

**EXPLANATORY MEMORANDUM TO
THE TOYS (SAFETY) REGULATIONS 2011**

2011 No. 1881

1. This explanatory memorandum has been prepared by the Department for Business, Innovation and Skills and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Toys (Safety) Regulations 2011 (“the Toys Regulations”) revoke and replace The Toys (Safety) Regulations 1995 (SI 1995/204) (“the 1995 Regulations”), which transposed the requirements of Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (“the 1988 Directive”) and The Toys (Safety) (Amendment) Regulations 2010 (SI 2010/1928), which amended the 1995 Regulations. The Toys Regulations transpose the requirements of Council and European Parliament Directive 2009/48/EC (“the 2009 Directive”), whose purpose is to ensure a high level of toy safety.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 The Toys Regulations implement the 2009 Directive. A transposition note has been prepared and is attached as an annex to this explanatory memorandum.

4.2 Our approach to transposing the Directive has been to employ "copy out" where possible.

4.3 Business, Enterprise and Regulatory Reform (BERR) submitted an EM on Council Doc No 5938/08 on 18th November 2008 relating to the "Supplementary Explanatory Memorandum - Proposal for a Directive of the European Parliament and of the Council on the safety of toys; Commission Staff Working Document to the proposal amending Directive 88/378/EEC on the Safety of Toys - Impact Assessment and Executive Summary of Impact Assessment". The Commons European Scrutiny Committee considered it politically important and cleared it by debate, 20th January 2009. The Lords Select Committee on the EU cleared it (POS 19th December 2008, Session 08/09).

4.4 BERR submitted an EM on Council Doc No 5938/08 on 29th February 2008 relating to the " Proposal for a Directive of the European Parliament and of the Council on

the safety of toys and accompanying Commission Staff Working Documents to the proposal amending Directive 88/378/EEC on the safety of toys - Impact Assessment + Executive Summary of Impact Assessment". The Commons European Scrutiny Committee considered it politically important and cleared it by debate, also 20th January 2009. The Lords Select Committee on the EU cleared it (POS 19th December 2008, Session 08/09).

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 The Regulations implement the 2009 Directive into UK law in accordance with our EU obligations. The 2009 Directive has two overarching aims: the harmonisation of the requirements for the marketing of toys on the EU market and the safety of toys for use in play by children under the age of 14. It is a fundamental recast of the 1988 Directive (as amended).

7.2 The major areas of change between the 1988 and 2009 Directives have been designed to strengthen the safety provisions relating to toys and to align the 2009 Directive to Decision No 768/2008/EC on a common framework for the marketing of products (part of the EU's New Legislative Framework). The 2009 Directive includes new safety provisions in the following areas: chemical requirements (due to come into force in 2013), warnings on toys, choking and suffocation risks (including as a result of the association of toys with food), safety assessments and CE marking. The alignment of the 2009 Directive with the New Legislative Framework brings in new obligations for businesses, common definitions with other EU harmonisation legislation, new requirements for market surveillance and for the notification of conformity assessment bodies (known as Notified Bodies) to the European Commission and other Member States of the European Union.

8. Consultation outcome

8.1 The Public Consultation ran from 4th February 2011 to 1st April 2011. Ten written responses were received from trade associations, businesses, a professional body and an enforcement authority. Meetings were also held with a group of trade associations and with a representative of the local authorities. The Government's response to the consultation will be available on the BIS website at

<http://www.bis.gov.uk/Consultations/category/closedwithresponse>. The consultation led to a revision to the Impact Assessment and revised drafting in certain areas of the regulations most notably the enforcement provisions in order to make them clearer.

9. Guidance

9.1 Guidance to the Regulations will be produced but in the meantime detailed guidance for business on how to ensure a product complies with the essential safety requirements is available from the European Commission website (http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm).

10. Impact

10.1 The impact on business, charities or voluntary bodies is expected to be average annual costs of £11m and best estimate transitional costs of £66m over a 2 year period.

10.2 The impact on the public sector is expected to be minimal because of the existence of the current toys regulations. Although there will be costs associated with familiarisation with the new regulations for local authorities, enforcement is not expected to have an overall impact.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the www.legislation.gov.uk website.

11. Regulating small business

11.1 The legislation applies to small business.

12. Monitoring & review

12.1 The Secretary of State must review the Toys Regulations, set out his conclusions in a report and publish that report before the end of the five year period commencing on the date on which the regulations came into force. This review process will be repeated before the end of every five year period thereafter. When carrying out the review the Secretary of State must, so far as is reasonable, have regard to the implementation of the 2009 Directive in other Member States.

13. Contact

Jeff Asser at the Department for Business, Innovation and Skills Tel: 020 7215 1481 or email: jeff.asser@bis.gsi.gov.uk can answer any queries regarding the instrument.

This Transposition Note, in tabular form, explains how The Toys (Safety) Regulations 2011 (S.I. 2011/[XXX]) (the Regulations) transpose Directive 2009/48/EC of 18th June 2009 on the safety of toys (the Directive).

The tables seek to explain how the main elements of the Directive, are being transposed in relation to Great Britain.

Transposition Table

Directive Article	Objective listed	Implementation
1	Sets out the purpose of the Directive.	This is a general provision which does not require specific implementation.
2	Sets scope of the Directive – which toys are covered	Regulation 4
3	Definition of terms used throughout Directive	Relevant definitions are at regulation 3 (most of the definitions are transposed, although not all are necessary)
	Requirements for manufacturers	
4.1	Requires manufacturers to comply with essential safety requirements	Regulation 10(1) and Regulation 11 require a manufacturer to comply with essential safety requirements, Regulation 10(2) prohibits a toy being placed on the market without compliance with the listed regulations. <i>[A breach will trigger a section 12 CPA offence for breaching prohibition to supply or offering or agreeing to supply goods.]</i>
4.2	Requires manufacturers to draw up technical documentation and carry out conformity assessment procedure, draw up EC declaration of conformity and affix CE marking	Regulation 10(2)(d),(e), Regulation 13,
4.3	Requires manufacturers to keep technical documentation for 10 years	Regulation 17(5)
4.4	Requirement about procedures for series production and sample testing	Regulation 21, 23(2)
	Requirement for register of complaints	Regulation 23(2)(c)
4.5	Requirement as to	Regulation 19

	identification of toys	
4.6	Requirement for identification of manufacturer	Regulation 19
4.7	Requirement for instructions and safety information	Regulation 20
4.8	Requirement to take corrective measures or withdraw or recall toy	Regulation 24
4.9	Requirement to provide information and documentation in response to reasoned request from national authority, to cooperate with the authority and take action to eliminate risks	Regulation 24(3)-(5)
5	Provision for appointment of authorised representative, and the functions that may be mandated	Regulation 25
	Requirements for Importers	
6.1	Only compliant toys to be placed on market	Regulation 26
6.2	Requirement to ensure conformity assessment carried out,, technical documentation conformity marking and identification and identification of manufacturer markings Third paragraph about bringing toy into conformity and informing manufacturer and market surveillance authorities where toy presents a risk	Regulation 26(2) Regulation 30
6.3	Requirement for importer's identify and contact details	Regulation 27
6.4	Requirement to ensure toy accompanied by certain information	Regulation 26(2)(v)
6.5	Requirement to ensure importers do not jeopardise	Regulation 28

	compliance with essential and particular safety requirements during transport etc	
6.6	Requirement to carry out sample testing where appropriate	Regulation 29(2)
6.7	Requirement to take corrective measures	Regulation 30(3)
	Requirement to inform national authorities where toy presents a risk	Regulation 30(2)
6.8	Requirement to keep EC declaration of conformity and technical documentation for 10 years	Regulation 31(1)
6.9	Requirement to provide documentation to national authorities in response to a reasoned request	Regulation 31(2) to (4)
	Requirement to co-operate with national authority to eliminate risks	Regulation 30(5)
	Requirements for Distributors	
7.1	Requirement to act with due care in relation to the applicable requirements	Regulation 33(1)
7.2	Requirement to verify conformity marking, documentation, instructions and safety markings in right languages, and that manufactures and importers identification markings as required	Regulation 33(3)
	Requirement not to bring toy on market until satisfied essential safety requirements	Regulation 33(2) <i>Regulation 33(2) triggers s12 CPA offence and also implements Article 7.2</i>
	Requirement to inform manufacturer or importer and market surveillance authorities that essential safety requirements not satisfied	Regulation 35(1),(2)

7.3	Requirement to ensure essential safety requirements not jeopardised	Regulation 34
7.4	Requirement to take corrective measures. Where toy presents risk, to inform national authorities.	Regulation 35(3),(4)
7.5	Requirement to provide information and documentation in response to reasoned request, to cooperate	Regulation 35(5), (6), (7), 36
	GENERAL	
8	Importer or distributor shall be considered a manufacturer in certain circumstances	Regulation 32 and 37
9	Requirement to identify other economic operators	Regulation 38
10	Essential safety requirements	Obligation on ms, not directly transposed although is given effect through regulations 5 and 10 which set out essential safety requirements on manufacturers and distributors.
11	Requirements as to warnings	Regulation 20 and Regulation 5(4)
12	Requirement on member state to ensure free movement	No need to transpose
13	Presumption of conformity	Regulation 7
14	Formal objection to a harmonised standard	No need to transpose as matter is between member state and Commission
15	Requirements and effects of the EC declaration of conformity	Regulation 16
16.1	General principles of CE marking	Regulation 18(1)
16.2/3	CE marking subject to general principles set out in Article 30 of RAMS	See definition of CE marking in Regulation 3. Regulation 18(8)
16.4	Exception for trade fairs	Regulation 8
17	Rules and conditions for	Regulation 18

	affixing CE Marking	
	Conformity Assessment	
18	Requirement for manufacturer to carry out safety assessment	Regulation 12
19.1	Requirement for manufacturer to use conformity assessment procedure to ensure compliance with essential safety requirements	Regulation 13(1)
19.2	Requirement to use internal production control procedure in Module A of Annex II to Decision No 768/2008/EC (the Decision) where harmonised standards applied	Regulation 13(2)
19.3	Requirement to submit toy to EC-type examination in listed circumstances	Regulation 13(3)
20.1	EC type examination carried out in accordance with Module B of Annex II to the Decision	Regulation 14(b), 42(1)
20.2	Application for EC-type examination include certain information	Regulation 14(c) and (d)
20.3	Requirement on notified body to evaluate manufacturer's hazard analysis	Regulation 43(1)(b)
20.4	Requirements about EC-type examination certificate Second paragraph – requirement to review certificate whenever necessary Third paragraph – requirement to withdraw certificate if toy fails to comply with Art 10 and annexe 2 Fourth paragraph- no	Regulation 44(2) Regulation 47(5),(6) Regulation 45(3)

	certificates granted where certificate has been refused or withdrawn	Regulation 45(3)(b)(iii)
20.5	Technical documentation and correspondence in official language of member state in which notified body is established	Regulation 17(4)
21.1-2	Requirements of technical documentation	Regulation 17(1), 17(2), 17(3)
21.3	Requirement for manufacturer to provide translation upon reasoned request	Regulation 17(6)(b), 17(7), 17(8)
21.4	Market surveillance authority may require test performed at manufacturer's expense where technical documentation requirements not complied with	Regulation 17(10), (11)
22	Requirement on member states to notify Cion and other member states of authorised conformity assessment bodies	Not transposed into regulations. The SoS will notify under administrative procedures
	Notifying authority	
23.1	Member states to designate notifying authority	Not transposed into regulations. The SoS will designate himself as notifying authority by way of administrative procedure.
23.2	National accreditation body may carry out assessment and monitoring	Not transposed into regulations. The SoS will contract with UKAS for this function.
23.3	Requirements of entity to which notifying authority may delegate	Not transposed into regulations. Should the SoS as notifying authority delegate, the SoS will ensure that it is in accordance with Article 23.
23.4	Notifying Authority to take responsibility for actions of delegated body	
24	Requirements relating to notifying authorities	No implementation necessary. SoS as notifying authority will ensure compliance with these requirements.
25	Requirement on member states to inform Cion of their procedures for the	No implementation necessary. SoS as notifying authority will ensure compliance with these requirements.

	assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and any changes	
	Notified Bodies	
26	Requirements for conformity assessment bodies	Regulation 40(5)
27	Presumption of conformity with Article 26 requirements	Regulation 40(6)
28	Formal objection to harmonised standard, Article 14 procedure shall apply	No implementation necessary – Article 14 procedure is between Commission and member state
29	Requirements of subsidiaries of and subcontracting by notified bodies Paragraph 1 – ensuring meets Article 26 requirements and informing SoS accordingly, Paragraph 2 – NB’s retain responsibility Para 3- agreement of client Para 4 keeping documents	Regulation 49 Regulation 49 (1)(a) and (2)(a) Regulation 49 (2)(b) Regulation 49 (1)(b) Regulation 49(3)
30	Stipulation for application by conformity assessment body for notification	Regulation 40(4). Para 2 and 3 about content of application not transposed in regulations, but will be required under administrative provisions and set out in guidance for NB’s
31	Notification procedure	Not transposed in regulations as obligations are on SoS and will be applied administratively
32	Requirement on Cion to assign identification numbers to and make available lists of notified conformity assessment bodies	No implementation necessary as actions are of Commission
33	Requirement on notifying authority to amend notification as appropriate,	Regulation 41(3)-(6)

	and make contingency plans where necessary	
34.1 and 34.4	Requirement on Cion to investigate re competence of notified body and (4) requirement notify member state if notified body no longer meets requirements	Reg 41(3)(c) and (4)(d) allow variation and termination of NB designations by SoS upon request of Cion. So although no need to transpose, the regs provide for the Notifying Authority to act on result Cion's investigations.
34.2 and 34.3	Requirement on member state to provision Cion all information relating to above and on Cion to treat sensitive information confidentially	No need to transpose
35.1 and 35.2	Requirements on notified bodies to carry out conformity assessment procedures Procedures shall be proportionate nevertheless respecting level of protection required for compliance with the Directive	Regulation 42(1) Regulation 43(1)(c)
35.3	Notified body must require manufacturer to take appropriate corrective action if necessary	Regulation 44(5)
35.4	Where toy no longer in compliance, notified body must require corrective action or amend EC-type examination certificate.	Regulation 45(1),(2)
34.5	Restrict, suspend or withdraw EC-type examination certificate where corrective measures not taken	Regulation 45(3),(4)
36.1	Information obligations on notified bodies to the notifying authority - refusal etc of EC-type examination certificate - circumstances affecting notification - request for information	Regulation 51 (1)(a) and (b) (1)(c) (1)(d)

	- upon request, conformity assessment activities performed.	(2)(a)-(c)
36.2	Requirement on notified bodies to inform other notified bodies in certain circumstances	Regulation 46
37	Obligation on Cion to organise exchanges of experience	No implementation necessary
38	Obligation on Cion and member states re co-ordination of notified bodies	No implementation necessary
39	Obligation on member states re precautionary principle	Regulation 55(3)
40	Obligation on member states re market surveillance under RAMS	No specific implementation necessary in these Regulations
41.1	Power of market surveillance authority to request info re EC-type examination form notified body	Regulation 47(1),(2)
41.2	Power of market surveillance authority to instruct notified body to withdraw EC Type examination certificate	Regulation 47(4)
41.3	Power of market surveillance authority to instruct notified body to review EC-Type examination certificate`	Regulation 47(5)
42	Procedure for dealing with toys presenting a risk at national level.	
42.1	Market surveillance authority must: Carry out evaluation covering all the requirements laid down by the Directive Market surveillance authorities must inform the relevant notified body	Regulation 53(2)(a) Regulation 54(2)

	accordingly	
42.2	Inform Cion and other member states as necessary	Regulation 54
42.3	Require economic operator to take corrective action to bring toy into compliance	Regulation 53(2)(b)
42.4	If this is not done, must take provisional measures to prohibit or restrict availability on market, and inform of those measures	Regulation 53(2)(c) and (d) and regulation 54
42.5	Specifics of information that must be provided and arguments from relevant economic operator	Regulation 54(1)
42.6	Other member states to notify of related measures	No transposition necessary
42.7	Justification of measures where no objection within 3 months	No transposition necessary
42.8	Member states to ensure that appropriate restrictive measures taken without delay, such as withdrawal from market.	Regulation 57 amends the General Product Safety Regulations to make the powers to remove products from the market available as necessary. The procedures for domestic enforcement (requirement to carry out an evaluation) at regulation 53 are disapplied by regulation 53(6) where another member state has taken action.

43	Community safeguard procedure – at Community level	No implementation necessary, except to the extent required by the second paragraph of article 43.2 of the Directive, which is implemented by regulation 55(4), as enforcement powers under the General Product Safety Regulations are available (see above).
44	If measure notified through RAPEX, not necessary to notify under this Directive	This provision will be addressed administratively
	Formal non-compliance	Power to service compliance notice in cases of non-compliance as follows;
45.1(a)	Require economic operator to comply with CE marking, EC declaration of confirmation and technical documentation matters.	Regulation 52(1)(b)
45.1(b)		Regulation 52(1)(a)
45.1(c)		Regulation 52(1)(c)
45.1.(d)		Regulation 52(1)(d)
45.1(e)		Regulation 52(1)(e)
45.2	Requirement on member state to restrict, withdraw, prohibit marketing of toy where non-compliance persists	Regulation 52(5)-(7) provide that powers of withdrawal and recall are available where formal non-compliance has persisted
46 - 47	Committee procedures	No implementation necessary
48	Reporting requirements on member states	No transposition into domestic law necessary, the UK will report to Commission in accordance with administrative procedures.
49	Confidentiality requirements	No explicit transposition is necessary.
50	Motivation of measures Prohibition or restrict placing on market, withdrawal or recall from market. Measure must state exact grounds on which it is based and	Regulation 55 and, where General Product Safety Regulations powers are exercised, see therein regulation 16

	remedies available and applicable time limits	
51	Requirement on member states to pay down penalties for breach	Part 5 of Regulations and the applicable provisions of the General Product Safety Regulations 1995 and the Consumer Protection Act 1987
	FINAL AND TRANSITIONAL PROVISIONS	
53.1	Transitional periods – toys on the market before 20 th July 2011 in accordance with Directive 88/378/EEC	Regulation 2(2) provides that 1995 regulations apply to toys placed on the market before the Regulations come into force
53.2	Extra transitional period to 20 th July 2013 for chemical requirements	Regulation 6
54	Transposition Bringing provisions into force Accompanied by reference to Directive	Regulation 1 brings provisions into force on 19 th August 2011 See explanatory note which addresses that the regulations transpose the Directive
55-57	Repeal, entry into force, addressees	No transposition into domestic law necessary