


Basic information	
<p>2008/0018(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Directive</p>	Procedure completed
<p>Safety of toys</p> <p>Amended by 2017/0353(COD)</p> <p>Subject</p> <p>2.10 Free movement of goods 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.60.04.02 Consumer security 4.60.08 Safety of products and services, product liability</p>	







Key players				
European Parliament	Committee responsible		Rapporteur	Appointed
	IMCO	Internal Market and Consumer Protection	THYSSEN Marianne (PPE-DE)	28/02/2008
	Committee for opinion		Rapporteur for opinion	Appointed
	ENVI	Environment, Public Health and Food Safety	FERREIRA Anne (PSE)	07/03/2008
	ITRE	Industry, Research and Energy	HAMMERSTEIN David (Verts/ALE)	27/05/2008
	Council of the European Union	Council configuration		Meetings
Competitiveness (Internal Market, Industry, Research and Space)		2871	2008-05-29	
Competitiveness (Internal Market, Industry, Research and Space)		2910	2008-12-01	
Competitiveness (Internal Market, Industry, Research and Space)		2891	2008-09-25	
Education, Youth, Culture and Sport		2941	2009-05-11	
European Commission	Commission DG		Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		VERHEUGEN Günter	

Key events			
Date	Event	Reference	Summary
25/01/2008	Legislative proposal published	COM(2008)0009 	Summary

11/03/2008	Committee referral announced in Parliament, 1st reading		
29/05/2008	Debate in Council		
25/09/2008	Debate in Council		
06/11/2008	Vote in committee, 1st reading		Summary
12/11/2008	Committee report tabled for plenary, 1st reading	A6-0441/2008	
01/12/2008	Debate in Council		
15/12/2008	Debate in Parliament	CRE link	
18/12/2008	Decision by Parliament, 1st reading	T6-0626/2008	Summary
18/12/2008	Results of vote in Parliament		
11/05/2009	Act adopted by Council after Parliament's 1st reading		
18/06/2009	Final act signed		
18/06/2009	End of procedure in Parliament		
30/06/2009	Final act published in Official Journal		

Technical information	
Procedure reference	2008/0018(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Nature of procedure	Legislation
Legislative instrument	Directive
	Amended by 2017/0353(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/6/58655

Documentation gateway				
European Parliament				
Document type	Committee	Reference	Date	Summary
Committee draft report		PE407.804	06/06/2008	
Amendments tabled in committee		PE409.734	25/07/2008	
Amendments tabled in committee		PE412.141	19/09/2008	
Amendments tabled in committee		PE412.121	24/09/2008	
Committee opinion	ITRE	PE409.475	09/10/2008	
Committee opinion	ENVI	PE409.407	15/10/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0441/2008	12/11/2008	
Text adopted by Parliament, 1st reading/single reading		T6-0626/2008	18/12/2008	Summary
Council of the EU				
Document type	Reference	Date	Summary	

Draft final act	03744/2008/LEX	18/06/2009	
European Commission			
Document type	Reference	Date	Summary
Document attached to the procedure	SEC(2008)0039 	25/01/2008	
Legislative proposal	COM(2008)0009 	25/01/2008	Summary
Document attached to the procedure	SEC(2008)0038 	25/01/2008	
Commission response to text adopted in plenary	SP(2009)402	29/01/2009	
For information	COM(2016)0560 	09/09/2016	
For information	SWD(2016)0289 	09/09/2016	
For information	SWD(2016)0290 	09/09/2016	

Additional information		
Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act
<p>Corrigendum to final act 32009L0048R(01) OJ L 355 31.12.2013, p. 0092</p> <p>Directive 2009/0048 OJ L 170 30.06.2009, p. 0001</p> <p style="text-align: right;">Summary</p>

Safety of toys

2008/0018(COD) - 18/12/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 481 votes to 73 with 40 abstentions, a legislative resolution amending the proposal for a directive of the European Parliament and of the Council on the safety of toys. The report had been tabled for consideration in plenary by Marianne **THYSSEN** (EPP-ED, BE), on behalf of the Committee on the Internal Market and Consumer Protection. The amendments were the result of a compromise between the Council and the Parliament. The main amendments - adopted under the 1st reading of the codecision procedure - were as follows:

Subject-matter: the compromise text simply states that this Directive lays down rules on the safety of toys, and on their free movement in the Community

Scope: Parliament confirms that the Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age. A list of products not regarded as toys is annexed to the text. It includes party decorations, collectors' items clearly intended for people aged fourteen or over (including reproductions of real firearms or faithful scale models), puzzles with more than 500 pieces, fireworks, and fashion accessories for children, which are not for use in play.

Safety: manufacturers and importers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned. Distributors must ensure that toys are accompanied by the required documents and by instructions and safety information in a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market.

Importers' obligations: amongst importers' obligations, the compromise text states that, when deemed appropriate with regard to the risks presented by a toy, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.

Economic operators: economic operators shall be able to present prescribed information for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and 10 years after they have been supplied with the toy, in the case of other economic operators.

Warnings: Parliament clarified and strengthened the rules regarding warnings on packaging and on toys themselves. The warnings shall be preceded by the words "Warning" or "Warnings", as the case may be. With regard to the specific warnings listed in the Annex, such as those required on toys for children under 36 months, the compromise text stipulates that toys shall not bear one or more of these specific warnings, if they contradict the intended use of the toy, as determined by virtue of their function, dimension and characteristics. The manufacturer shall mark the warnings in a clearly visible and easily legible, easily understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys that are sold without packaging shall have appropriate warnings affixed to them.

Warnings, which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, must appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including when the purchase is made on-line.

A Member State may, within its territory, stipulate that those warnings and safety instructions shall be written in one or more languages, easily understood by consumers, which it shall determine.

CE marking: the CE marking shall be affixed visibly, legibly and indelibly to the toy, or to an affixed label, or to the packaging. In the case of small toys and toys consisting of small parts the CE marking may alternatively be affixed on a label or an accompanying leaflet. If that is not technically possible in the case of toys sold in counter displays, and on the condition that the counter display was originally used as packaging for the toys, the CE marking shall be affixed to the counter display.

If the CE marking is not visible from outside the packaging, if any, it shall at least be affixed on the packaging.

Conformity assessment body : Parliament specified that A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Chemicals: limit values for certain metals, namely arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the Commission's scientific committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present. The text states that nickel in stainless steel has proven to be safe and consequently it is appropriate to provide that it can be used in toys.

The Commission may adopt specific limit values for chemicals used in toys intended for children under 36 months or in other toys intended to be placed in the mouth taking into account the packaging requirements for food as laid down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, and the differences between toys and materials which come into contact with food. The Commission shall amend Appendix C to Annex II accordingly. Those measures will be adopted in accordance with the regulatory procedure with scrutiny.

CMR: substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B or 2 according to Regulation (EC) No .../... [on classification, labelling and packaging of substances and mixtures] shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys. The compromise text contains derogations to this prohibition, with the proviso that certain prescribed conditions must be met. Nitrosamines and nitrosable substances are prohibited for use in toys intended for children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.

Allergenic fragrances: the Commission proposal contained a list of prohibited allergenic fragrances and a list of fragrances subject to labelling. Parliament added to the first list of banned substances 17 more substances including musk ambrette and treemoss extracts. However, the presence of traces of these substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and does not exceed 100 ppm.

In addition there are now 11 substances in the list of allergenic fragrances which, if added to toys, as such, at concentrations exceeding 0,01 % by weight, might be listed on the packaging and in instructions attached to the toy. However, the use of certain of these fragrances from both lists shall be allowed in olfactory board games, cosmetic kits and gustative games under certain circumstances, which include the requirement that those fragrances must be clearly labelled on the packaging and the packaging contain the warning: "contains fragrances that may cause allergies". Such olfactory board games, cosmetic kits and gustative games shall not be permitted to be used by children under 36 months and must comply with provisions on specific warnings.

Risk of choking: toys and their parts must not present risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose. They must be of such dimensions as not to present risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways. Toy packaging which is spherical, egg-shaped or ellipsoidal and any detachable parts of this, or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

Noise: the compromise text does not follow the Parliament's competent committee's recommendation on noise limit figures. The text follows the commission's proposal and states that toys which are designed to emit a sound should be so designed and manufactured in terms of the peak values for impulse noise and prolonged noise so that the sound from them is not able to impair children's hearing.

Precautionary principle : when competent authorities of the Member States take measures as provided for in this Directive, and in particular measures under the provisions on their general obligation to organise market surveillance, they shall take due account of the precautionary principle.

Transitional periods: in order to allow toy manufacturers and other economic operators sufficient time to adapt to the new requirements, Members provides for a transitional period of two years after the entry into force of the Directive during which toys which comply with Directive 88/378/EEC may be placed on the market. In the case of chemical requirements, this period is set at four years so as to allow the development of the harmonised standards which are necessary for compliance with those requirements.

Penalties: these may be increased if the relevant economic operator has previously committed a similar infringement of this Directive.

Safety of toys

2008/0018(COD) - 18/06/2009 - Final act

PURPOSE: to lay down rules on the safety of toys and on their free movement in the Community, and to repeal Directive 88/378/EEC.

PROPOSED ACT: Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (text with EEA relevance).

CONTENT: following a first reading agreement reached with the European Parliament, the Council adopted a directive aimed at reinforcing the safety of toys in the internal market. The new directive, which replaces directive 88/378/EEC, **updates and completes current Community rules** to take account of technological developments of toys and new scientific knowledge, in particular as concerns safety issues that were unknown when the original Toys Safety Directive was adopted. In accordance with the existing legislation on marketing of products, economic operators placing toys on the EU market will have responsibility of ensuring that these toys comply with Community legislation in order to ensure a high level of protection of consumers and of the environment. The new legislation reinforces market surveillance and essential safety requirements for toys, in order to ensure that toys sold to consumers in the EU are safe.

This directive is the first specific directive following the principles of the new legislative framework for market surveillance and CE marking agreed last year. The provisions on chemicals are adapted to meet the requirements of the regulation on the classification, labelling and packaging of chemical substances and mixtures.

The main elements of the Directive are as follows:

Scope: the Directive shall apply to products designed or intended, whether or not exclusively, for use in play by **children under 14 years of age**. The products listed in Annex I shall not be considered as toys within the meaning of this Directive. Moreover, it shall not apply to: (i) playground equipment intended for public use; (ii) automatic playing machines, whether coin operated or not, intended for public use; (iii) toy vehicles equipped with combustion engines; (iv) toy steam engines; (v) slings and catapults.

Obligations of manufacturers: manufacturers shall, inter alia: (i) ensure that toys have been designed and manufactured in accordance with the requirements of this Directive; (ii) draw up the required technical documentation and carry out the applicable conformity assessment procedure; (iii) keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market; (iv) ensure that their toys bear a type, batch, serial or model number or other element allowing their identification; (v) indicate their name, registered trade name and the address at which they can be contacted on the toy; (vi) ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers; (vii) immediately take the corrective measures necessary to bring a non-conforming toy into conformity, to withdraw it or recall it and immediately inform the competent national authorities of the Member States in which they made the toy available.

Obligations of importers and distributors: they shall, inter alia: (i) ensure/verify that the toy bears the required conformity marking, that it is accompanied by the required documents and by instructions and safety information in a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market, and that the manufacturer has complied with the requirements set out in the Directive; (ii) ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance; (iii) immediately take the corrective measures necessary to bring a non-conforming toy into conformity, to withdraw it or recall it.

In particular, importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy and carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls.

Essential safety requirements: Member States shall take all measures necessary to ensure that toys are not placed on the market unless they comply with the essential safety requirements as regards physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity. Manufacturers shall, before placing a toy on the market, carry out an analysis of these requirements and an assessment of the potential exposure to the hazards that the toy may present.

In particular, **stricter rules**, responding to consumer concerns, will apply as regards hazards caused by certain **chemical substances** (in particular carcinogenic, mutagenic or toxic for reproduction (CMR) substances and **fragrances** used in toys, as well as **noise** from toys. The Directive also restricts the use of heavy metals in toys and strengthens the measures to prevent choking and suffocation.

Warnings: the directive also complements and reinforces existing provisions on clearly legible warnings for toys in order to reduce inherent risks when they are used. The warnings shall be preceded by the words 'Warning' or 'Warnings', as the case may be. The manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging. A Member State may, within its territory, stipulate that those warnings and the safety instructions be written in a language or languages easily understood by consumers. Toys shall not bear one or more of the specific warnings set out in Part B of Annex V where that warning conflicts with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

Toys which might be dangerous for children under 36 months of age shall bear a warning such as 'Not suitable for children under 36 months' or 'Not suitable for children under three years' or a warning in the form of a graphic.

CE marking: this directive is the first specific directive following the principles of the [new legislative framework for market surveillance and CE marking](#) agreed in 2008. Member States shall presume that toys bearing the CE marking comply with this Directive. The manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them. Where, in the case of toys sold in counter displays, that is not technically possible, and on condition that the counter display was originally used as packaging

for the toy, the CE marking may be affixed to the counter display. Where the CE marking is not visible from outside the packaging, if any, it shall as a minimum be affixed to the packaging.

Notification: Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks. They shall designate a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies. The Directive sets out the requirements relating to notifying authorities and to notified bodies, as well as the notification procedure.

Market surveillance: Member States shall organise and perform surveillance of toys placed on the market. Where, in the course of their evaluation, the market surveillance authorities find that a toy does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take appropriate corrective action to bring the toy into compliance with those requirements, to withdraw the toy from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

Penalties: Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of this Directive.

Reporting: by 20 July 2014 and every five years thereafter, Member States shall send the Commission a report on the application of this Directive. The report shall contain an evaluation of the situation concerning the safety of toys and of the effectiveness of this Directive, as well as a presentation of the market surveillance activities performed by that Member State.

ENTRY INTO FORCE: 20/07/2009.

TRANSPOSITION: 20/01/2011.

APPLICATION: 20/07/2011.

Safety of toys

2008/0018(COD) - 25/01/2008 - Legislative proposal

PURPOSE: to repeal the 1988 Toy Safety Directive.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: one of the first new approach Directives to be adopted, the 1988 Directive on the approximation of the laws of the Member States concerning the safety of toys (88/378/EEC) has proven, by and large, to be a success. It is, however, in need of updating.

Adopted in the context of the Internal Market the main objective of the Toy Safety Directive is twofold. Firstly, to offer consumers, especially children, safe products and secondly, to remove a plethora of national rules and regulations that stifle free trade across the Community. One of the key concepts of the New Approach Directives is to lay down, in legislation, the essential safety requirements. The technical product specifications are left to the standardisation bodies CEN and CENELEC to regulate.

Since its adoption, however, a number of deficiencies have been identified, which have triggered the need to assess the existing legal framework. The most pressing needs are to:

- update and complete existing provisions;
- address safety issues that were unknown at the time of the TSD adoption;
- improve implementation and enforcement;
- clarify the Directive's scope; and
- offer greater consistency with provisions set out in other legislative acts concerning the marketing of goods

The purpose of this proposal, therefore, is to repeal the 1988 Toy Safety Directive and to replace it with a more updated version. The overall objective is to improve the quality and efficiency of toy safety regulations and to simplify current legislation for both economic operators and market surveillance authorities.

The main elements of the proposal, in summary, are as follows:

Chemical substances used in toys: Current provisions require that toys must comply with the Community's general chemicals legislation, including Regulation EC N° 1907/2006 (REACH). This will remain the same particularly as far as CMRs 1 or 2 are concerned. One of the main innovations of the revised Directive will be the introduction of specific rules on **CMR** (carcinogenic, mutagenic, or toxic for reproduction) in toys. Further, in order to take account of new scientific knowledge, the Directive provides for an update of certain chemical substances to be used in toys and to raise the limit values for these substances.

Warnings: The proposed revision will require warnings to specify, where appropriate, user limitations (such as minimum and maximum ages) the maximum or minimum weight of users, and whether or not a toy is to be used under adult supervision.

Choking and suffocation: The revised Directive will extend provisions on "toys placed in the mouth" (such as toy instruments) to children above 36 months. Similarly, the revised Directive, will extend provisions concerning the external and internal obstruction of the mouth and/or nose (suffocation risk) to cover all toys – and not just toys intended for children under 36 months, as is currently the case.

Toys in food: Currently no specific provisions exist for toys in food. The revised Directive proposes a set of new requirements: 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 any choking hazard (namely that it passes the safety 'small parts cylinder test') and iii) to ban toys that are firmly coupled with foodstuffs in such a way that prior consumption of the food item is necessary to access to the toy itself.

Definition of the general safety requirement: Clarifying the general safety requirement is essential because it is the only legal basis for taking dangerous toys out of the market in cases where a new risk is discovered, that is, a risk which was previously unknown and which is therefore, not

covered by specific standards. The Commission proposes to amend the general safety requirement to refer to the "behaviour" of children to take account of their, often unpredictable, behaviour.

Reinforcement of the Member States market surveillance measures: The proposal reinforces market surveillance obligations under the General Product Safety Directive by granting certain specific powers to the market surveillance authorities such as: the right of access to the premises of economic operators; the right to request information from Notified bodies; the right to give instructions to the Notified bodies; and the right to obtain mutual assistance from other Member States.

Information on chemicals in the technical file: The proposal contains an update of the documentation which toy manufacturers and importers have to keep available for inspection purposes.

Information on chemicals in the technical file: A completely new provision requires that the CE mark must always be affixed on the packaging even if the marking on the toy is not visible from outside the packaging.

Safety assessment: A new obligation will require an analysis of the hazards that the toy may present, and to make it available - as part of the toy's technical file - to the market surveillance authorities for inspection.

Clarifying scope and definitions: The scope of the Directive has been clarified, by completing the list of products which are not within its scope. This concerns, in particular, certain new products, such as videogames and peripherals. Certain new definitions are also foreseen specific to the toys sector including: functional toys, activity toys, trampolines, hazard, risk, harm, suffocation and design speed.