessment.

(2) Such a designation (a “notified body designation”) must be made in accordance with paragraphs (4) to (8).

(3) A person in respect of whom a notified body designation has been made is a UK notified body to the extent that the designation remains in effect provided that—

- (a) the designation has been notified by the Secretary of State to the European Commission and the other member states,
- (b) no objections have raised by the Commission or the other Member States within the time periods in Article 31 of the Directive.

(4) A person wishing to be a UK notified body must apply to the Secretary of State for designation under this regulation.

(5) A notified body designation must not be made unless the Secretary of State is satisfied that the person meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (the “notified body criteria”).

(6) A person who meets the relevant assessment criteria laid down in a published harmonised standard shall be presumed to meet that part of the notified body criteria which corresponds to the criteria in that standard.

(7) The presumption of compliance in paragraph (6) is rebuttable.

(8) A notified body designation—

- (a) must be in writing;
- (b) must specify the conformity assessment procedures that the person designated may carry out;
- (c) may designate a person for a specified period; and
- (d) may be made subject to such other conditions as are specified in the designation, including conditions which are to apply upon or following termination of the designation.

(9) In making a notified body designation the Secretary of State may have regard (in addition to the notified body criteria) to any other matter which appears to the Secretary of State to be relevant.

(10) A UK notified body must comply with any request of the Secretary of State to provide information relevant to determining its compliance with the notified body criteria, these Regulations, or any condition to which its designation is subject.

Duration, variation and termination of designation

41.—(1) A notified body designation other than one which designates a person as a UK notified body for a specified period has effect until it is terminated under paragraph (4).

(2) A notified body designation which designates a person as a UK notified body for a specified period expires in accordance with its terms unless the period so specified is extended or shortened under paragraph (3) before the date on which it had been due to expire.

(3) The Secretary of State may vary any aspect of a notified body designation if—

- (a) the UK notified body so requests;
- (b) it appears to the Secretary of State necessary or expedient to do so; or
- (c) upon a request of the European Commission.

(4) The Secretary of State may suspend, restrict or withdraw a notified body designation—

- (a) on the expiry of 90 days’ notice in writing at the request of the UK notified body;
 - (b) if it appears to the Secretary of State that any condition of the designation is not complied with;
 - (c) if the Secretary of State considers that the UK notified body no longer satisfies the notified body criteria;
- or

(d) upon a request of the European Commission.

(5) Where the Secretary of State is minded to vary a designation in accordance with paragraph (3)(b), or to suspend, restrict or withdraw a notified body designation under paragraph (4)(b) to (d), the Secretary of State must—

- (a) give notice in writing to the UK notified body of the proposed variation or suspension, restriction or withdrawal and the reasons for it, stating that the body has 21 days from the date of the notice in which to make representations to the Secretary of State in respect of the proposed variation or termination; and
- (b) consider any representations received in accordance with the notice.

(6) If a designation is suspended, restricted or withdrawn under paragraph (4), the Secretary of State may, by notice in writing—

- (a) authorise another UK notified body to take over the functions of the UK notified body whose designation has been suspended, restricted or withdrawn in respect of such cases as are specified in the notice; and
- (b) give such directions as the Secretary of State considers appropriate (either to the UK notified body whose designation has been suspended, restricted or withdrawn or to another UK notified body) in respect of the UK notified body's files or any other matter which the Secretary of State considers expedient for the purposes of ensuring that another notified body carries out the functions of a notified body for the existing customers of the body whose designation has been suspended, restricted or withdrawn.

PART 4

UK Notified Bodies: Functions

Duty to perform EC-type examinations

42.—(1) A UK notified body to whom an application for EC-type examination is made in accordance with regulation 14 must carry out the functions specified in Module B (EC-type examination) in relation to that application.

(2) But a UK notified body is not obliged to carry out such functions where—

- (a) the documents submitted to it in relation to the carrying out of the functions are not in English or another language acceptable to the body;
- (b) the manufacturer has not submitted with its application the fee which the body requires (in accordance with regulation 50);
- (c) the body reasonably believes that, having regard to the number of outstanding applications made to it in relation to its designation, it will be unable to carry out the required work within 6 months of receiving the application; or
- (d) the terms of the body's designation do not entitle the body to carry out the functions of notified bodies specified in Module B in relation to the application.

Performance of EC-type examinations

43.—(1) A UK notified body performing an EC-type examination in relation to a toy must—

- (a) perform that examination in accordance with the provisions of Module B;
- (b) evaluate (if necessary together with the manufacturer) the analysis carried out by the manufacturer in accordance with regulation 12 (safety assessment); and
- (c) while respecting the need for the requirements that are imposed by these Regulations in relation to the toy to be complied with, perform the examination—
 - (i) in a proportionate manner, avoiding unnecessary burdens for economic operators; and
 - (ii) taking due account of—
 - (aa) the size of the relevant economic operator;
 - (bb) the sector in which the economic operator operates;

- (cc) the structure of the economic operator;
- (dd) the degree of complexity of the technology of the toy; and
- (ee) the mass or serial nature of the production process for the toy.

(2) Point 2 of Module B shall be treated as requiring EC-type examination to be performed in the manner specified in the second indent of point 2 (combination of product type and design type).

Issue and content of EC-type examination certificate, and refusal and appeal against refusal to issue certificate

44.—(1) A UK notified body who has performed an EC-type examination in relation to a toy must comply with the provisions of Module B relating to the issue of (or refusal to issue) an EC-type examination certificate.

(2) An EC-type examination certificate must include—

- (a) a reference to the Directive;
- (b) a colour image of the toy;
- (c) a clear description of the toy, including its dimensions;
- (d) a list of the tests performed during the EC-type examination of the toy; and
- (e) a reference to the test report for each listed test.

(3) A UK notified body must refuse to issue an EC-type examination certificate if—

- (a) in the body's opinion the toy will not comply with the essential safety requirements during its foreseeable and normal period of use;
- (b) the body is aware that an EC-type examination certificate that was previously issued in relation to the toy has been withdrawn by any notified body; or
- (c) the body is aware that a notified body has previously refused to issue an EC-type examination certificate in relation to the toy.

(4) But sub-paragraphs (b) and (c) of paragraph (3) do not preclude a UK notified body from issuing an EC-type examination certificate if, following the withdrawal of, or refusal to issue, an EC-type examination certificate, the manufacturer has taken corrective measures in relation to the toy which have the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(5) If a UK notified body has refused to issue an EC-type examination certificate under paragraph (3)(a), the body must inform the manufacturer of the corrective measures which in the body's view the manufacturer needs to take in relation to the toy.

(6) A UK notified body must make provision for a manufacturer to appeal against a refusal by the body to issue an EC-type examination certificate in relation to a toy.

Action (after issue of EC-type examination certificate) where a toy fails to comply with essential safety requirements

45.—(1) This regulation applies where—

- (a) an EC-type examination certificate has been issued in relation to a toy; and
- (b) a UK notified body finds that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use—
 - (i) following the review by the body of the certificate on its submission to the body for review by the manufacturer; or
 - (ii) in the course of any other monitoring by the body of whether the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) The UK notified body must—

- (a) consider—
 - (i) what corrective measures the manufacturer needs to take in relation to the toy in the light of the body's findings; and
 - (ii) whether it is necessary to suspend or withdraw the EC-type examination certificate;

- (b) send the manufacturer a notice in writing—
 - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
 - (ii) setting out the reasons for those conclusions; and
 - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
- (c) make a decision on the matters specified in sub-paragraph (2)(a), taking into account any response received from the manufacturer within the period specified in the notice; and
- (d) inform the manufacturer of the decision and the reasons for it.

(3) The UK notified body must restrict, suspend or withdraw the EC-type examination certificate issued in relation to the toy, as appropriate, where—

- (a) the manufacturer has been informed in accordance with paragraph (2)(d) of the corrective measures that the manufacturer needs to take in relation to the toy; and either
- (b) the manufacturer—
 - (i) fails within such period as is reasonable in the circumstances to take those measures; or
 - (ii) takes those measures, but the UK notified body forms the view that those measures have not in fact had the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use; and
 - (iii) the EC-type examination certificate issued in relation to the toy has not already been withdrawn under paragraph (2)(c).

(4) Before restricting, suspending or withdrawing an EC-type examination certificate under paragraph (3) the UK notified body must—

- (a) consider which of those actions it is appropriate to take in the circumstances; and
- (b) send the manufacturer a notice in writing—
 - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
 - (ii) setting out the reasons for those conclusions; and
 - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
- (c) make a decision on the matter specified in sub-paragraph (a), taking into account any response received from the manufacturer within the period specified in the notice; and
- (d) inform the manufacturer of the decision and the reasons for it.

Provision of information by UK notified bodies to other notified bodies

46. A UK notified body must provide other notified bodies which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Instructions to UK notified bodies in relation to EC-type examination certificates

47.—(1) An enforcement authority may request a UK notified body to provide to it, within such period as the body may specify, information relating to—

- (a) an EC-type examination certificate which that body has issued or withdrawn in relation to a toy; or
- (b) a refusal by that body to issue an EC-type examination certificate in relation to a toy.

(2) The information which may be requested under paragraph (1) includes test reports and the technical documentation which relate to the toy.

(3) A UK notified body must comply with a request.

(4) If an enforcement authority forms the opinion that a toy will not comply with the essential safety requirements during its foreseeable and normal period of use, it must, where appropriate, require a UK notified body who issued an EC-type examination certificate in relation to the toy to withdraw it.

(5) An enforcement authority must, where it considers it to be necessary, require a UK notified body to review an EC-type examination certificate issued by that body in relation to a toy.

(6) The following are examples of when an enforcement authority may consider it to be necessary to impose a requirement under paragraph (5)—

- (a) where any change has been made to the following without the certificate having been reviewed by a notified body—
 - (i) the manufacturing process for the toy;
 - (ii) any raw material used in the toy; or
 - (iii) any component of the toy;
 - (b) where 5 years have elapsed since the certificate was issued without it having been reviewed by a notified body;
 - (c) where 5 years have elapsed since the certificate was last reviewed by a notified body without it having been reviewed again by a notified body.
- (7) A UK notified body must comply with a requirement imposed under paragraph (5).

Participation by UK notified bodies in sectoral groups of notified bodies

48.—(1) A UK notified body must participate in the work of each relevant sectoral group of notified bodies put in place by the European Commission in accordance with Article 38 of the Directive (coordination of notified bodies).

(2) A UK notified body may participate by means of a representative designated by it to participate on its behalf.

Subcontracting by a UK notified body

49.—(1) A UK notified body may subcontract a specific task or activity connected with conformity assessment or have recourse to a subsidiary to carry out a task or activity if—

- (a) the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (requirements relating to notified bodies); and
- (b) the economic operator for whom the task or activity is to be carried out has consented to the task or activity being performed by that person.

(2) A UK notified body which subcontracts a specific task or activity connected with conformity assessment or has recourse to a subsidiary to carry out a task or activity—

- (a) must inform the Secretary of State that the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive; and
- (b) remains responsible for the proper performance of the task or activity (irrespective of where the subcontractor or subsidiary is established).

(3) The Secretary of State may request a UK notified body to provide to the Secretary of State, within a specified period, any relevant documents concerning the assessment of the qualifications of the subcontractor or subsidiary and the tasks or activities carried out by the subcontractor or subsidiary.

(4) A UK notified body must comply with a request.

Charging of fees by UK notified body

50.—(1) A UK notified body may charge such fees in connection with, or incidental to, the carrying out of its functions under regulations 42 to 45 as it may determine

(2) But any such fee shall not exceed the sum of—

- (a) the costs incurred or to be incurred by the body in performing the relevant functions; and
- (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by the body for the manufacturer, and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) A UK notified body may require the payment of fees or a reasonable estimate of fees in advance of carrying out the work for the manufacturer.

Provision of information by UK notified bodies to the Secretary of State

51.—(1) A UK notified body must notify the Secretary of State of—

- (a) any refusal by the body to issue an EC-type examination certificate in relation to a toy;
- (b) any restriction, suspension or withdrawal by the body of an EC-type examination certificate issued in relation to a toy;
- (c) any circumstances affecting the scope of the body's designation or any conditions to which its designation is subject; and
- (d) any request which the body has received from an enforcement body for information about conformity assessment activities.

(2) The Secretary of State may request a UK notified body to provide to the Secretary of State, within such period as the Secretary of State may specify—

- (a) information about any conformity assessment activity carried out by the body within the scope of the body's designation;
- (b) information about any other activity carried out by the body, including cross-border activities and sub-contracting; and
- (c) information relevant to determining the body's compliance with any of the requirements laid down in paragraphs (2) to (11) of Article 26 of the Directive (requirements relating to notified bodies), any provision of these Regulations or any condition to which the body's designation is subject.

(3) A UK notified body must comply with the request.

PART 5

Enforcement

Enforcement action in cases of formal non-compliance

52.—(1) An enforcement authority may serve a compliance notice on an economic operator if it finds that a non-compliance of any of the following types has occurred in relation to a toy—

- (a) no CE marking has been affixed;
- (b) a CE marking has been affixed but any provision of regulation 18 or regulation 39 has not been complied with or has been contravened;
- (c) the manufacturer has not drawn up an EC declaration of conformity;
- (d) the manufacturer has drawn up an EC declaration of conformity but the declaration does not comply with any provision of regulation 16(1) to (4); or
- (e) the technical documentation is unavailable or incomplete.

(2) A compliance notice must—

- (a) require the economic operator—
 - (i) to put an end to the non-compliance within such period as may be specified in the notice; or
 - (ii) to provide evidence within that period to the satisfaction of the enforcement authority that the non-compliance has not in fact occurred; and
- (b) warn the economic operator that, if the non-compliance continues, or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken by an enforcement authority in respect of that toy or any toy of the same type supplied by that person.

(3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

(4) A compliance notice has effect throughout the United Kingdom.

(5) Where an economic operator fails to comply with the requirements of a compliance notice, the enforcement authority may—

- (a) serve a withdrawal notice under regulation 14(1) GPSR;
- (b) serve a recall notice under regulation 15(1) GPSR;

(6) For the purposes of taking an action referred to in paragraph (5), regulations 14, 15, 16, and 17 of the GPSR are applicable

(7) Where a notice is served under paragraph (5), the grounds for serving the notice that would otherwise apply under the GPSR are satisfied by complying with this Regulation.

Enforcement action in cases of toys presenting a risk

53.—(1) This regulation applies where—

- (a) an enforcement authority or other person has taken any action under the 1987 Act or the GPSR to ensure that a toy which presents a serious risk requiring rapid intervention is recalled, withdrawn or prohibited from being made available on the market; or
- (b) an enforcement authority has sufficient reason to believe that a toy presents a risk to the health or safety of persons.

(2) An enforcement authority—

- (a) must carry out an evaluation in relation to the toy covering all the requirements of these regulations;
- (b) may require the relevant economic operator to take appropriate corrective action to bring the toy into compliance with these regulations;
- (c) may serve a withdrawal notice under regulation 14(1) GPSR;
- (d) may serve a recall notice under regulation 15(1) GPSR.

(3) For the purposes of taking an action referred to in paragraph (2)(c) or (d), regulations 14, 15, 16 and 17 of the GPSR are applicable.

(4) Where a notice is served under paragraph 2(c) or (d) the grounds for serving the notice that would otherwise apply under the GPSR are satisfied by complying with this Regulation.

(5) Where any of the actions in paragraph (2)(c) or (d) is taken and then considered unjustified in accordance with Article 43(2) of the Directive (Community safeguard procedure), the enforcement authority must withdraw the measure or apply to the court to withdraw the notice as necessary.

(6) This regulation does not apply where any provisional measure taken by another Member State in relation to a toy pursuant to Article 42(4) of the Directive is deemed under Article 42(7) of the Directive to be justified or is decided by the European Commission to be justified pursuant to Article 43(1) of the Directive (and that decision is communicated to the United Kingdom).

Notification of enforcement action taken in cases of toys presenting a risk

54.—(1) An enforcement authority, or other person who has taken action under the 1987 Act or the GPSR, must give immediate notice to the Secretary of State of any action taken by it, finding made or other opinion formed by it, or other matter within its knowledge, which is required to be notified to the European Commission or the other Member States under Articles 42, 43 or 44 of the Directive.

(2) An enforcement authority which has taken action under regulation 53 must inform the relevant notified body accordingly.

Requirements relating to certain measures taken by enforcement authorities or other persons

55.—(1) Paragraph (2) applies in relation to any measure taken by an enforcement authority or other person to—

- (a) prohibit or restrict a toy from being made available on the market;
- (b) withdraw a toy; or

(c) recall a toy.

(2) The following requirements must be complied with in relation to the measure—

- (a) the measure must state the exact grounds on which it is based;
- (b) the measure must be notified without delay to the party concerned; and
- (c) at the same time as the measure is notified to the party concerned that party must also be informed of—
 - (i) any remedy available to that party in relation to the measure; and
 - (ii) any time limit to which that remedy is subject.

(3) Where an enforcement authority takes any measure in relation to a toy, the authority must take due account of the precautionary principle.

Commencement of proceedings

56.—(1) In England and Wales a magistrates' court may try an information, and in Northern Ireland a magistrates' court may try a complaint, in respect of an offence committed under section 12 of the 1987 Act in relation to a contravention of or a failure to comply with these Regulations if the information is laid or the complaint is made within twelve months from the discovery of the offence by the prosecutor.

(2) In Scotland summary proceedings in relation to an offence committed under section 12 of the 1987 Act in relation to a contravention of or a failure to comply with these Regulations may be begun at any time within twelve months from the discovery of the offence by the prosecutor.

(3) No such proceedings shall be brought more than three years after the commission of the offence.

Amendment to the General Product Safety Regulations 2005

57. The General Product Safety Regulations 2005⁽²²⁾ are amended as follows—

- (a) In regulation 2 (Interpretation) insert the following at the end of the definition of “Community law” – “and does not include Regulation (EC) No 765/2008 of the European Parliament and the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁽²³⁾.”.

PART 6

Review

Review

58.—(1) Before the end of each review period, the Secretary of State must—

- (a) carry out a review of these Regulations
- (b) set out the conclusions of the review in a report, and
- (c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (which is implemented by means of these Regulations) is implemented in other member States.

(3) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved, and

⁽²²⁾ S.I. 2005/1803.

⁽²³⁾ OJ No L218, 13.8.2008, p. 30

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) “Review period” means—

(a) the period of five years beginning with the day on which these Regulations come into force, and

(b) subject to paragraph (5), each successive period of five years.

(5) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

	<i>Name</i>
	Title
Date	Department for Business, Innovation and Skills

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ No L 170, 30.06.2009, p.1). The Directive sets harmonised safety requirements for toys and minimum requirements for market surveillance, in order to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market.

The Directive repeals and replaces Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ No L 187, 16.7.88, p.1) (as amended), which was implemented in the United Kingdom by the Toys (Safety) Regulations 1995 (S.I. 1995/204) (as amended). These Regulations revoke and replace S.I. 1995/204, subject to the continuing application of S.I. 1995/204 to toys placed on the market before XX July 2011 (regulation 2).

The requirements in the Regulations come into force on XX July 2011 (regulation 1). Regulation 4 sets out the toys to which the Regulations apply. In particular, they apply only to toys placed on the market on or after XX July 2011. Regulation 5 defines the essential safety requirements which apply to toys, and is subject to a transitional provision in respect of the requirements in respect of the chemical properties of toys placed on the market before 20 July 2013 (regulation 6).

Part 2 of the Regulations sets out the prohibitions and obligations on economic operators. These are divided into prohibitions and obligations on manufacturers and their authorised representatives (regulations 10 to 25), on importers (regulations 26 to 32), on distributors (regulations 33 to 37), and on all economic operators (regulations 38 and 39). The various categories of economic operator are defined in regulation 3. In certain circumstances, importers and distributors are required to comply with the duties on manufacturers in place of the duties on importers or distributors (regulations 32 and 37).

Part 3 of the Regulations sets out the process for the appointment of conformity assessment bodies as UK Notified Bodies.

Part 4 sets out the functions of UK notified bodies.

Part 5 of the Regulations deals with enforcement of the Regulations, both in cases of formal non-compliance and toys presenting a risk. Regulation 57 addresses the relationship between the GPSR and Regulation (EC) No 765/2008 so that the powers in the General Product Safety Regulations 2005 are available to supplement the enforcement provisions in these Regulations.

Part 6 of the Regulations requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

A transposition note and a full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector are available from the BIS website (www.bis.gov.uk). They are also annexed to the Explanatory Memorandum which is available alongside the instrument on www.legislation.gov.uk. Copies have also been placed in the Libraries of both Houses of Parliament.

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