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***Accompanying document to the***

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the safety of toys**

**Executive Summary of the Impact Assessment**

{COM(2008) 9 final}
{SEC(2008) 38}

## 1. BACKGROUND - THE REVISION OF TOY SAFETY LEGISLATION

This document provides a summary of the results of the Impact Assessment concerning the revision of Directive 88/378/EEC on the safety of toys (Toy Safety Directive, TSD).

This Directive was the first one applying the so-called New Approach method – introduced in 1985 – to mass market consumer goods. The key New Approach concept consisted in laying down in the legislation the essential safety related requirements, and leaving the technical specifications of products meeting the essential requirements in harmonised standards. Since 1988 the Directive has been amended only once in respect of the CE marking.

Whilst the TSD has in general proven successful in providing safe products and eliminating trade barriers between the Member States, a number of deficiencies have been identified over time, which have triggered the need to assess the existing legal framework (see section 3).

## 2. PROCEDURAL ISSUES AND CONSULATION OF INTERESTED PARTIES

The revision has been under consideration since 2003 and has been the subject of a wide ranging consultation, namely in the framework of the Expert Group on toys safety with the Member States authorities and other stakeholders like industry, consumer- and standardisation organisations. A public consultation obtaining more than 1500 replies took place in 2007. Three studies have been established, a general impact assessment as well as two studies with a focus on the use of certain chemicals in toys. The studies are available at: http://ec.europa.eu.enterprise/toys/index_en.htm.

## 3. PROBLEM DEFINITION

Three areas have been identified where the existing Directive does not fully meet its objective to allow for a smooth functioning of the Internal Market for toys while ensuring an adequate level of safety for children:

- Safety requirements;
- Enforcement;
- Scope and concepts.

The **safety requirements** are at the core of the TSD revision. Some of the existing safety requirements need to be enhanced to cope with recently identified hazards, e.g. with regard to certain chemicals used in toys and toys associated with food items. Others need to be enforced to take account of new types of toys, e.g. suffocation and choking hazards for toys with suction cups.

**Enforcement** of the Directive in the Member States does not seem as effective as it should be. The TSD is based on the manufacturers' responsibility for their toys' safety and not by ex-ante systematic checks by public authorities prior to the placing of toys on the market. Experience shows the need to improve the prevention of incidents by introducing an obligation to perform a product hazard and risk analysis, and to make it available - as part of the toy's technical file - for an inspection by the market surveillance authorities. Furthermore, a need has emerged to make the CE mark more visible and easily recognizable.

Almost two decades of application require a clarification of the **scope of application** of the TSD. Its definitions need to be tightened up, in order to enable the legislation to focus on products which correspond to the actual function of a toy, and to deal with new products. The Directive needs to be brought in line with the general legislative framework for the marketing of goods[1] and the relationship between the TSD and Directive 2001/95/EC on General Product Safety (GPSD) needs to be clarified as well.

## 4. OBJECTIVES

The overall objective of the revision is to enhance the level of safety of toys while maintaining and improving the smooth functioning of the Internal Market for toys. In order to achieve this overall objective, the following specific objectives have been identified:

- Strengthening, completing, clarifying and modernising the safety requirements for toys in order to respond, in particular, to scientific progress, to market developments and to an increased awareness of health and safety issues,
- Improving the implementation and enforcement of the Directive with regard to market surveillance obligations of Member States and conformity assessment requirements,
- Clarifying and updating the scope, concepts and definitions of the Directive and ensuring consistency with the general framework for the marketing of products in the EU.

These objectives can reasonably be expected to be met over a 2 to 4 year time-span, taking into account the time required for the adoption of the national implementing measures, the necessary compliance of producers and distributors, and the adaptations to the market surveillance systems.

## 5. POLICY OPTIONS AND ANALYSIS OF IMPACTS

Five options to tackle the identified problems have been identified:

- Repealing of Directive 88/378/EEC;
- No Commission action;
- Non-regulatory approach: guidance documents; recommendations;
- A new Directive that contains detailed rules based on the "Old Approach";
- A revised Directive to the extent necessary to ensure that safe toys can circulate in the EU internal market.

The latter has been chosen as the preferred option because it seems adequate and proportionate to cope with the identified problems without requiring a fundamental change of the system that has proved workable, thus keeping an adequate balance between on the one hand new (compliance and administrative) costs and on the other hand benefits for children's health and safety.

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[1] Proposal for a Regulation on accreditation and market surveillance; COM(2007)37 final of 14/02/2007. Proposal for a Decision on a common framework for the marketing of goods; COM (2007) 53 final of 14/02/2007.

Within the option to adapt the Directive to the extent necessary, a number of sub-options – ranking from a no change scenario to a regulatory approach with various degrees of stringency - have been identified and assessed:

- ***To enhance safety requirements for toys***

– New provisions on the chemical requirements;

– More stringent requirements on warnings;

– Changes to the requirements concerning the choking risk;

– Clarifying the suffocation risk;

– Clarifying the general requirement of safety;

– Special requirements for toys in food;

- ***To improve the enforcement and efficiency of the Directive***

– Changes to the technical file as regards information on chemicals;

– Changes to the CE marking and traceability information;

– Changes to the conformity assessment procedures;

**5.1. New provisions on the chemical requirements**

A no change scenario would mean that toys have to respect the general chemical legislation including REACH (Registration, Evaluation, Authorization and Restriction of Chemicals - Regulation (EC) No 1907/2006 and Directive 2006/121/EC), as well the existing specific provisions of the current Toys Directive, which include in particular limit values for eight chemical substances. This option has been disregarded since it does not seem appropriate to cope with the risks inherent to chemicals in toys.

As a consequence a regulatory option implying a change of the current rules has been chosen as the preferred option. Within this option various approaches could be envisaged:

– Approach 1: the maintenance of the status quo + a ban on allergenic fragrances according to Directive 67/548/EEC,

– Approach 2: the maintenance of the status quo + a ban on allergenic fragrances according to Directive 67/548/EEC + a ban of CMR (Carcinogenic, Mutagenic or toxic for Reproduction) substances Cat.1 & 2 unless authorised under REACH,

– Approach 3: the maintenance of the status quo + a ban on allergenic substances according to Directive 67/548/EEC + a ban on all CMR Cat. 1, 2 & 3 in accessible parts of toys, unless authorised by comitology procedure.

The approaches to ban CMR which are today present in toys to a certain extent - even though mostly in trace amounts or left-overs from production processes - would require (comprehensive) testing, might in certain cases lead to substitution or to a withdrawal of certain toys from the market. It would therefore increase manufacturing costs and - to a lesser extent - administrative costs. New costs for industry have been analysed in light of the expected health benefits quantified in terms of Disability Adjusted Life Years saved and in view to an expected reduction in the burden on the health systems of the Member States. Furthermore the implications of the REACH regime for chemicals have been assessed. In this respect

it has been taken into consideration that it will take time for the REACH system to become fully operational. While CMR substances must be registered under REACH by 30 November 2010, the possible authorisation of substances of high concern will take probably further years. It should also be noted that REACH applies a different regime for substances on their own and substances in articles. Whenever a substance is produced in the EU, all uses of CMRs must be assessed, including use in toys. However, this does not apply to CMRs already included in articles, except where a substance is intended to be released. Therefore, substances in imported toys normally do not have to be registered with the exception of CMRs included in the "candidate"-list for authorisation.

Considering the particular vulnerability of children and to ensure children's health and safety to the greatest extent possible, the third approach has been chosen. While it is susceptible to trigger higher costs for industry, it is at the same time adapted to provide considerable long-term beneficial health effects.

**5.2. New provisions on warnings**

As the current TSD contains provisions on warnings, the new measures are meant to improve their effectiveness in the prevention of accidents. The chosen option provides for the mandatory display of the minimum/maximum age for users at the point of sale, whilst the general provisions on warnings will be expanded to include – where appropriate - specific warnings on age or ability related risk, as well as on the minimum/maximum user weight and the need that the toy be used under adult supervision.

Only general estimates of the likely compliance and administrative cost impact could be provided. There is reason to consider that the overall costs will prove lower than is expected by some industry respondents, and written off over a relatively short time span. Age related warnings are already commonly available either at the point of sale or on packaging, and the other categories of warnings are already used by most producers and distributors on a voluntary basis. Health benefits are expected to be considerable, while again not measurable in detail, in terms of prevention and child safety.

**5.3. New provisions on chocking risks**

The risk of inhalation of small parts is currently regulated in respect of toys intended for children under 36 months. Discarding more radical solutions of uncertain effectiveness (such as raising of the age limit to 60 months) which would have entailed additional costs for industry without providing the necessary safety benefits, the option to extend the provisions to those toys that are meant to be put in the mouth, even when destined to children above 36 months, has been chosen.

**5.4. New provisions on suffocation risks**

The suffocation risk, defined as an *external* airway obstruction of the mouth and nose, is already covered by the TSD, regardless of user age. The proposed new measures provide for extending the definition in question to *internal* airway obstruction, to deal with the risk presented by new toys such as those with suction cups. There should not be any immediate costs to industry since standards contain technical provisions covering this risk for those specific products that are primarily concerned.

### 5.5. New provisions on the general safety requirements

The current safety requirements have created problems of interpretation, in particular because of the reference to the "foreseeable" use of a toy taking into account the "normal" behaviour of children, which may result in a narrow consideration of safety issues that affect toys design and production. The chosen option to clarify the definition of the general safety requirement by referring to "behaviour of children does not seem susceptible to create major costs for industry.

### 5.6. New provisions on choking as a result of the association of toys and food items

The coupling of toys and food is not explicitly covered by the specific provisions in the current legislative framework. The available data is very limited, and to a certain extent not very reliable. Therefore this issue was analysed in the light of the precautionary principle.[2] The following measures have been identified:

- Prohibiting 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.
- Introducing the new requirement that i) toys within food or co-mingled with food must have their own packaging and ii) the packaging itself should not present any choking hazard (namely that it passes the safety 'small parts cylinder test');

These new provisions introduce a reasonable level of harmonisation in an area of high concern that has already resulted in some national legislative measures, with negative effects on the EU market as a whole. Industry estimated show that the costs of these requirements will be modest.

### 5.7. New provisions concerning the information on chemicals in the technical file

An update of the requirements for the technical documentation held by toy manufacturers and importers has been considered. It has been assessed which information besides a detailed description of the design and manufacture of the toy should be kept in the technical documentation as a list of components and materials used plus amounts of individual substances. After an evaluation of compliance and administrative costs and taken into account that an indication of all possible individual substances in toys and their concentrations would not be workable, the Impact Assessment concluded that the technical file need to contain information on components and materials.

### 5.8. New provisions on the CE mark

The CE mark's implications go beyond the scope of toy safety legislation and are tackled under the general legislative framework on the marketing of goods which was the subject of a separate Impact Assessment. The TSD revision focuses on guaranteeing the marking's visibility. Among a number of options, the preferred one is to foresee that the CE mark should always be affixed on the toy itself, and if it is not visible from outside the packaging, on the packaging itself. The costs entailed in this option seem limited since the large majority of toys bear the CE marking already on the packaging.

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[2] COM (2000) 1 final of 01/02/2000

### 5.9. New provisions on conformity assessment procedures

Two changes have been considered: i) the introduction of an explicit obligation for the manufacturer to carry out a safety assessment and ii) mandatory third party verification for all or for certain types of toys.

A new obligation will be introduced to perform 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. This new provision is designed to provide a reliable and systematic basis for the analysis of risk, which industry already performs as part of the process involved in the design and marketing of new products, with a view to evaluating their soundness and ensuring conformity with the essential safety requirements. The incidence of these measures on costs is estimated to be insignificant or very modest.

As regards mandatory third part verification for toys, the options to be considered have been to keep the current requirements, under which where the manufacturer has a choice between self verification of the product or an EC type examination by a designated third party or to impose mandatory third party verification for certain or all categories for toys which are subject to harmonised standards.

Imposing mandatory third party verification for certain categories of toys has been asked for by consumer organisations and by certain Member States. Responses from industry indicate that a number of manufacturers already undertake third party verification. Mainly small and medium sized companies have been reluctant with regard to mandatory third party verification because of the costs effects.

Mandatory third party verification for certain types of products would indeed generate further costs, which could be significant in some cases, as well as delays in putting the product on the market. Furthermore, mandatory third party verification does not render *per se* all toys put on the market safer. Only the prototype is certified by the third party and thus deficiencies during the production process can not be ruled out and avoided. Taking into account the expected considerable costs of this requirement and that a mandatory third party verification cannot sufficiently enhance the safety of all individual toys, it was decided that such an option is not proportionate in view to the expected benefits. However, the Directive foresees that third party verification is mandatory in case harmonised standards covering all the safety aspects for the toy do not exist. This does only apply in a limited number of cases.

## 6. CONCLUSIONS

The main objective of the Toys Safety Directive and of its revision is to ensure the health and safety of children while ensuring the free movement of toys in the Internal Market. Ensuring that toys do not endanger health and safety of children necessarily creates costs for economic operators.

The elements of the revision aim to reduce toy related accidents and achieve health benefits for children, not only in short-term but also in the long term. Because of the complex and very heterogeneous structure of the toy industry, ranging form large world-wide operating companies to very small producers of certain specific kinds of toys, and the rapidly evolving conditions of the market, a complete set of data and costs is not available. Therefore case studies were carried out and estimates were made, in close cooperation with relevant stakeholders.

For the majority of the considered options for a revision, the costs appear reasonable, sometimes modest. The chosen options which will entail higher costs for industry concern safety issues. This concerns specifically the new requirements for chemicals in toys which are susceptible to trigger considerable manufacturing costs. Bearing in mind that the toys industry is competitive, it can be expected that these costs will be passed on to consumers, who will have to bear higher toy costs for the reduced probability of contracting diseases from chemicals as regards children.

The Impact Assessment concludes that the elements of the revision strike an appropriate balance between costs and benefits and will help to eliminate low-quality or hazardous toys from the market while ensuring that the EU toy industry is at the forefront of marketing quality products with high safety levels. The long term trend towards higher safety will be reinforced through safety-enhanced legislation and the corresponding technical standards.