

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.