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Accompanying document to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 88/378/EEC on the safety of toys

IMPACT ASSESSMENT

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1. INTRODUCTION

The object of this Impact Assessment is the revision of Council Directive 88/378/EEC of 3 May 1988 on the approximation of laws of the Member States concerning the safety of toys.

The Toys Safety Directive (TSD) was the first major EC Directive applying the method of the so-called New Approach. The New Approach was introduced in the 1980s to remove technical barriers to trade in the Internal Market through the encouragement of a system of European Standards. The Directive includes mandatory essential safety requirements, conformity assessment procedures, provisions on the CE marking[1] and foresees an obligation of Member States to take all appropriate enforcement measures that non-conforming toys are withdrawn from the market. Specific technical requirements for toys are not enshrined in the Directive but laid down in harmonised standards (EN 71).

The revision aims at strengthening the essential safety requirements for toys as well as the enforcement of the Directive whilst ensuring the proper function of the internal market for toys. It also aims at clarifying the scope of the existing Directive and at simplifying the legal rules in line with the Commission's Simplification Programme. The revision of the TSD is linked to the revision of the general legislative framework on products, i.e. the Commission's proposals for a regulation on accreditation and market surveillance and for a decision on a common framework for the marketing of goods that are under consideration by Council and the European Parliament[2].

The Impact Assessment provides an analysis of the problems that have been identified in the functioning of the current provisions. It identifies the objectives to respond to these problems, and most importantly the policy options that have been considered to translate these objectives into new legislative measures. Whenever this proves relevant, the IA accounts for the reasons that support a conclusion in favour of no policy changes. For those elements that have been selected for new regulatory measures (or significant alterations to the existing ones) a comprehensive explanation is provided of the underlying reasons.

The Impact Assessment comes to the conclusion that over its almost twenty years of operation the TSD has in general worked well to achieve its objectives i.e. to ensure the free circulation of toys which comply with essential safety requirements as laid down in the Directive. On the one hand the Directive has improved access to the EU market. On the other hand the overall safety of toys in the internal market could be significantly improved. Whilst the regulatory approach chosen in 1988 is considered to remain valid and appropriate, several areas of application have been identified where the overall objectives of the Directive have not been fully achieved. These concern i) the safety of toys due to the development of new products and improvements in scientific knowledge, ii) the efficient enforcement of the Directive, and iii) changes in view to definitions and concepts. The core of the proposal lies in addressing the safety requirements for chemicals in toys. Others relate to toy conception, to the need to lay down more stringent warnings, and to the necessity of a hazard/risk analysis prior to the

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1 The TSD was amended in 1993 (Directive 93/68/EEC) as part of a general modernisation of the conformity system in the New Approach Directives. This amendment was not designed to reconsider or update the safety requirements or other issues specific to the TSD.

2 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.

marketing, in line with the overall objective to ensure that toys circulating freely in the EU do not pose any risk of damaging children's health.

This Impact Assessment report uses the analysis conducted in three impact assessment studies (a general one and two focusing on the use of chemicals in toys). While every effort has been undertaken to base the proposed areas for a revision of reported deficiencies and on sound proof, one has to recognize that some data – namely with regard to both the number of accidents due to unsafe toys and concrete, measurable benefits for children's health - is not available.

The characteristics and the economic importance of the toys sector are described in an annex to the Impact Assessment.

2. FOLLOW-UP OF THE RECOMMENDATIONS OF THE IMPACT ASSESSMENT BOARD

Following the recommendations of the Impact Assessment Board of 22 October and 7 December 2007 the Impact Assessment Report has been modified substantially in a number of key areas.

The section concerning the identified problems (safety requirements, enforcement, scope and concepts) and the – overall and specific - objectives of the revision have been re-drafted with a view to present a more focused problem definition (namely with regard to the use of CMR in toys and their health implications) and a clear set of objectives that correspond with the problems identified. Where possible, indicators for the definition of objectives have been added. In the options-section, the sub-options have been presented in a more systematic way in line with the objectives to be achieved.

The analysis of compliance costs has been deepened in view to the new provisions on the chemical requirements in the Directive. These new provisions are the main elements of the revision with regard to both; considerable costs implications for industry, as well as with regard to potential benefits for children. Under point 7.2.3 costs due to new rules for chemicals are explained more explicitly. The revised Impact Assessment Report gives indications on the manufacturing- and the distribution costs. It explains that the cost estimates are subject to a number of uncertainties due a possible overestimation by stakeholders concerned and thus to be regarded as the Commission's best judgment available. The same applies for the estimations on possible benefits that are supposed to occur due to the new provisions. Safety benefits have been set out more explicitly. A comprehensive table on the benefits attributable to the different approaches on the basis of Disability Adjusted Life Years (DALYs) has been inserted in the report. The revised report states that there are also a number of uncertainties surrounding the analysis of the health benefits due to the lack of statistics that would allow for a more thorough assessment and because the estimations are likely to represent an underestimate of the true benefits since the general reduction in the burden of health systems could not been calculated as well as a potential productivity loss due to children falling ill due to the use of dangerous chemicals in toys.

The revised Impact Assessment replies to the recommendation of the Board to elaborate on the links to the REACH legislation in terms of timing and costs in general. It explains why the costs estimates for the revision of the TSD are not directly comparable with those of the REACH Impact Assessment and why the revision does not follow the approach to base the use of chemicals in toys on the general chemicals legislation.

The revised Impact Assessment contains a new section (7.2.12) on administrative costs based on the Standard Cost Model with regard to those new provisions that will lead to an obligation of industry to provide more information compared with the current legal situation. In addition sections 7.2.3 and 7.2.9 concerning chemicals in toys have been rendered more explicit with regard to administrative costs. Uncertainties in the analysis due to data that are not available from industry have been flagged.

Following the recommendations of the Impact Assessment Board, chapters 7.1.2 and 8 contain an enhanced description and analysis of the overall economic impacts, including the impacts on competitiveness and trade. Statistics with regard to the considerable number of toy imports from non-EU countries have been added. A summary table of all costs and benefits that are expected by the proposals has, however, not been added because of the risk being misinterpreted and/or giving a misleading picture. The considerable number of uncertainties surrounding some of the calculations and some non-quantifiable costs and benefits would have not been adequately reflected in such a table.

Concerning the specific issue of "toys in food" (section 7.2.8), the reasoning for the option chosen has been strengthened by applying the Precautionary Principle from the 2000 Commission Communication (COM (2000)1).

3. PROCEDURAL ISSUES AND CONSULTATION OF THE INTERESTED PARTIES

3.1. Organisation and timing

The revision of Directive 88/378/EEC on the safety of toys is part of the Commission's 2006 work programme (2006/ENTR/004). It has been postponed to take into account the proposals on the marketing of products the Commission adopted in February 2007 (see 3.2.4) and is included as priority initiative in the CLWP 2007.

3.2. Consultation and Expertise

The revision has been discussed thoroughly with the Member States' authorities, the stakeholders (industry and consumer organisations), and standardisation organisations within the framework of the Expert Group on Toys Safety. The discussions in the Group started in 2001. Several meetings per year have been organised, which has permitted to deeply explore the need of revision and the areas to be revised. Since 2003 concrete drafts in the form of a Commission's proposal for a revised Directive have been discussed in the Expert Group.

A general impact assessment study was carried out in 2004 by an independent consultant to assess different possible modifications to the Directive. The results of this study can be found at http://ec.europa.eu/enterprise/toys/index_en.htm.

A specific study on certain chemicals used in toys was carried out in 2006 to provide certain elements for the revision of the chemicals requirements of the Directive. The objective was to update the limits of bioavailability of chemical substances in the Annex of the Directive and to explore possibilities of setting specific requirements for toys for children under 36 months and for other toys intended to be put in the mouth. The results of the study are published at http://ec.europa.eu/enterprise/toys/index_en.htm.

At the beginning of 2007, the Commission services launched a specific study aimed at

complementing the general impact assessment study as regards the chemical requirements in order to explore in depth the impacts of this essential and sensible area of the revision. The results of this study are published at http://ec.europa.eu/enterprise/toys/index_en.htm.

The different studies that have provided the basis for the impact assessment have been followed by inter-service steering groups: The general impact assessment study was followed by a steering group with the participation of DG ENTR and DG SANCO. The study on certain chemicals used in toys was supervised by an inter-service group with the participation of DG ENTR Chemicals Unit and of DG SANCO.

A public consultation was organised in May and June 2007 to invite all interested parties to send their observations on those questions which have been identified as potential objects for changes in the Expert Group discussions. The results of the public consultation are published at http://ec.europa.eu/enterprise/toys/public_consultation.htm

The public consultation drew 1531 replies. 138 replies were submitted from Member States or organisations, such as industry, consumer or standardisations organisations. Although the vast majority of the feedback came from individuals, because of the nature and or the focus of the comments it could be assumed that a part of these individual replies originates from individuals who are to various degrees involved in the toys business (distributors, retailers, company managers, etc.).

4. PROBLEM DEFINITION

4.1. Directive 88/378/EEC and its functioning

4.1.1. Context

Directive 88/378/EEC on the safety of toys was adopted in the context of the achievement of the internal market. The proliferation of different safety provisions across the Member States had led to barriers to trade and marketing. This went hand in hand with the recognition that a proliferation of different national safety regimes across the EU did not necessarily afford consumers in the EU, especially children, with effective protection against hazards arising from toys.

The TSD was, therefore, adopted in 1988 to harmonise the safety levels throughout the Member States as well as to remove the obstacles to trade and to prevent market fragmentation. This Directive is one of the 25 Directives in force that apply the principles and method of the so-called New Approach[3]. It only sets the essential safety (and other)

[3] The basic concepts of the New Approach of the free circulation of goods in the single market can be summarised as follows:
Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community. The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards. Application of harmonised or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements. Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements. The operation of the New Approach requires that the standards offer a guaranteed level of protection with regard to the essential requirements established by the directives, and that the national authorities carry out their responsibilities for the protection of safety or other interests covered by the directive. Further, a safeguard clause procedure is necessary to allow

requirements, while technical details are set out by specialised technical bodies, such as the standardisation organisations CEN and CENELEC.

The TSD was amended in 1993 by the CE Marking Directive 93/68/EC which imposed uniform standards on all New Approach directives implemented prior to 1993. Besides, toys are subject of a number of other EC-Directives and Regulations[4].

4.1.2. Analysis of the achievement of the objectives of the Directive

The directive on the safety of toys has achieved over its almost 20 years of existence a considerable number of its objectives, particularly in bringing down market barriers and in ensuring harmonised safety standards across the EU. This is supported by a study[5], which is based on extensive stakeholder consultation. It concluded that the Directive has succeeded in leading to:

– enhanced market access and a free circulation of toys within the Internal Market;

– better manufacturer awareness of requirements for toy safety;

– reductions in the level of non-conformity of toys on the EU market and

– reduction in the number of toy-related accidents.

4.2. Problems identified

Following the extensive consultation, the analysis carried out by the consultants and the discussions in the framework of the Expert Group on Toys Safety 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. These specific problems relate to:

(1) Safety requirements (Section 4.2.1);

(2) Enforcement (Section 4.2.2) and

(3) Scope and concepts (Section 4.2.3).

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the possibility of contesting the conformity of a product, or failures or shortcomings of harmonised standards.

4 The Directives that all or certain toys have to comply with include in particular:
Council Directive 2001/95/EC on General Product Safety;
Council Directive 99/5/EC on Radio & Telecommunications Terminal Equipment;
Council Directives 89/109/EEC and 90/128/EEC on Contact with Foodstuffs;
Council Directive 89/336/EEC on Electromagnetic Compatibility;
Council Directive 73/23/EEC on Low Voltage Equipment;
Council Directive 67/548/EEC on Dangerous Substances;
Council Directive 76/769/ on the marketing and use of certain dangerous substances and preparations;
Council Directive 76/768/EEC on Cosmetic Products.

5 Study on the Impact of the Revision of the Council Directive 88/378/EEC on the Safety of Toys (RPA 2003).

4.2.1. Safety requirements

4.2.1.1. Introduction

Children are a particularly vulnerable group of consumers who lack the ability to take informed decisions on their own. It is their parents who have to take those decisions on their behalf. Although a certain degree of supervision from parents can reasonably be expected, parents are often not in a position to judge themselves how safe a toy is, particularly regarding substances that are not visible from the outset, namely chemicals and their harmfulness, noise emission levels or the dangers of laser components. In addition, children are also particularly vulnerable as they may be more susceptible to adverse health consequences due to their young age.

The TSD contains an obligation for Member States to ensure that only safe toys are placed on the market This obligation is based on the respect of essential safety requirements which foresee that toys must not present any health hazards or risk of injury. Technical details for the application of the general safety requirements can and have been enshrined in harmonised technical standards covering in detail the hazards in question. However, due to the particular vulnerability of children the TSD itself as the legal basis needs to set the core of the safety requirements and to cover all hazards that toys may present. All essential safety aspects should be foreseen in the Directive since the application of the standards remains voluntary and other technical solutions are possible as long as the production is in conformity with the essential safety requirements. Furthermore, the essential safety requirements are the basis for the future development of standardisation and therefore should be as complete as possible.

A couple of deficiencies in the application of the safety requirements of the TSD have been identified that would not allow to reach its objective which aims to ensure that only safe toys are put on the market in a sufficient manner*: *The existing essential safety requirements of the TSD do not always correspond to the technical progress and are thus outdated* (4.2.1.2). *They do not respond fully to recently identified hazards* (4.2.1.3). *There is a need to clarify the general safety requirement (4.2.1.4). There is a lack of adequate warning requirements (4.2.1.5).

These deficiencies have emerged from the experiences the national experts of toys safety have made and from the reports received from Member States authorities and stakeholders within the framework of the three impact assessment studies. Some of the issues have been raised due to accidents or incidents that have occurred in the Member States. It is, however, important to note that data available on toy related accidents do not allow for fully fledged quantified evidence, in the way that the number of accidents concerning a particular type of hazard would require immediate legal action for this kind of hazard. No consistent EU wide statistics on toy related accidents exist. The data that is available in some Member States (only three Member States have injury systems with potential ability to provide useful data) present several handicaps. In particular, the exact cause of accidents is not available from sources of accident data. The toy is normally only cited as a factor in the accident which required admission to some form of hospitalisation. This does not necessarily imply that the responsibility for the accident lies with either the toy or its manufacturer or that the cause of the accident would be such that it could be prevented by legislative action. Also several products included in statistics are not toys within the meaning of the toys directive. Accidents and incidents not involving hospital visits or consultation of a medical doctor are not reported and do not figure in the statistics.

4.2.1.2. Outdated safety requirements

Firstly, according to the evidence gathered in the study and by the Expert Group, certain essential safety requirements included in Annex II of Directive 88/378/EEC are not up to date anymore. This is the case, in particular with the requirements on electrical properties which do not take into account the technical progress made since the adoption of the Directive. Also some requirements in the physical and mechanical field are not up to date any more, such as the requirements on suffocation and choking hazard, as they do not cover adequately certain types of products which have become popular recently, i.e. toys with suction caps. Suffocation accidents due to suction caps have been reported in several Member States.

4.2.1.3. Lack of safety requirements for recently identified hazards

Essential safety requirements for recently identified hazards are lacking. In particular, there is a need for enhanced requirements on chemicals, noise, laser, activity toys and for speed limit for ride on toys as well as specific requirements for toys in food. As regards magnets, a specific problem has emerged. After discussion with the stakeholders and the national authorities in 2006 an ad hoc mandate was given to the European Committee for Standardisation, which is working on an amendment of the existing standard.

As a main element of discussion with all stakeholders emerged the need to devote specific attention to safety requirements with regard to ***chemical substances used in the production of toys***. When the Directive was originally adopted there was limited knowledge of the relevance of chemicals to toys. Since then the awareness of the hazards and risks associated with the use of chemicals in (consumer) products has been risen constantly. A comprehensive new regulatory system was introduced by Regulation 1907/2006 and Directive 2006/121/EC (REACH), and the Directive 76/768/ECC on cosmetics has been amended seven times. Permanent restrictions on the use of phthalates in toys were introduced in 2005 (Directive 2005/84/EC). Market surveillance surveys carried out in the Member States[6], have highlighted the presence of dangerous chemicals in toys some of which are not regulated at Community level, such as allergens and nitrosamines. The increasing awareness of the potential (dangerous) consequences in using chemicals for the production of sensitive products requires an in-depth assessment of the regime that would be appropriate for the use of chemicals in toys, in the light of both, the general principles of the chemicals legislation and the peculiar safety issues that arise in respect of toys destined for children.

As regards the potential negative health effects from exposure to chemicals from toys among other sources, children need special protection. They are a particularly sensitive group of consumers because they eat and breathe more than adults by weight and have also different behaviour patterns (hand/mouth). Children are undergoing rapid growth and development, and their developmental processes are easily disrupted. (see, for instance, WHO report 2007

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[6] See for instance survey on plastic toys by the Netherlands Food and Consumer Product Safety Authority (Bouma K, Reus HR (2004) Market surveillance on toy safety. Report no NDOo063/01, Food and Consumer Product Safety Authority, Groningen, the Netherlands); survey by Danish Ministry of Environment on toys made of foam plastic (Borling et al (2006) Survey, migration and health evaluation of chemical substances in toys and childcare products produced from foam plastic" Survey of Chemical Substances in Consumer Products, No 70, DTC Health and Environment); survey by Danish EPA ((2005) Survey and release of chemical substances in "slimy" toys); survey by the Netherlands Food and Consumer Products Safety Authority on migration of N-nitrosamines and n-nitrosatable substances from latex balloons (2004).

"*Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals"[7])*. While traditionally the main threats to children's health were infectious diseases, the current threats appear to come increasingly from the environment including chemicals in the environment, in air, food, water and from proximity to individual exposures. Chronic illnesses including asthma, paediatric cancer, neurodevelopmental and behavioural disorders, congenital defects etc are becoming increasing burden to society.[8]

Against this background, the present provisions on chemical properties in the toys directive need to be assessed whether they address the situation of children as consumers requiring special protection adequately with a view to avoiding harmful medium and long-term effects. A problem occurs in particular because there are no specific provisions on the use of certain dangerous substances in toys, such as CMRs (substances that are carcinogenic, mutagenic or toxic for reproduction) or allergenic fragrances. For cosmetic products that enter into direct contact with the skin, specific EU-rules exist with regard to the use of CMR chemicals and allergenic fragrances. Given the fact that children are susceptible to get in direct contact with toys by e.g. sucking, the current legal framework might present deficiencies that have to be taken into consideration. In this respect it has to be taken into account that a potential exposure depends on the characteristics of the toy, namely on the question whether the chemical substance is accessible.While a considerable number of toys contain encapsulated chemical preparations or substances as e.g. toys using electronic circuits in micro-chips, there are toys - e.g. those which contain plastics - where an exposure can take place, i.e. where the chemicals on the surface of a toy is susceptible to pass to the child.

According to information received from toys industry (TIE) 110 CMR substances can possibly be found in toys, albeit most of them only in trace amounts as left-overs from production processes. A major problem is that the toy industry has only limited control over the chemical specifications and the quality of the materials obtained in open market which is necessary for the production of toys.

There is scientific evidence that ***noise*** exposure can induce hearing impairment. Data from animal experiments indicate that children may be more vulnerable in acquiring noise-induced hearing impairment than adults, and toys constitute one specific source of exposure to noise (see for instance WHO Guidelines for Community noise[9]). The Toys directive does not contain any essential safety requirement on noise, although technical requirements on noise level in toys have already been introduced in the toy standard EN 71:1. Hence the objective of introducing specific provisions in this respect, as such an essential safety issue could not rely exclusively on technical requirements as explained above (4.2.1.1)

Lasers are nowadays commonly used in toys. The human body is vulnerable to the output of certain lasers, and under certain circumstances, exposure can result in damage to the eye and skin. However, the Toys Directive does not contain any safety requirement on lasers although technical requirements on them have been introduced in standardisation.

Standards already contain technical requirements on speed limit for electrically powered ride on toys and on activity toys (such as swings and slides) but there is no specific provision to

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7 http://whqlibdoc.who.int/publications/2006/924157237X_eng.pdf

8 Landrigan, P.J, Schechter, C.B, Lipton, J.M, Fahs, M.C., Schwartz, J. 2002. Environmental pollutants and disease in American children: Estimates of morbidity, mortality, and costs for lead poisoning, asthma, cancer, and developmental disabilities.Environ.Health Perspect. 110:721–28]

9 http://www.who.int/docstore/peh/noise/guidelines2.html

cover the inherent risks (of falling, crushing etc) presented by these kinds of toys in the Toys Directive itself.

The potential specific hazards presented by ***toys inside food***, such as toys in chocolate eggs, are not addressed at Community level although several Member States have specific legislation on these kinds of products. The association of a toy and food could namely be the cause of a specific risk (of choking) that is distinct from the risks associated with the toy alone. A study carried out by the European Parliament ("inedibles in food product packaging", RPA 2003) indicated that the risks associated with inedibles in food are demonstrably low but could not be ruled out. It has been reported[10] that several accidents resulting in a hospital call have occurred since the 80s, although no fatal accidents have been recorded in the EU since the beginning of 90s. These data present severe limitations, but represent an indication of a safety issue that is worth of consideration.

4.2.1.4. Lack of clarity in the general requirement of safety

In addition to the need to modernise the particular safety requirements of the Directive, the general safety requirement contained in the Directive needs clarification. According to the general safety requirement "*the users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children*". The term "normal behaviour of children" has created problems of interpretation in the past, since there are differing views on what "normal" means in this context.

4.2.1.5. Lack of complete warning requirements

Finally, experience shows that rules on the safety information to be given with toys (warnings) are not sufficiently complete for the purpose of guaranteeing that toys are used by children under conditions guaranteeing a high level of safety for them. The current Directive lays down that toys must be accompanied by clearly legible warnings in order to reduce inherent risks in their use. The Directive also sets out the warnings and indications to be given for certain categories of toys. This list of specific warning is completed by the standard EN 71. These provisions presents gaps because they do not, in particular, provide that the warnings should always contain appropriate user limitations such as those related to age, ability and weight of the user, as well as the need to ensure that the toy is used under adult supervision, which means that these warnings essential to the safe use of the toy might in some cases be lacking.

4.2.2. Enforcement

Efficient enforcement of the Directive is one of the cornerstones for guarantying that a high level of safety of toys is attained in the European market. The enforcement of the Directive by Member States authorities shows room for improving its consistency and effectiveness, in particular in the area of market surveillance.

Given the huge number of diverse toys on the market, the Directive is based on the manufacturers' responsibility for the safety of their product without requiring mandatory third party verification. Public authorities do not, in principle, control toys before their placing on

[10] The data is controversial and not validated by governmental sources or public health organisations; besides it is fiercely criticised by the industry, which considers it unscientific and biased.

the market. Instead, the authorities carry out market surveillance of toys placed on the market, which needs to be efficient enough to attain the safety objectives of the Directive. The recent recalls of toys in summer 2007 by a major manufacturer provide a compelling example of such situations. Many of the items concerned had been produced with paints containing an excessive amount of led, a risk that went undetected after their placing on the market.

A specific problem which is linked to efficient market surveillance concerns the analysis of the hazards and risks a toy may present. The existing TSD does not contain any explicit obligation for the manufacturers to carry out such an analysis. There isn't any requirement for them to document the hazard/risk analysis and to keep it available for inspection to the market surveillance authorities (in the technical file). Responsible manufacturers do already carry out a hazard/risk analysis in order to respect their other obligations under the directive. However, since the analysis is not mandatory, it is difficult for the market surveillance authorities to check whether analysis has been undertaken.

There is also a lack of appropriate institutional framework for the Member States and the Commission to deal efficiently and rapidly enough with some issues concerning the implementation of the Directive, in particular with updating Annex I concerning the scope of the directive and with certain aspects of the chemical requirements. Rapid adaptation of these questions concerning the implementation of the Directive is for the moment only using the procedure to amend the Directive which the co-decision procedure by the Council and the European Parliament.

The rules on the information to be provided with the toys (as the CE-marking and traceability information) are not completely satisfactory to allow an efficient enforcement of the Directive. The present rules require that the CE-marking is affixed either on the toy or on the packaging, and in case of small toys it can also be on a label or a leaflet. Therefore, the CE-marking does not always appear on the toy which has been seen as problematic for the consumer who cannot any more verify its presence once the packaging has been thrown away. The existing rules on the affixing of the CE-marking do not either require the CE-marking to be visible without opening the packaging which complicates the task of the market surveillance authorities. This issue is relevant to the good management of the legislative framework, because the marking provides the goods it is apposed to a presumption of conformity with the safety requirements.

4.2.3. Scope and concepts

In the light of the experience accumulated over nearly twenty years it is has become evident that the ***TSD's scope of application lacks clarity***.

According to Article 1, the Directive applies to any products or materials designed or clearly intended for use in play by children of less than 14 years of age. The main difficulty of this definition is the concept of "use in play" or "playing value". Virtually, everything has playing value for a child, but this does not make every object fall into the definition of toy. Annex I completes this general definition by enumerating a certain number of products not considered as toys for the purposes of the Directive. However, the scope of the Directive lacks clarity with regard to certain new products, such as videogames and peripherals. Unclear scope leads to problems of interpretations for the manufacturers and for surveillance authorities, who have often difficulties in determining whether a certain product is covered by the requirements of the Toys Directive or not. These difficulties can in turn lead to different rules being applied to the same product in different Member States and thus to market.

Furthermore, ***the TSD does not comply with the Commission standards for Better Regulation and good legislative practices***[11]. The Directive contains ambiguities, uses long and complicates sentences that include both external and internal cross-references which makes its understanding and interpretation difficult. Individual articles do not have titles and they are not grouped under sections-heading, which would help the reader to better understand the logic of the legal text. The aim is to simplify the application of the Directive and its correct implementation in 27 Member States.

Finally the relationship between the Toys Directive and Directive 2001/95/EC on General Product Safety (GPSD) also needs clarification. The GPSD applies to toys in some cases, but those cases that represent grounds for its application are not clearly defined, which leads to lack of legal certainty for manufacturers and distributors.

4.3. Treaty base and subsidiarity

In considering the issue of subsidiarity within the meaning of of Article 5 of the EC-Treaty, it should be taken into account that Directive 88 /378/EEC is a total harmonisation directive adopted on the basis of Article 95 of the Treaty with the objective of the establishment and functioning of the internal market for toys. National legislation cannot impose additional provisions on the safety of toys which would require the modification of the product or affect the conditions for its placing on the market. Therefore, the revision of provisions of Directive 88/378/EEC is, as far as the safety requirements for toys or the conditions of their placing on the market are concerned, within the exclusive competence of the Community. The application of the principle of subsidiarity within the meaning of Article 5, second paragraph, of the EC-Treaty does not arise.

It is important to note that the revision aims at clarifying the scope of products covered by the Directive, but not at extending or changing it otherwise. Therefore the issue of subsidiarity within the meaning of Article 5, second paragraph, of the EC-Treaty does not arise in this respect either.

The respect of the subsidiarity principle, therefore, only arises with regard to the other areas of the revision, namely with regard to the improvement of effective enforcement of the Directive. Experience has shown that coherent and effective enforcement and market surveillance has not been sufficiently achieved by Member States acting alone. The recent massive recalls of toys have shown deficiencies to detect unsafe products on the market. As a consequence, the issue of setting some mandatory common minimum requirements arises. As a result of the proposal, this activity would remain within the authority of the national authorities but some general EU-wide requirements would be introduced to ensure equal treatment, a level playing field for economic operators, and a similar level of protection for the citizens in all the Member States.

4.4. Proportionality

In accordance with the principle of proportionality (article 5, third paragraph, of the EC-Treaty), the proposed modifications do not go beyond what is necessary to achieve the objectives set. In order to protect the benefits of the single market in the toys sector, any

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[11] The Toys Directive has been taken as exemple by Martin Cutts in his book "Clarifying Eurolaw" (2001) to show how Community Directives could be written better http://clearest.co.uk/files/ClarifyingEurolaw.pdf.

changes to the existing directive have to be dealt with at the Community level. If Member States acted on their own, there would be a proliferation of safety requirements which would hamper and undermine the achievements of the single market, and very likely lead to confusion for consumers and producers alike. The consequences could be higher prices for consumers, as producers would have to revert to abiding by member state specific requirements, while there would be a lack of clarity regarding the safety of toys bought in another Member State

The proposed modifications have been discussed at length in the Expert Group on Toys safety composed of the representatives of the Member States, industry, consumers, standardisation organisations and notified bodies and have been subject to the two impact assessment studies carried out by independent consultants mentioned in chapter 1. All the modifications have, therefore, been assessed in terms of proportionality so as to not impose unnecessary burden and costs on industry, especially on small and medium sized enterprises, or administrations.

A number of options contained in this impact assessment concern the improvement of clarity of the existing Directive without introducing significant new requirements with cost implication. Where modifications have more significant impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified.

5. OBJECTIVES

The legal framework put in place through Directive 88/378/EEC has allowed both, free circulation of toys in the Internal Market and a uniform level of toy safety across the EU. Since the Toys Directive was originally adopted, the need and usefulness of an EU legislative framework have not been questioned. However, as outlined in detail in section 3.2 a number of problems regarding the optimal functioning of the Directive have been identified. In response to these problems the Commission pursues the following objectives with the revision of the Directive.

5.1. Overall objective

To enhance the level of safety of toys while maintaining and improving the smooth functioning of the Internal Market for toys

The current toys safety directive aims at ensuring the free movement of toys between Member States while also ensuring a uniform level of toy safety across the EU. The smooth functioning of the Internal Market for toys remains a valid objective of the Directive in a Union of 27 Member States. Over time however, the need to ensure the highest possible level of safety of consumer goods has become a major concern of EU-legislation in the EU. This concern does especially apply with regard to toys used by children, a particularly vulnerable group of consumers. Thus the main overall objective of the revision is, to enhance the safety of toys, in particular to prevent harmful medium and long term negative health effects in children arising from the use of toys.

The indicator to measure the achievement of this objective would be the number of reduction of accidents caused by toys and the reduction of medium and short term negative health effects in children from toys. However, these are in practise very difficult to measure due to the problems indicated above in section 4.2.1.1. Current data makes it impossible to determine the extent of reduction in accidents that could arise as a result of the proposed modifications.

In particular, the available data cannot be used to develop a statistical relationship between specific safety requirements and the number of toy-related accidents. Even if such a relationship could be developed, it is inherently difficult to value the human satisfaction gained from children playing with a safe toy or the pain suffered as a result of a major or a minor injury. Moreover, the available statistics do not reflect longer-term impacts on health, for example from chemicals contained within toys.

5.2. Specific objectives

In order to achieve the above mentioned overall objective, the revision pursues the following specific objectives:

Strengthening, completing, clarifying and modernising the safety requirements for toys in order to respond, in particular, to scientific progress, to market developments and an increased awareness of health and safety issues (5.2.1),

The indicator to measure the achievement of this objective is the extent to which today known hazards presented by toys are covered in the safety requirements, boosting innovation due to the possibility to apply innovative technological solutions which ensure the safety of toys as well as the reduction of medium and long term negative health effects arising from the use of toys.

Improving the implementation and enforcement of the Directive with regard to market surveillance obligations of Member States and conformity assessment requirements (5.2.2)

The indicator to measure the achievement of this objective is the effectiveness and efficiency of the operation of the Directive to reduce the number of non-compliant toys circulating on the market in order to guarantee that all market players compete under equal conditions as well guaranteeing a high level of protection for the public.

Clarifying and updating the scope, concepts and definitions of the Directive (5.2.3),

Indicator is the more uniform application of the Directive by economic operators and by national authorities in all Member States and resulting from this fewer legal disputes in national courts. However, it would not be in practise possible to measure the reduction in the number of legal disputes, since there is no readily available information on the number of legal cases brought against companies operating in the toy sector that would be avoided in the future.

Ensuring consistency with the general framework for the marketing of products in the EU (5.2.4).

These objectives can reasonably be expected to be met over a 2 to 4 years 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.

5.2.1. Strengthening, modernising, completing and clarifying the safety requirements for toys

As set out in section 4.2.1 of the Impact Assessment a number of deficiencies in the application of the existing safety requirements of the TSD have been identified which need to be addressed through a revision.

New safety requirements are especially needed to ensure the protection of children against recently discovered medium and long term health risks in the field of chemicals. The aim of these requirements is to reduce the exposure of children to harmful chemicals and to have the effect of potentially reducing the incidence of diseases or medical conditions associated with these chemicals found in toys. Whilst taking into account the principles and the methodology of the existing chemicals legislation, the aim is to adapting the requirements to the particular circumstances of toys marketing and use.

It is also intended to clarify certain safety requirements to cover risks presented by new popular products that appear on the market. This is in particular the case of toys with suction caps.

The objective of the revision is also to modernise outdated safety requirements so as to allow new technological solutions to be applied which would not be permitted under the current directive but which can nowadays ensure a high level safety of the toy, and in this way also contribute to boost innovation. This applies in particular to electrical properties of toys.

As regards the special case of toys in food, experience shows that the association of toys and food produces a peculiar category choking hazard which needs to be taken into account in the safety requirements to prevent the possibility of accidents arising from these kinds of products.

Furthermore, the revision also aims at clarifying the general requirement of safety foreseen in the Directive in order to be more explicit as to what kind of behaviour of children with toys needs to be taken into account when ensuring the safety of toys.

Also safety information (warnings) to be given with the toys should be improved to guarantee safe conditions of use for toys in all circumstances.

As explained in section 4.2.1, apart from the case of chemicals in toys and the special case of toys in food, the aim of modernising, completing and clarifying the safety requirements is not to directly and immediately respond to accidents or negative health effects that have occurred but to ensure an efficient operation of the legislative framework based on the New Approach principles, which require establishing a complete set of essential safety requirements, and to pave the way for the development of standards in the future. It is however realistic to expect that, indirectly, ensuring the completeness of the safety requirement should in general lead to improved safety of toys which is the overall objective of the whole legislative framework. It appears realistic to expect that, in due course, the revision will achieve a reduction in the number of recalls of dangerous or defective toys from the market[12].

[12] Currently, about two thirds of RAPEX notifications concern toys.

5.2.2. Improving the implementation and enforcement of the Directive with regard to market surveillance obligations of Member States and conformity assessment

Lack of adequate market surveillance of toys has been identified as a major problem in the operation of the Directive and therefore an important obstacle to the achievement of Directive´s safety objective. There is a general consensus that improved enforcement and implementation of the Directive by economic operators and market surveillance is the key to improved safety of toys and thus to the reduction in the number of toy related accidents.

The revision aims, firstly, at developing conditions for a better common approach by national market surveillance authorities in the implementation of the legislation in force. In order to ensure a satisfactory level of market surveillance in all Member States, the objective of the proposal is also to reinforce the consistent and effective enactment of the measures to be taken by the national market surveillance authorities.

The revision also aims at resolving certain specific problems related to the efficient enforcement of the Directive: In order to facilitate a better enforcement of the Directive, the revision pursues to clarify and specify the rules on the CE-marking which is the first indication for the market surveillance of the conformity of the toy with the Directive. As regards the technical file, the revision aims to ensure that the technical file contains all the necessary information for the market surveillance to carry out efficient controls of conformity.

5.2.3. Clarifying and updating the scope, concepts and definitions of the Directive

In order to facilitate the understanding and the application of the Directive by manufacturers and surveillance authorities and to enhance legal certainty, the proposal aims at clarifying the material scope of the Directive, in particular with regard to certain new products, such as videogames and peripherals. The revision aims to clarify the scope as regards other products too, such as electrically driven vehicles. The proposal also aims to clarify the relationship between the Toys Directive and the General Product Safety Directive (*inter alia* the European rapid alert system for dangerous non-food products RAPEX, safeguard-measures, administrative co-operation) to ensure legal safety.

The revision aims at clarifying certain concepts used in the Directive which are susceptible to differences in interpretation. The proposal aims, in general, at removing the ambiguities in the text of the Directive. The objective is also to simplify and improve the wording in order to enhance better understanding of the provisions of the Directive and promote their uniform application by the authorities of the Member States.

5.2.4. Ensuring consistency with the general framework for marketing of products

On 14th February 2007, the Commission adopted its proposals for a Council and European Parliament Regulation and Decision within the framework of the revision of the New Approach[13].

The proposal for Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products contains provisions on accreditation of conformity assessment bodies and provisions on market surveillance. According to the proposal, the provisions of the Regulation on market surveillance shall apply to the toys sector

[13] http://ec.europa.eu/enterprise/newapproach/review_en.htm

only as regards controls at external borders (see Article 13(2) of the proposed Regulation). Otherwise market surveillance of toys continues to be governed by the provisions of Directive 2001/95/EEC on General Product Safety.

The proposed Decision on a common framework for the marketing of products sets standard Articles to be used in the New Approach Directives. These Articles include, in particular provisions on common definitions, obligations of economic operators, general principles of the CE-marking and certain conditions for its affixing, harmonised standards and presumption on conformity, objections against harmonised standards, the conformity assessment procedures, notification of conformity assessment bodies and safeguard procedures. In order to ensure a consistent approach with the other New Approach directives, the proposal for a revision of the Toys Safety Directive will be aligned to the proposed Decision. In other words, the standard articles will be integrated into the toys proposal with only some adaptations necessary due to the specificities of the toys sector.

– The impact assessment of the TSD concentrates on the specific questions that will be regulated in the Toys Directive itself and not those that emerge from the horizontal revision, which was subject to a specific impact assessment.

6. POLICY OPTIONS

6.1. The main policy options

Option A - repeal of Directive 88/378/EEC

One option could be to repeal the existing EU legal framework, i.e. Directive 88/378/EEC. The option "to not to regulate" is a purely theoretical one. The free circulation of safe toys cannot be achieved on the basis of the EC-Treaty only, without having recourse to specific harmonisation legislation. Namely the same, adequate level of safety of toys throughout the EU can only be achieved by the use of uniform rules. The rules on the product safety in the General product safety directive (2001/95) are not specific enough to take into account the needs of the sector of toys, especially taken into account that the users of toys are a particularly vulnerable group of consumers who need special protection.

Option B – no action by the Commission.

Under this option there would be no legislative proposal. The current Directive would continue to apply as it does since 1988. Pursuing this option would mean that the problems identified in section 4 would persist. However, this option will be analysed as the "baseline scenario" more in detail as regards the main issues of the revision (which are specified under 6.2).

Option C - Non regulatory Approach, guidance documents, recommendations

In general, only a few problems identified under section 4.2 could be addressed to certain degree by adopting and revising guidance documents or recommendations, namely clarifying the scope and concepts of the Directive. However, most of the identified deficiencies that relate to the safety of toys do not seem appropriate to be tackled by soft law. This concerns namely requirements for a wide range of properties in toys as contained in the annex of the directive that need to be clearly set to allow for legal security for both, users and industry. A more stringent effective enforcement might be achieved through recommendations only with

less restrictive administrative burden for responsible toy manufacturers who fully apply with the rules for the production of toys. However, the problems identified have not effectively addressed in this way in the past, so that it is unlikely that non-binding rules would be sufficient.

In any case, some new legally binding requirements and obligations are needed, such as new essential safety requirements, new rules on the affixing of the CE markings and warnings, and, therefore, these requirements and obligations could not be imposed using this option. It is also important to note that integrating into the Toys Directive the horizontal provisions adopted in the proposed Decision on the common framework for the marketing of products explained in section 5.2.4, can only be done by adopting them in a legally binding instrument.

This option will, however, be analysed more in detail in section 6 as regards the main issues of the revision (which are specified under 6.2).

Option D – substantially new Directive for the safety of toys based on the "old approach"

It could be envisaged to not use any longer the New Approach method, that is setting only essential safety requirements in the legislation and leaving technical details to the harmonised standards, but to include in the Directive all detailed technical specifications ("Old approach").

However, adopting all (detailed) technical requirements would not allow the same flexibility and light legislation as using the New Approach method does. Keeping the directives free from detailed specifications has facilitated a flexible legal framework, which is technology-neutral and serves as a catalyst for innovation and growth. It has allowed keeping legislation slim and avoids the need for frequent adaptations to technical progress, an important factor in a business environment which is characterised by fast developing technologies. Manufacturers are given the freedom to choose any appropriate technical and innovative solution that meets the required safety level without being pressed in legal corset running behind technology evolutions.

Option E – adapting the Directive to the extent necessary to ensure that safe toys can freely circulate within the EU

This option would maintain the major New Approach principles of the existing directive with those modifications that are needed to address new safety and implementation challenges. This option would concentrate on improving, updating and completing the regulatory framework in force. It allows for a revision of the existing legal framework in a number of areas that can be precisely identified and where a need to strengthen safety and enforcement requirements exist.

Within the scope of option E, various degrees of stringency and a variety of different tools need to be considered.

6.2. The sub-options for the main issues of the revision

In this section the various sub-options for the main issues of the revision will be described before analysing their impacts under section 6. As will be explained in 6.1, the impact analysis concentrates on those changes which are susceptible of having an impact on industry costs. These are the following:

To enhance safety requirements for toys:

– New provisions on the chemical requirements (6.2.1.);

– More stringent requirements on warnings (6.2.2);

– Changes to the requirements concerning the choking risk (6.2.3);

– Clarifying the suffocation risk (6.2.4)

– Clarifying the scope of the general safety requirements (6.2.5);

– Special requirements for toys in food (6.2.6);

To improve the enforcement and efficiency of the Directive:

– Changes to the technical file as regards information on chemicals (6.2.7).

– Changes to the CE marking and traceability information (6.2.8);

– Changes to the conformity assessment procedures (6.2.9);

6.2.1. Chemical requirements

Option 1: no change scenario or non -regulatory approach

The first option to consider is to make no changes to the current requirements on chemicals in toys. This means that toys have to respect the general chemical legislation, including REACH, as well as the specific provisions of the current toys Directive, which include in particular the limit values for 8 elements specified in the Directive.

A non regulatory approach would include recommendations to the manufacturers on the use of certain hazardous substances in toys, such as CMRs and fragrances.

Option 2: Regulatory approach

The Second option would be to change the current rules. Within this option various approaches could be envisaged:

Approach 1: Status quo + ban of allergenic fragrances

This approach is based on the principle of respect of the general chemicals legislation, including REACH, and contains a new provision for allergenic substances in line with the Cosmetics Directive (ban/labelling requirement) as well as updated limit values for elements.

Approach 2: Status quo + ban of allergenic fragrances and ban of all CMR's Cat.1 & 2 unless authorised under REACH

This approach takes over the principle of respect of the general chemicals legislation, including REACH, contains a provision for allergenic substances and fragrances in line with the Cosmetics Directive (ban/labelling requirement), as well as a ban on the use of CMR

substances (categories 1 and 2) unless authorised by the procedure foreseen in the REACH Regulation. The limit values for elements would also be updated.

Approach 3: Status quo + ban of allergenic substances and ban of all CMR's Cat. 1 & 2 & 3, unless authorised by dedicated comitology procedure.

This third approach takes over the principle of respect of the general chemicals legislation, including REACH, includes a provision for banning CMR substances (categories 1, 2 and 3) unless evaluated by a Scientific Committee and authorised by the comitology procedure. In addition, it bans substances classified as allergens according to Directive 67/548/EEC. This special regime for CMRs foreseen in the toys Directive would continue to be applied even when the REACH regime becomes fully operational. The limit values for elements would also be updated.

6.2.2. Warnings

Option 1: No changes in the current provisions and non regulatory approach

The option of no change scenario would keep the current rules of the Directive which lay down that toys must be accompanied by clearly legible warnings in order to reduce inherent risks of their use. The Directive also sets out the warnings and indications to be given for certain categories of toys. This list of specific warnings is completed by the standard EN 71.

A non regulatory approach would consist in issuing non binding recommendations to the distributors on the visibility of warnings at the point of sale.

Option 2: Regulatory Approach: all safety information visible at the point of sale

A stringent regulatory approach would consist in requiring that *all information required for safe use shall be readily visible, clearly legible and conspicuously displayed at the point of sale.*

Option 3: Regulatory Approach: minimum and maximum ages displayed at the point of sale; appropriate user limitations to accompany the toy

A less stringent regulatory approach would limit the requirement of displaying warnings at the point of sale to warnings specifying minimum and maximum ages for users.

In addition to the rules on warning to be displayed at the point of sale, it has been proposed to complement the current general provisions of the Directive on warnings, which lay down that toys must be accompanied by clearly legible warnings in order to reduce inherent risks in their use. It has in particular been suggested to require that warnings specify, where appropriate for safe use, user limitations, such as minimum and maximum ages or ability of the user of toys or maximum or minimum weight of the users as well as the need to ensure that the toy is used under adult supervision

6.2.3. Choking risk

Option 1: No change to the current requirements

No change to the current requirements means that choking risk, that is the risk of inhalation of small parts is covered for toys intended for children up to 36 months.

Option 2: Regulatory approach

A stringent regulatory option would consist in changing the directive so that the risk of choking would be covered for all toys for children up to 60 months (instead of the current limit of 36 months) and toys intended for children of all age categories, if the toy is intended, likely or enticing to be put in the mouth

Option 3: Regulatory approach

This option would involve changing the Directive so that the risk of choking would be extended to choking risk requirements to toys which are intended to be put in the mouth, such as toys instruments.

6.2.4. Suffocation

Option 1: No change to the current rules or a non regulatory approach

No change to the current requirements would mean that the suffocation risk is covered for all toys and packaging of toys, when suffocation is commonly understood as an external airway obstruction external to the mouth and nose.

The non-regulatory approach could consist in clarifying the concept of "suffocation" in a guidance document.

Option 2 Regulatory Approach

A strict regulatory approach would consist in adding a definition for suffocation in the Directive which would read "Suffocation means the result of airway obstruction external to the mouth and nose, or internal airway obstruction by closing off the flow of air also from the mouth and nose by objects being wedged in the mouth or pharynx". In addition to this, the rules on suffocation in Annex II would be left unchanged. This would mean that not only all toys but also their packaging should not present any risk of internal airway obstruction.

Option 3 Regulatory Approach

A less stringent approach for changes as regards the suffocation risk consists in covering the risk of internal airway obstruction only for the toy itself.

6.2.5. Scope of the general safety requirement

Option 1: No change in the current rules or non regulatory approach

If no changes are introduced, the general safety requirement would continue to read: *the users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.*

Option 2: Non-regulatory Approach

A non regulatory approach would consist in issuing a non binding guidance document to clarify the exact meaning of this requirement.

Option 3 Regulatory Approach: clarifying the definition in the Directive

A regulatory approach would consist in inserting a clear definition into the legal text.

6.2.6. Toys in food

Option 1: No change in the current requirements

If no changes were introduced to the current Directive, this means these products are covered by the same requirements on choking hazard and warnings as other toys, and there would be no specific provisions in the Directive addressing the risk arising from the fact that the toy and food product are associated.

Option 2: Non-regulatory Approach

A non-regulatory approach would consist in issuing non binding guidance documents or recommendations to industry addressing the risks presented by this special category of products.

Option 3: Regulatory approach: separate packaging and prohibition of toys melted into food items

An adequate set of mandatory requirements could include the following:

- the toy should always be in a separate packaging;
- the packaging/capsule should not present any choking hazard and should, therefore, pass the small parts cylinder test;
- prohibition of products consisting of a toy firmly attached to a food product at the moment of consumption, in a way that the food product needs to be consumed in order to get direct access to the toy;
- an explicit warning “adult supervision recommended”.

6.2.7. Information on chemicals in the technical file

Option 1: No change scenario or non regulatory approach

The first option is to make no changes to the provisions on the technical file. This means that there is no specific obligation to include information on chemicals used in toys in the technical file to be available to the market surveillance authorities although there is a general obligation to include a detailed description in the technical file. The suppliers of toys are also obliged under the chemicals legislation to provide a safety data sheet on the chemicals they supply to downstream users.

A non regulatory approach would include a guidance or recommendation on the information on chemicals to be included in the technical file.

Option 2: Regulatory approach:

The second option would consist in introducing provisions in the Directive as regards information on chemicals in the technical file. Within this option different approaches may be envisaged:

Approach 1

It could be envisaged to foresee an obligation to include in the technical file a detailed description of the design and manufacture, including the safety data sheets on chemicals used to be obtained from chemical suppliers.

Approach 2

An another possibility would be to foresee an obligation to include in the technical file a detailed description of the design and manufacture, including a list of components and materials used in toys as well as the safety data sheets on chemicals used to be obtained from chemical suppliers.

Approach 3

The most stringent requirement would consist in an obligation to include in the technical file a detailed description of the design and manufacture, including substances contained in the toy, as well as the amount of the individual substances and the relevant Safety data sheets on chemicals to be obtained from chemical suppliers.

6.2.8. Affixing of the CE-marking

Option 1: no change scenario or non-regulatory approach

The first option to consider is to make no changes to the current requirements which require that the CE-marking be affixed either on the toy or on the packaging and in case of small toys also on a label or leaflet.

Using non regulatory instruments such as guidelines or recommendations could also be envisaged to give better visibility to the CE-marking on a voluntary basis.

Option 2 Regulatory approach: affixing the CE-marking both on the toy and on the packaging

During the discussions in the Expert Group on Toys safety it has been proposed that the CE-marking should always be affixed both on the toy and on the packaging. However, the exception for small toys would remain.

Option 3 Regulatory approach: affixing the CE-marking on the toy or on the packaging + always on the packaging if not visible from outside (a transparent) packaging

A less stringent approach would be to require that the CE-marking should, in principle, be affixed on the toy or on the packaging, as the current Directive foresees. In addition, it is required that if the CE-marking it is not visible from outside the (transparent) packaging, it should be always fixed at least on the packaging.

6.2.9. Conformity assessment procedures

As regards conformity assessment procedures are concerned, two changes could be envisaged: a) introducing an explicit obligation for the manufacturer to carry out safety assessment; b) mandatory third party verification for certain types of products.

a) Safety assessments (hazard/risk analysis)

Option 1: No change in the current requirements

If the current rules are left unchanged, there is no specific mention of an obligation to carry out a hazard/risk analysis in the Directive.

Option 2: Non-regulatory approach, such as guidance documents/recommendations

This option would consist in issuing non binding guidance documents or recommendations to the industry on the safety assessments that should be carried out.

Option 3: Regulatory approach: explicit obligation to carry out a hazard analysis and to keep it in the technical file

The Regulatory approach would consist in requiring the manufacturers to carry out an assessment of the hazards that the toy may present before it is placed on the market and to include the assessment in the technical file.

b) Mandatory third party verification for certain types of toys

Option 1: No change in the current requirements

No change to the current rules means that the manufacturer can carry out the conformity assessment by his own means or by any test laboratory competent to carry out testing, and a verification of the toy by third party is not mandatory unless harmonised standards have not been applied.

Option 2: Non regulatory approach

A non regulatory approach could consist in issuing non binding guidance or recommendations on the use of the third party recommendation.

Option 3: Regulatory approach

A regulatory approach would consist in laying down mandatory third party verification for all or certain types of toys or in any case where no harmonised standards covering all the safety aspects of the toy exist.

6.3. Consistency of the objectives with other EU policies and horizontal objectives, such as better regulation and Lisbon strategy or respect for fundamental rights

The objectives pursued by the revision are in line with the EU strategy for jobs and growth. The toys industry is stable and competitive. While a number of elements of the revision will entail higher compliance costs, they will not endanger industry's competitiveness due to the

high likelihood that increased costs will be passed through the end user. Job losses are considered to be minimal and most probably will occur outside the EU.

The objectives also fit into the Community policy of better regulation and simplification. The overall goal is to improve the quality and efficiency of the toys safety regulations and to simplify the current legislation for both economic operators and market surveillance authorities.

Aspects of fundamental rights are not concerned by this proposal.

7. ANALYSIS OF THE IMPACTS

7.1. Identifying impacts

In this section, the general expected impacts from the revision are first presented as they result from the impact assessment studies that were carried out, before analysing in detail the costs and benefits of the main changes and different possible options.

7.1.1. General economic impact

In general terms, the envisaged modifications to the Directive are considered to improve its efficiency, its functioning and reliability as well as its transparency, thus contributing to benefit all stakeholders.

The proposed modifications are expected to have a considerable positive impact on the activities of the authorities of the Member States because the level of ambiguity as to how to apply various provisions would be removed. Many of the measures are aimed at clarifying responsibilities and definitions and making information more accessible. These should make authorities´ duties easier and reduce costs. The simplification of the safeguard procedure in accordance with the horizontal revision of the New Approach should also reduce administrative costs for the Commission and the national administrations.

Manufacturers and conformity assessment bodies would benefit from greater efficiency, reliability and transparency in the operation of the Directive. Industry should benefit from the clarification of the definitions, scope and responsibilities; these clarifications are likely to reduce legal uncertainty, helping to reduce costs in the future, since in the future legal issues will be solved more easily and quickly, or may not arise in the first place.

Furthermore, the general impact assessment study concluded that setting out in detail the power and obligations of the market surveillance authorities under the proposal could have a significant positive impact for manufacturers, in particular by reducing the level of counterfeiting that currently takes place within EU market.

As far as the analysis of the specific modifications proposed during the discussions are concerned, many of them are considered by those consulted within the framework of the impact assessment study to provide useful clarification to the existing Toys Safety Directive without any major impact on industry costs. The clarifications which do not incur costs include, in particular the proposals to clarify the definitions and scope of the Directive as well as proposals to introduce into the Directive essential safety requirements on noise and speed limit as well as on hazards presented by laser and activity toy. As explained previously, toy standards already contain technical requirements on these hazards, and introducing an

essential safety requirement in the directive will not have at least any immediate effect on these technical requirements to which manufacturers already are adhering.

However, as explained under section 6.2 envisaged changes as regards the following issues are susceptible to have an impact on industry costs:

- 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.

Therefore, these questions are analysed more in depth as regards the impacts of different options that can be envisaged for each problem identified.

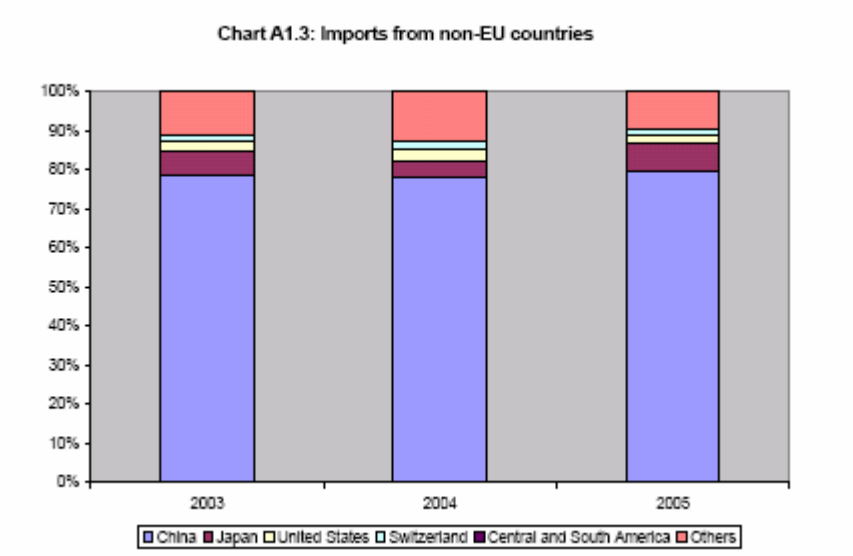
There might be additional costs to the administrations as a result of the provisions reinforcing Member States´ the market surveillance obligations, but according to the authorities themselves they are likely to be minimal since many of the obligations are already covered by the General Product Safety Directive. The new requirements on chemicals may also result in higher costs of monitoring and enforcement for the national authorities; these costs are likely to be manageable and part of the general strengthening of the monitoring of chemicals due to the EU framework legislation (REACH) in this area.

7.1.2. Indirect costs, Impact on trade and competitiveness

In the framework of the impact assessment study, industry was asked to comment on the impact of the proposed modifications for international trade and competitiveness of the EU toys sector. Views on these impacts differed. Some industry respondents thought that they would increase costs, making EU industry less competitive. Others were of the opinion that the increased cost of meeting safety requirements would discourage imports of low cost and low quality toys into the EU which will benefit consumers in the form of increased safety. Some companies also felt that the clarification of which toys needed to comply with the directive by the proposed modifications would improve the competitiveness of high quality and high value toy manufacturers.

It is plausible to draw the conclusion that overall market competitiveness should not be affected since EU and non EU manufacturers need to adhere to the same standards if they wish to sell their products in the EU. However, it cannot be excluded that that those manufacturers producing toys in the EU and selling some overseas and some domestically might have some contained cost increase in foreign markets as it is unlikely that they are able to develop two separate production chains.

When considering the impact of the revision, it should be noted that a major part of the toys sold in the EU are imported[14]: an estimated range of €6-9bn of the toys sold within the EU are imported from outside the EU, the overall turnover of the toy industry in Europe 2005 (the last year for which data are available) being roughly €13 billion.



Since Chinese imports of toys represent by far a greatest proportion of all imports into the EU, Chinese manufacturers were also asked to comment on the proposed modifications. Their views can be summarised as follows: Costs may result to them from the envisaged modifications, but no major concerns were expressed over the impacts of the proposal for their industry. It was pointed out that manufacturers would adjust their operational strategy to develop new products and thus remain competitive. Some modifications were also identified as having potential benefits/positive implications by improving the quality of exports and their international competitiveness. The higher degree of responsibility placed on the economic operators under the revision would eliminate manufacturers that do not maintain similar standards.

7.1.3. Social impacts

The main social benefits of the revision are likely to be experienced by consumers, namely by children. Strengthening of essential safety requirements is likely to result in significant public health and safety benefits.

As regards safety benefits, overall, consumer organisations and authorities responsible for implementing the Directive and market surveillance authorities agreed that most of the proposed modifications will give rise to significant benefits through reduction in the number of toy-related accidents. Some industry consultees pointed out that in order to result in

[14] Toys Industries of Europe, 2006

significant safety benefits, the legislative modifications need to be combined with a more efficient enforcement, which is one of the objectives of the proposed modifications.

As far as the positive health impacts are concerned, the most important benefits should arise as a result of the modifications to the chemical safety requirements. The prohibition/limitation of the use of certain harmful chemicals in toys would reduce the migration of chemicals in children from toys. This in turn would reduce the number of children developing diseases and other chemical-related harmful medium and long term effects (i.e effects on the reproductive system).

The positive social/health impacts can only be estimated, not precisely calculated. Toy related accidents are not uniformly and systematically reported in the Member States or at Community level. However, it is important to note that even a limited decrease in toy related accidents represents a significant social benefit in public health terms.

No significant impacts on employment can be foreseen according to the present knowledge of development trends. According to industry there might be some job losses as regards the new rules for chemicals in toys in a range between 1200 to 3000 jobs from 2008-2051.

7.1.4. Environmental impacts

Environmental protection per se is not within the objectives of the Directive. No direct environmental impacts are thus expected from this proposal.

The only modifications which could potentially result in (indirect) environmental impacts are the proposed restrictions of the use of certain chemicals in toys. These impacts would be beneficial on environment if any since the new limits for or ban of certain dangerous chemicals would limit the amount of these chemicals which could potentially enter the environment[15].

7.2. Analysis of the impacts of the main issues at stake

7.2.1. The method followed in the analysis

In the assessment of the costs and benefits, the following factors have been taken into account, since they determine the chosen approach:

– the complexity of the structure of the toy market (see Annex I) makes it impossible to develop meaningful aggregate estimates of the likely costs of the existing Toys Safety Directive, and of the proposed modifications to it, on the sector as a whole;

– companies were unable to provide the data required to undertake a quantitative assessment of costs and benefits or sometimes they were reluctant to do so; instead, the conclusions must be more quantitative in many cases;

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15 The impact assessment study on the revision of the chemical requirements did not identity any specific environmental benefits (see page 26 of that study). This is due primarily to two reasons. In the first instance, the disposal of toys is already governed by a number of existing Directives, such as WEEE, ROHS; and Packaging and Packaging waste and the Batteries Directive. Further, the issue of general issue of exposure of chemicals through the environment is usually much less than that of specific exposure gained through playing and everyday of the toy.

– where companies did provide data, in several instances they were inconsistent, as answers varied between their domestic, European and in some cases world-wide operations.

For the above reasons, the analysis of the costs of the revision have been approached through case studies performed within the framework of the general impact assessment study, which were, as far as possible, developed to be representative of the different types of companies operating within the sector. These are a large multinational company, a medium manufacturer, a SME company and an importer. The characteristics of the case study companies and the assumptions used in the analysis are presented in the Annex 2 attached to this Report.

The chemicals part of the revision (including changes to the technical file as regards information on chemicals used in toys) was considered to require a deeper analysis in the form of a specific study, due to the particular complexity and sensitivity of this area of the revision. The approach and method in this analysis was somewhat different: three different scenarios defined by different levels of stringency were presented for analysis.

7.2.2. Main issues

As indicated above in 7.1.1, the main issues in the revision from the point of view of cost impact are the following and these issues will be analysed in more detail in the following subsections:

- To enhance safety requirements for toys:

– New provisions on the chemical requirements (7.2.3);

– More stringent requirements on warnings (7.2.4);

– Changes to the requirements concerning the choking risk (7.2.5);

– Clarifying the suffocation risk (7.2.6);

– Clarifying the general requirement of safety (7.2.7);

– Special requirements for toys in food (7.2.8);

- To improve the enforcement and efficiency of the Directive

– Changes to the technical file as regards information on chemicals (7.2.9);

– Changes to the CE marking and traceability information (7.2.10);

– Changes to the conformity assessment procedures (7.2.11).

– In section 7.2.12 a summary of the administrative costs of the various proposals is presented.

7.2.3. Chemical requirements

Option 1: No change scenario or non regulatory approach

The options of no change to the current requirements or a non regulatory approach have been disregarded at an early stage because of the following reasons: the level of risk is generally

high, and the scientific knowledge accumulated over the last decades has permitted to discover new medium and long term risks to health due to chemical substances which need to be taken into account in legally binding requirements to ensure effective protection of children. As a consequence, the basic option retained to address this sensitive area is a regulatory one, and the impact analysis relates to the different levels of stringency of the regulatory option.

Option 2: Regulatory Approach

The revision of the chemical requirements was the object of a separate impact assessment study carried out by an outside consultant. The following subsections present the cost-benefit analysis made by the consultant on three options for chemical requirements. All the options foresee new limit values for certain chemical substances that are accessible to children during use (on the basis of a previous study carried out by an independent consultant referred to above in chapter 1). Besides this, their main content is the following:

Approach 1 Status quo + ban of allergenic fragrances

This approach is based on the principle of respect of the general chemicals legislation, including REACH, and contains a new provision for allergenic substances in line with the Cosmetics Directive (ban / labelling requirement).

Approach 2 Status quo + ban of allergenic fragrances and ban of all CMR's Cat.1 & 2 unless authorised under REACH

This approach takes over the principle of respect of the general chemicals legislation, including REACH and contains a provision for allergenic substances and fragrances in line with the Cosmetics Directive (ban/labelling requirement), as well as a ban on the use of CMR substances (categories 1 and 2) unless authorised by the procedure foreseen in the REACH Regulation.

Approach 3 Status quo + ban of allergenic substances and ban of all CMR's Cat. 1 & 2 & 3, unless authorised by dedicated comitology procedure

This third approach takes over the principle of respect of the general chemicals legislation, including REACH, includes a provision for banning CMR substances (categories 1, 2 and 3) unless evaluated by a Scientific Committee and authorised by the comitology procedure. In addition, it bans substances classified as allergens according to Directive 67/548/EEC. This special regime for CMRs foreseen in the toys Directive would continue to be applied when the REACH regime becomes fully operational.

The study analysed the impact of each proposed regulatory approach against the baseline counterfactual of "do-nothing". In order to calculate the costs stemming from the options the consultant relied on the results of a questionnaire addressed to toy manufacturers, toy importers and retailers, consumer and health groups and other bodies including chemical testing laboratories and environmental groups. Questionnaires contained common questins and also a number of questions specific to particular groups, i.e. manufacturers were asked about the impacts in the manufacturing process, whereas health agencies where asked about health impacts. In total the questionnaire accessed over 500 stakeholders in the toys industry and elicited around 80 useful replies The period of analysis is between 2008 and 2051, which

is the last year for which Eurostat population projections are available. The costs were calculated using the standard discount rate of 4 percent.

The table below which is based on the stakeholder consultation summarises the overall costs and benefits associated with each approach relative to the counterfactual of "do nothing". The table presents the central estimates that were obtained. They should not be taken as a precise indication of costs. In particular, it is to be noted that the main source of data was a stakeholder questionnaire. Thus responses are stakeholders' interpretation of the cost impacts of the proposed options and may not be fully reliable because of the inherent stakeholder's interest in the assessment.

Table 1: Costs and benefits of the three proposed revision approaches to the TSD (millions €) 2008 – 2051

	Approach 1	Approach 2	Approach 3
Costs			
NPV financial costs	5,036	13,490	13,744
Of which			
Administrative	488	1,306	1,331
Distributional	2,227	5,966	6,078
Manufacturing	2,321	6,217	6,334
Comitology*			3
Other economic	Enforcement and compliance costs	Enforcement and compliance costs	Enforcement and compliance costs
	Costs of delay to innovation and in authorisation	Costs of delay to innovation and in authorisation	Costs of delay to innovation and in authorisation
	Administrative burden	Administrative burden	Administrative burden
Other social	Risk from substitutes	Risk from substitutes	Risk from substitutes
	1,200 jobs lost	3,000 jobs lost	3,300 jobs lost
Other environmental	None	None	None
Benefits			
NPV financial benefits	12,447	12,787	12,855
Other economic			
Other social	Reduction in burden on health systems	Reduction in burden on health systems	Reduction in burden on health systems
	Reduction in productivity losses	Reduction in productivity losses	Reduction in productivity losses
Other environmental	None	None	None

To calculate the *manufacturing and distribution cost*s the consultant calculated an average percent cost increase of each of these cost categories for each of the different options. Then an average ratio was calculated between turnover and operating costs in the toys industry from the annual reports of companies operating in the European market. The last step needed to estimate costs is a measure of overall turnover to which the calculated ratio has to be applied (According to the Toy Industries of Europe the overall turnover of the toy industry in Europe 2005 was roughly €13 billion). With these data a stream of costs from 2008 to 2051 were calculated assuming no adjustment will take place in the toy industry i.e. that the increase in ongoing costs is permanent.

It has to be pointed out that the *cost estimations* are subject to a considerable number of uncertainties. The level of future costs will not be known for certain. In particular, it is likely that the costs have been overestimated by the stakeholders. The costs have been calculated

asking European toys manufacturers to estimate the annual costs for the different options in the range of 0-5%, 6 - 10%, 11-20% and more than 20%. This calculation is, therefore, based on estimates rather than actual cost data.

Based on the information provided by industry consulted the *manufacturing costs* have been allocated to the following processes:

What percentage of your total manufacturing costs are allocated to the following processes				
Moulding	Sewing	Glueing	Finishing	Other
23%	13%	8%	19%	37%

"Other" costs include, in particular, costs of testing; they do not include the cost of the manufacturing process itself. It has to be taken into consideration that a distinction between the use of CMR in products which are accessible to children and those which are not could not be calculated due to the variety of toys. It could, however, be estimated that manufacturing costs would be lower than the estimated ones if a ban of CMR is limited to toys and their components accessible to children. One can assume that industry has also included the costs for a substitution of CMR.

It is also to be noted that the consultant assumed that the increase in manufacturing costs is permanent and there wouldn't be any adjustment from the manufacturers at all, which is very unlikely to be the case. Manufacturers are supposed to gradually develop new products and/or adjust the existing ones. It also can be assumed that the costs for replacing certain substances will decrease over time due to economies of scale. In addition, testing costs are likely to be less important than assumed because companies will only test their articles for a limited number of substances, and not for all CMRs of which hundreds are very unlikely to occur in toys at all.

Particular uncertainties are related to the amount of *"distributional"* costs estimated by the economic operators at around € 6 billion. Based on the questionnaire the consultant has estimated nearly similar costs for manufacturing and distribution. It is not completely clear how the proposed changes to the chemical requirements which indeed render manufacturing more costly have the same effects on costs related to the distribution. One explanation could be that in general distributional costs are a much larger share of total costs than manufacturing costs. It is also likely that the distributional costs contain an element of manufacturing costs as some EU-importers might have included a possible increase in manufacturing costs in third countries in their estimates. In general these assumptions lead to the conclusion that the distributional costs seem to some extent overestimated.

The *administrative costs* were calculated using the standard cost model defined in the Commissions impact assessment guidelines which assesses administrative costs on the basis of the average of the required action multiplied by the total number of actions performed during a given year. The administrative requirements relate to the costs of having to find out more information about the products concerned, fill in forms related to testing and other regulations

Administrative costs have been calculated on the assumption that the total European toys industry employs approximately 98.000 employees, of which 45.000 are not involved in

manufacturing. It has thus been assumed that 5000 of these are directly involved in administrative activities. The average labour cost per hour is given as 21.22€ based on information from Eurostat. The administrative burden has then be calculated over the period 2008-2051 using the standard discount rate of 4%. The breakdown of the costs is the following:

Table 5.2: Administrative burden of each approach (€m)

	Approach 1	Approach 2	Approach 3
Administrative	488	1,306	1,331
Additional time (hours)	226	605	616

Source: Europe Economics calculations.

It has to be noted this calculation of administrative costs has to be handled with care with regard to the timing of costs. The administrative burden of new legislation can be expected to fall over time with probably a strong emphasis on the first years of implementation. It is therefore to a certain extent questionable that each of the 5000 employees in charge of administrative activities will be spending almost six 40 hours working weeks or 15 40 hours working weeks in 44 years to administer the new legislation.

Table 2 presents the break down of the overall result by company size.

Table 2: Change in ongoing costs of the three proposed revision approaches to the TSD (millions €) 2008 – 2051

	Approach 1	Approach 2	Approach 3
Manufacturers	**2.5%**	**5.2%**	**6.0%**
Of which			
Multinational	1.9%	4.1%	4.8%
SME	2.5%	5.1%	7.6%
Importers	**2.8%**	**5.6%**	**6.0%**
Of which			
Multinational	1.4%	3.3%	4.0%
SME	2.9%	5.7%	6.0%

As it could be expected, the incremental costs to SMEs are larger that those of multinationals. The next table shows the possible price increases that might be associated with each approach, based on central estimate calculations

Table 3: The impact on prices of each approach

	Expected price change		
	Approach 1	Approach 2	Approach 3
All companies	2.2%	4.4%	4.9%
Multinational	1.7%	3.8%	4.5%
SME	2.2%	4.5%	5.0%

As the above table 1 shows, no *environmental costs or benefits* have been identified. This is primarily for two reasons. In the first instance, the disposal of toys is already governed by a number of existing Directives such as WEEE, ROHS, and Packaging and Packaging Waste. Further, the issue of general exposure of chemicals through the environment is usually much less

than that of specific exposure gained through playing and everyday use of the toy.

Thus, the main *costs and benefits* relate to the *economic and social* (in particular, health) categories.

As regards health benefits, the health impacts were quantified in terms of Disability Adjusted Life Years (DALYs) saved by each option. The consultant divided the number of DALYs saved by the total costs increase associated with the various approaches.

The approach was similar to that used in Life Cycle Impact Assessment (LCIA), which according to the Commission guidelines on Impact assessment can be defined as "the process of evaluating the effects that a product has on the environment over the entire period of its life". More precisely LCIA entails the comparison of products according to their total estimated environmental impact, summed over all chemical emissions and activities associated with a product at all stages in its life cycle (from raw material acquisition to final disposal). The study looked into one particular aspect of LCIA, i.e. the health impacts associated to chemicals. However, the LCIA approach had to be modified to take into account the fact that the study was not dealing with the emissions of polluting chemicals in the environment but with the chemical content of toys that are not meant to be released. Therefore the LCIA approach was modified to obtain an intake fraction that can be applicable to children playing with toys.[16]

As in the case of costs, the benefits were calculated in 2007 prices assuming that the different options would be instantaneously implemented at the end of 2007. The benefits were discounted at 4 percent to be consistent with the discounting of costs.

The Table below presents the results of some scenarios concerning benefits:

[16] More details of the methodology can be found in section 5 of the study.

Table 5.9: Benefits attributable to the different approaches under different scenarios
Total value over the period 2008 – 2051 (2007 prices)

Scenario Name:		Lowest	Highest	High DALY	Low DALY high hours	Median hours	High ingestion	Middle
Input Data:								
DALY	Value of DALY (€)	45000	90000	90000	45000	67500	45000	67500
	DALY Irreversible	6.7	12.8	12.8	6.7	12.8	12.8	9.75
	DALY Probably Irreversible	0.67	1.28	1.28	0.67	1.28	1.28	0.975
	DALY Reversible	0.067	0.128	0.128	0.067	0.128	0.128	0.0975
Ingestion	Hours played per day	1	4.5	1	4	2	1	2.75
	Amount ingested per hour (mg)	8	20	8	8	8	20	14
Incremental Benefits (Millions of €)								
Risk-based approach		1,185	50,930	4,527	4,739	6,791	5,659	12,447
Combined hazard/risk-based approach		32	1,392	123	130	185	155	340
Hazard/risk-based approach with authorisation by Comitology procedure		6	278	25	26	37	31	68

Source: Europe Economics calculations

These scenarios show that the variation of benefits between scenarios is large: in the lowest case scenario with a low monetary value of a DALY, low ingestion and low damages associated to the various chemicals the overall benefits of approach 1 would be €1.2 billion. In the highest case scenario of high ingestion, high damages associated with the chemicals and high value of a DALY this figure would increase to €50.9 billion.
In the scenario labelled as "middle" comparing the costs and benefits, where all these values have been calculated as the average between the highest and the lowest scenario the benefits of the approach 1 are €12.4 billion. The variation is evident even for the two remaining approaches: the incremental benefits associated with the combined hazard/risk based approach vary from a minimum of €32 million to a maximum of €1.4 billion (with €340 million as the middle estimate), while for approach 3 the incremental benefits vary from €6 million to €278 million (with €68 million as the middle estimate).The incremental benefits associated with approach 2 and 3 with respect to the benefits of approach 1 alone are always very small.

The consultant also calculated the cost per DALY saved associated with each approach by dividing the number of DALYs saved by the total costs increase associated with the various approaches. The resulting figure using the central estimates is €27,000, €71,000 and €72,000 for approach 1, 2 and 3 respectively. It should be noted, however, that a value of €71,000 and €72,000 is not necessarily high enough to be higher than a reasonable reference DALY.

The estimated benefits are likely to represent an underestimate of the true benefits for the following reasons:

- the reduction in the burden on the health systems of the various Member States is not taken into account. It could not be calculated, although it would be reasonable to expect benefits in terms of disease and accident prevention,

- the productivity loss due to children falling ill is not taken into account (either regarding children themselves, if they fall ill when they are adults, or their parents if children fall ill when still children)

Choice of the preferred option

Before elaborating on the reasoning behind the choice of the preferred option, it is useful to explain the cost estimates of the REACH Impact Assessment since both REACH and the Toys Directive contain rules for chemicals in toys. It is namely important to understand that the cost estimates of the Toys directive proposal are not directly comparable with those of the REACH Impact Assessment.

The impact assessment of the Toys directive includes *inter alia* costs directly resulting from the banning of the use of certain chemical substances from usage in toys. In contrast, the impact assessment of the REACH proposals focussed on the costs of the registration procedure for chemical substances estimated between € 2.8 – 5.2 billion. Substances were assumed to be withdrawn purely for commercial reasons, notably avoiding the payment of testing and registration costs. The further work on the REACH impact assessment does, however, provide some evidence that the costs of more widespread withdrawal of substances would have significantly higher cost effects.

The REACH impact assessment outlined the following potential major costs of REACH:

1. Costs of registration and supply chain management

2. Costs resulting from the potential withdrawal of substances as part of the registration process

3. Costs resulting from the potential withdrawal of substances as part of the authorisation process

4. Other costs resulting from impacts on innovation etc.

The €2.8-5.2 billion estimate of costs contained in the REACH impact assessment was based solely on the likely costs of the registration phase of REACH[17] (i.e. categories 1 and 2 above only). It was not found to be possible to quantify the potential costs on innovation etc. (category 4).

The potential costs of the authorisation phase of REACH (category 3) were not considered in the impact assessment. It was assumed that the authorisation process would always be accompanied by an individual assessment of the net benefits of restricting the usage of substances. Because of this, provided the authorisation procedures were carried out correctly, the net social benefits could thus always be assumed to be positive (or at least non-negative). These costs could potentially be an order of magnitude higher than the registration costs.

Following the adoption of the REACH regulation by the Commission, considerable further Impact Assessment work was carried out in conjunction with industry. This assessment largely focussed on the costs of potential withdrawal from registration (category 2 above). However, the studies did indicate that "if a substantial withdrawal of substances occurred the extent and costs of reformulation and re-engineering could be significant". In particular, the loss of only a few critical substances might result in large scale reformulation. If this were to happen, reformulation and re-engineering costs would require time-consuming testing and approval procedures ad may require fundamental changes at product- or process-level.[18]

Approach 1: As regards the choice of the preferred option for the revision of the chemical requirements of the Toys Directive, approach 1 leads to a scenario where the benefits are considered higher than the costs according to the calculations of the consultant. At a cost of a net present value (NPV) of €5 billion, one would gain a financial benefit of NPV €12.5 billion, whereas the costs of the other two approaches (€13.4 billion for approach 2 and 13.7 for approach 3) would appear to be higher than the benefits.

However, as already pointed out above the cost estimations are subject to a number of uncertainties and have been likely overestimated by the stakeholders.

It is also probable that the benefits have been underestimated, as explained above, because the reduction in the burden on the health systems of the Member States and productivity effects have not been taken into account. Moreover, science so far has not been able to identify without doubt the actual effects of the use of CMR substances in toys. The actual amount of potential cost savings or additional positive health effects therefore remains unknown.

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[17] Impact Assessment of the REACH Proposals (see table 5 on page 19) http://ec.europa.eu/enterprise/reach/docs/reach/eia-sec-2003_1171.pdf

[18] See Commission "Note on the Studies Undertaken in the Framework of the Memorandum of Understanding on Further Work concerning the Impact Assessment of REACH"

As noted above, toys are not exempted from REACH. The REACH obligations will apply to toys that are substances, preparations or articles according to the definition in Art.3. Member States and consumer organisations did not consider REACH as being fully adequate to address the problem of chemicals in toys.

It will take time for the REACH system to become fully operational. According to REACH Art. 23 (1a) CMR substances must be registered by 30 November 2010.The authorisation of substances of high concern including CMRs under REACH will take probably further years and only a limited number of substances can be included in the system every year. The authorisation process will only become fully operational once the first SVHC ("substances of very high concern") will be listed in Annex XIV. Accordingly with the prioritisation criteria set up in Art. 58(3) it difficult to envisage when the substances found to be of concern for toys could be picked up. In fact, it will not be possible to deal with all CMRs in a reasonable amount of time, compared to the expectations expressed in the framework of the Directive's revision, and a selection of those substances that are most likely to occur in toys would have to be made first.

It would then be necessary also that these substances would be given the highest priority under REACH to be included first. However, in the REACH authorisation process priority is given to persistent, bioaccumulative and toxic (PBT) substances, because these are less well regulated than CMRs. It is therefore unlikely that general support would be given to the prioritisation of CMRs possibly used in toys all the more so since there is limited knowledge on the extent of the use of CMRs and associated risks in toys generally.

It should also be noted that REACH applies a different regime for substances on their own or in preparations and substances in articles. Whenever a substance or preparation 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 articles, including toys, normally do not have to be registered. Nevertheless, CMRs included in the "candidate" – list for authorisation have to notified to the REACH Agency.

According to the strict approach favoured by most Member States and consumer organisations, measures based on hazard would be justified on certain dangerous chemicals in toys because they are used by children who are a particularly sensitive group of consumers.

Taking into account the uncertainties in the cost calculations and especially the need to ensure a high level of safety of children, it has been decided to disregard option 1 even if it would be the least costly for industry in accordance with the results of the impact assessment study.

Approach 2: It had been suggested under approach 2 described in the study to ban CMR 1 and 2 substances in toys unless authorised by the REACH system. As explained above, the authorisation of substances of high concern including CMRs under REACH will not start immediately. However, option 2 results in an immediate ban of CMR 1 and 2 substances in toys. The option mentions that CMR substances authorised by the procedure stated in REACH will still be allowed, but in practice, since authorisation under REACH will take probably several years and only a limited number of substances can be assessed per year, not many substances are likely to profit from this exemption. This would lead to a situation in which imported toys would be banned, but would not be covered by the REACH authorisation system. This scenario could lead to criticism from third countries and likely challenges in the WTO. This option therefore has been discarded.

Approach 3: Considering the particular vulnerability of children, which justifies a strict approach to the use of chemicals in toys, and the strong concerns expressed by the general public about the use of dangerous chemical substances in toys as recently amplified by the massive recalls of toys containing dangerous chemicals, the uncertainties and problems related to the other options considered, approach 3 has been retained in the proposal. This option will ensure that within a short timeframe no toys that contain hazardous CMR substances will be placed on the EU market any more, which is the only measure that can guarantee that children are not exposed to these substances in a WTO compatible manner.

In order to adopt a measure that is workable in practise, these substances will be banned if they are accessible to children and above a limit of 0.1 percent which is a well established limit in chemicals legislation, except for those substances for which another (lower) limit exists in chemicals legislation. A content of 0% for any given chemical would be quasi-impossible to achieve. This is because modern analytical methods can detect trace amounts of any substance practically everywhere (even food safety legislation makes allowances for traces of regulated substances). Thus for any prohibition or restriction of a chemical a limit value have to be set, which allows distinguishing between the deliberate additions of the chemical or its occurrence as an unwanted trace contaminant. 0.1% is the typical value to achieve no deliberate addition.

As regards costs and benefits, this change to the original option 3 submitted to impact assessment would not have effect to the analysis of benefits, since the benefits are based on the 0.1 per cent scenario and thus traces of CMRs are still present in toys when the consultant calculated the intake fraction of the various CMRs. This is the reason why it would make no difference for the number of QALYs saved under the "even more stringent" option.

7.2.4. Warnings

Option 1: No changes in the current provisions and non regulatory approach

If not changes were introduced to the current requirements, high level of safety of toys would not be guaranteed, since toys might not contain all warnings necessary for the safe use of the toy, and the warnings that are essential for the consumer at the moment of purchasing the toy would not be visible at the point of sale.

A non-regulatory approach, like issuing a guidance document or recommendation to industry could not be used efficiently to guarantee that all necessary warnings would accompany the toy or would be visible at the point of sale, because they would not change the current binding rules on warnings.

Option 2 Regulatory Approach: all safety information visible at the point of sale

During the discussions in the Expert Group, it has been proposed that safety information on toys should be already visible at the point of sale. It has been proposed that *all information required for safe use shall be readily visible, clearly legible and conspicuously displayed at the point of sale.*

However, during the discussions it has become clear that requiring *all* safety information to be visible at the point of sale would not be necessary and justified by safety reasons, since all this information would not necessary be relevant for the consumer at the moment of purchasing the toy. Furthermore, industry has indicated that the costs incurred by this requirement would

not be important. The requirement to display at the point of sale all information for safe use would create severe difficulties because this equates to an obligation to place the information in various languages on the outer packaging. This would result in a reduction in the number of languages used on a box and in some cases would result in single language packaging. Therefore, this proposal would make a toy specific toy a country or regions. Inventory would not be able to be transferred and sold around the EU. This would be very costly to the industry. Therefore, this option has been disregarded.

Option 3 Regulatory Approach: minimum and maximum ages displayed at the point of sale; appropriate user limitations should accompany the toy

Since requiring all safety information to be displayed at the point of sale was considered as a disproportionate requirement, other possibilities have been considered. During the Expert Group discussions, it was agreed to limit the requirement of displaying warnings at the point of sale to warnings specifying minimum and maximum ages for users. These warnings are the most important ones from the consumer's point of view to ensure that toy is used correctly under safe conditions.

In addition to the rules on warning to be displayed at the point of sale, it has been proposed to complement the current general provisions of the Directive on warnings, which lay down that toys must be accompanied by clearly legible warnings in order to reduce inherent risks in their use. It has in particular been suggested to require that warnings specify, where appropriate for safe use, user limitations, such as minimum and maximum ages or ability of the user of toys or maximum or minimum weight of the users as well as the need to ensure that the toy is used under adult supervision

These proposed modifications were submitted to the cost analysis. The costs arising from the modifications to the case study companies are presented in tables 1-3.

Table 1 Costs of Proposed Modifications to the warning requirements TSD to a Multinational Company

Proposed Modifications	**Costs(€)**		
	Low	**Medium**	**High**
Labelling (warnings)	700	1,400	3,500

Table 2: Costs of Proposed Modifications to the TSD for a SME Company

Proposed Modifications	**Costs (€)**		
	Low	**Medium**	**High**
Labelling (warnings)	18,750	37,500	93,750
Total	120,000	350,625	686,250

Table 3: Costs of Proposed Modifications to the TSD for a Medium-sized Manufacturer and for an Importer			
Proposed Modification	**Costs (€)**		
	Low	**Medium**	**High**
Medium Manufacturer			
Labelling (warnings)	137,500	275,000	687,500
Total	**357,500**	**825,000**	**1,787,500**
Importer			
Labelling (warnings)	31,000	62,000	155,000

Respondents from industry generally agreed that costs might increase due to the need to assess appropriate ages for each product and consequent changes in packaging. No information was provided on the costs of assessing appropriate ages for each toy from industry, therefore it was not possible to evaluate this cost.

The costs of modifying labelling and packaging in this manner are expected to be relatively low (see more about the administrative costs in section 7.2.12). This is because of the short life cycle of products and the rapid changes in marketing strategies that normally take place, which would ensure that designs accommodate changes quickly. As a result, it should be possible to incorporate the proposed age related labelling easily and with minimal cost, although some respondent companies expressed concern - but not any objective demonstration - that costs may be increased by up to 100%.

In view of the relatively low costs of these requirements and the expected benefits to the safety, these changes to the general warning requirements were retained[19].

7.2.5. Choking risk

Option 1: No change to the current requirements

Under the current directive, the choking risk, that is the risk of inhalation of small parts, is covered as regards toys intended for children under 36 months. The reason is that children below that age tend to put objects in their mouth, and after that age, the risk of choking is considerably reduced. However, the accidents involving choking can happen at other ages as well, especially with certain kind of toys (toys that are also put in the mouth by older children).

General information on choking related incidents is available within the scope of the IDB - EU Injury Database[20] - including a study involving 15 countries[21] and 4439 cases. The IDB is

[19] This conclusion seems reasonable and proportionate, despite the results of the public consultation (influenced by respondents close to the industry's views), which were not in favour of laying down these requirements.

[20] https://webgate.ec.europa.eu/idb/

a database set up in cooperation between the Commission and the Member States within the scope of public health policy, with a view to preventing leisure and home accidents in the EU.

From a regulatory standpoint, if the current rules were left unchanged, there would be no legal obligation to cover choking risk for certain situations where a real risk for children older than 36 months exists which would have a negative impact on safety of toys.

Option 2 Regulatory approach: choking risk covered for toys for children up to 60 months as well as for all toys intended, likely or enticing to be put in the mouth

In the Expert Group discussion it has been proposed to cover choking risk for all toys intended for children up to 60 months (instead of the current limit of 36 months) and/or to cover the choking risk for toys intended for children above 36 months if the toy is intended, likely, or enticing to be put in the mouth. This would mean that that these toys could not contain small parts that can be inhaled.

Industry has indicated that choking risk for toys intended for children up to 60 months would increase risk and hazard assessment costs, and more significantly it would result in many small toys being removed from the market. It would also make product development and research much more costly, because very few toys are currently intended solely for children between 36 and 60 months.

This kind of requirement would also incur administrative costs in the form of new labelling requirements, since the warning on toys containing small parts should be changed ("not suitable for children below 60 months" instead of the current "not suitable for children below 36 months") although these costs should not be significant because of the relatively short lifecycle of toy as indicated above as regards new warnings.

The costs to manufacturers of increased hazard and risk assessment following this proposed change costs would mirror the cost of EC-type examination for each time a product has to be sent to a testing or laboratory facility. Thus, they would amount between €500 to €2,000 per toy product for an SME. The costs of potential product withdrawal, and the impacts on research and development, are likely to be significantly higher but cannot be calculated at this stage.

The terms "likely" and "enticing" included in the proposal to cover the choking risk for toys "likely or enticing to be put in the mouth" were seen as problematic in the Expert Group discussions, since they are open to different interpretations by enforcement authorities and if they were included could, therefore, lead to distortions of the internal market. Industry has indicated that if these terms were included in the Directive, it could be crucial for determining liability for toy related accidents. For instance, younger children tend to open toys using their teeth, even when this was not the intention of the manufacturer. It was also indicated that this requirement does not take into account the role of parents in ensuring that the toys given to children are safe to play with.

Tables 1 and 2 indicate the estimated costs to multinational company and to an SME of extending the choking risk:

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[21] A, B, DK, FIN, F, EL, IRL, I, L, NL, P, SL, SP, SE, UK.

Table 1 Estimated Costs of Other Proposals for a Multinational Company			
	Cost (€ 000)		
	Low	**Medium**	**High**
Choking risks/hazard analysis	1,120	2,800	5,600

Table 2 Estimated Costs of Other Proposals for a SME Company			
	Costs (€ 000)		
	Low	**Medium**	**High**
Choking risks/hazard analysis	30	75	150

As regards the safety benefits of increasing the age limit for choking they would be limited because the risks associated with choking were considerably reduced above 36 months. Furthermore, since it is important for the intellectual development of children to be able play with small parts, it is important to note that this the requirement in question would limit the development benefits of toys.

Taking into account the expected costs presented above, including some administrative costs due to changes in the labelling of toys, and the minor benefits as well as the negative effect on the role of the toys in the intellectual development of children, it has been decided to not to raise to age limit for covering choking risk to 60 months in the revised Directive.

In particular, in view of the problems of interpretation indicated above, it has also been decided not to extent requirements on choking risks to toys that are enticing or likely to be put in the mouth. This solution, would, namely not be workable in practise and is likely to lead to distortions of the internal market. It would also be disproportionate since almost everything could be considered as enticing to be put in the mouth by young children who tend to put everything in their mouth, which could lead to a prohibition of small parts in most toys.

Option 3 Regulatory Approach: choking risk covered for toys for children under 36 months and for other toys intended to be put in the mouth

While it has been considered disproportionate to raise the age limit for covering the choking hazard and unworkable to cover the choking hazard for toys that are enticing or likely to be put in mouth, it appears proportionate and workable to extent the choking risk requirements to toys which are intended to be put in the mouth, such as toys instruments.

During the impact assessment consultation and the expert Group discussion, industry respondents have agreed to this requirement. However, in the public consultation, most respondents did not agree that introducing such a requirement in the Directive would be beneficial to the safety of toys. This is because the respondents felt that this kind of requirement in the Directive would not be necessary because harmonised standards already cover such a risk. This opinion, however, does not take into account the fact that introducing

an essential safety requirement in the Directive on covering the choking risks for these kinds of toys is 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 argument presented in the public consultation by industry respondents also means 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.

Therefore, in view of the workability of this change and the non existence of immediate costs to industry, it is proposed to require that the choking risk be covered for toys intended for children under 36 months, like under the current directive, as well as for other toys *intended* to be put in the mouth even when intended for children above 36 months.

7.2.6. Suffocation risk

Option 1: No change in the current rules or a non regulatory approach

The safety requirements of the current directive cover the suffocation risk for all toys and packaging of toys, when suffocation is understood as an airway obstruction *external* to the mouth and nose. In contrast, the safety provisions of the current directive are not clear enough as regards the risks presented by a particular type of toys which may cause *internal* airway obstruction by closing the flow of air from mouth and nose. This kind of risk is presented in particular by toys with suction cups which are often put in the mouth by children of all ages because wetting them improves their functioning.

The risks presented by toys with suction cups are covered by the current harmonised standards. However, if the Directive is not clarified other similar products presenting the same risks which may appear on the market later, might not be caught by a requirement to cover such a risk of suffocation. Therefore, if the current requirement on choking were not clarified, toys presenting a risk of suffocation by internal airway obstruction might be commercialised in Europe in the future.

It could be argued that the definition of suffocation could be clarified by a non regulatory instrument, such a guidance document. However, it would not be technically adequate to extend the current provisions and to ensure a uniform application of this concept in the Member States by a non binding instrument.

Option 2 Regulatory Approach: Internal airway obstruction covered for both toy itself and packaging

A strict regulatory approach would consist in adding a definition for suffocation in the Directive which would read "Suffocation means the result of airway obstruction external to the mouth and nose, or internal airway obstruction by closing off the flow of air also from the mouth and nose by objects being wedged in the mouth or pharynx". In addition to this, the rules on suffocation in Annex II would be left unchanged. This would mean that not only all toys but also their packaging should not present any risk of internal airway obstruction.

However, covering also the risks presented by the packaging in the same way as for the toy itself would clearly impose costs to the industry which would be disproportionate to the benefits attained. There is a consensus that it is essential to ensure that the packaging of toys cannot provoke suffocation of children, when suffocation is understood as an airway obstruction external to the mouth and nose. In contrast, requiring that the packaging shall not

provoke internal airway obstruction when it is put in the mouth would put an important burden to the industry without such a significant safety benefit that would justify the burden. The packaging is normally thrown away and it is certainly not intended or even likely to be put in the mouth (like suctions cups mentioned above for example).

Indeed, it should be remembered that apart from the risk of suffocation, the packaging of toys is not covered by the Toys Directive. It would not be justified or proportionate to impose the same requirements on packaging as on the toy itself. Moreover, the packaging is covered by the general requirement of safety imposed by the General Product Safety Directive (GPSD), which provides that it must be safe taking into account its reasonably expected use. This provision of the GPSD together with the requirement to cover external suffocation in the Toys Directive can be considered adequate for ensuring safety of packaging of toys.

Therefore, it has been decided not to extend the requirement to cover internal airway obstruction to the packaging.

Option 2 Regulatory Approach: Internal airway obstruction covered for toy itself only

A less stringent and proportionate approach for changes as regards the suffocation risk, therefore, consists in covering the risk of internal airway obstruction only for the toy itself. Since standards already cover this risk for the products that primarily are at stake, there should not be any additional costs to the industry. Clearly stating in the Directive that also internal airway obstruction should be covered for all toys is important for the safety of toys in the future to ensure that possible new toys presenting risk of internal airway obstruction are not put on the market.

It is, however, important to clarify here that this risk is different from the choking risk which results from inhalation of small parts and which is only covered for toys for children below 36 months, as explained above in 7.2.5.

7.2.7. Scope of the general safety requirement

Option 1: No change in the current rules

The current general safety requirement 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 the safety issues that affect toys' design, production and commercialisation. Therefore, if the current rules were maintained, a high level of safety may not be ensured.

Option 2: Non regulatory Approach

Using a non regulatory approach, such as guidance documents to clarify the meaning of the general safety requirement would not be efficient to ensure a clear legal basis, legal certainty for economic operators and to impose a legally binding obligation to cover also - at least certain degree of - misuse.

Option 3: Regulatory Approach: clarifying the definition in the Directive

A clear cut definition of the general safety requirement is essential because it is the only legal basis for taking dangerous toys out of the market in cases were a new risk is discovered, that is a risk which has previously not been known and which is therefore, not covered by specific

standards. A recent example of such risk which was previously not known and which is not yet covered by any standards is the risk presented by certain powerful magnets.

The preferred option is therefore to clarifying the definition of the general requirement in the Directive. In this respect it is proposed to refer in the general safety requirement to "behaviour" of children to take into account that children's actions (and interaction with toys) can be unpredictable and may – more often than it is the case for adults – deviate from the appropriate behaviour. This approach is considered to achieve greater safety benefits when designing toys.

The option to clarify the definition does not seem susceptible to affect procedures for assessing safety. In view of its expected benefits for safety and taken into account that this amendment is not very likely to incur major costs to the industry - because it is not likely to affect toy conception and quality controls - it has been decided to retain this option in the proposal.

7.2.8. Toys in food

The current provisions of the TSD on the essential safety requirements do not include specific provisions to regulate the possibility of an hazardous association between toys and food items. The health hazards and the risk of physical injury that may arise from the joint marketing of toys and food (mostly in the form of a "surprise" or "gift" for the purchase of snacks, sweets and other foods) are nonetheless subject to the general safety requirements laid down in Annex II of Directive 88/378/EEC.

As the core object of the TSD is the safety of toy users, it seems appropriate to proceed to an assessment of the hazards posed by toys in food on the basis of the precautionary principle (PP)[22].Two fundamental pre-conditions for resorting to the PP are present in the 'toys in food' problem:

It is beyond doubt that the very fact that toys included in food items pose a peculiar kind of hazard – and potentially significant negative effects - because of the association between products that are intended for oral consumption and goods that are meant for play and entertainment;

The unsystematic and sketchy nature of the data available to the Commission, the national authorities and the scientific community makes it impossible to reach a solid determination as to the possibility of the hazard being the source of regular and effective risk. Nevertheless, there are indications that in the absence of regulatory measures harmful effects on human health may occur. This situation is at the root of a regulatory conundrum, as the Commission is confronted with the choice between:

- ruling out specific measures, on the basis of the lack of sufficient or appropriate scientific information, particularly as regards the reliability of the data on the handful of incidents reported over the years; and

[22] Commission Communication COM(2000) 1 of 1.02.2000

- introducing in the TSD provisions that entail costs for the economic operators, nothwithstanding the impossibility of producing a scientific demonstration of the direct connection between the measures in question and the reduction of risk.

It seems appropriate to assess this issue on the basis of various options, including the possibility of keeping the legal framework unchanged, whilst considering this issue in the light of the Commission's policy orientations on applying the precautionary principle to the protection of human health.

The available information can be summarised as follows.Since the introduction of the TSD, there have been sporadic reports of incidents involving toys in food. Some studies have been carried out at the national level; several questions have been tabled by members of the European Parliament; some Member States have adopted national measures to address this problem These incidents and initiatives were regularly assessed within the scope of the Expert Group on Toy Safety and not deemed a sufficient basis for specific measures at the EU level.

The collection of data in connection with the incidents in question appeared episodic and unscientific. On the one hand, the national health systems catalogue of emergency room calls and subsequent injury treatment is based on the nature of the medical problem, and it does not ordinarily provide information on the precise cause of the incident. On the other, the information collected for scientific investigation purposes on a local basis – limited to some areas of a restricted number of Member States - did not appear to be suitable for extrapolating general conclusions as to the recurrence of the same problems and the connection with the same causes throughout the EU. During the 90s, it was expected that more reliable and complete data could be assembled through the EHLASS Programme (European Home and Leisure Surveillance System), which was designed to collect statistics on home accidents, including those involving children and the coupling of toys with other consumer goods. EHLASS was discountinued and only in 2005 a new programme named IDB (Injury Data Base) has been set up as part of public health policy at the EU level. IDB's coverage includes seven Member States and no data relevant to toys in food has been produced to date.

Among the stake-holders, there is a discrepancy of views on the need for specific measures on toys in food at the EU level. As a matter of fact, the limited information that has been made available to the Commission and/or discussed by the Expert Group of Toy Safety is controversial, and criticised as arbitrary and unreliable by industry.

Finally, the scientific knowledge of the issue in question has not progressed significantly in the recent years. The latest, specific study was published in 2007[23]. It is an experimental study conducted with products that conformed to the requirements of Directive 88/378, and covers only four countries (Italy, Spain, Sweden and the United Kingdom). The study reaches no firm conclusion, because of some outstanding limitations, notably the unavailability of epidemiological data and the exclusive focus on children interaction/recognition in connection with 'toys in food' items (as opposed to a more comprehensive approach that woudl combine epidemiology and experiments). Besides the lack of epidemiological figures (a key aspect of

[23]"Are FPCIs [Food Products Containing Inedibles] a source of increased risk for children? Results of a multicenter, experimental study comparing children's behaviour with FPCIs and toys". Elsevier Journal of Safety Research, 38 (2007) 589-596.

risk assessment), the study recognises the need for further, more specific studies, particularly on the situations of physical and mental impairment, as well as some inherent methodological issues (the observer's influence on the child during the scientific experience). These scientific uncertainties and limitations suggest that the Commission's assessment needs to be conducted on the basis of the precautionary principle, with appropriate consideration being given to children's safety.

Option 1: No change in the current requirement

If no new requirements were introduced to the Directive as regards toys in food, the particular risk that the association of food and toy may present would not be addressed by the Directive, and accidents might happen in connection with products of this type in the future. On the basis of past experience, this occurrence seems highly likely, regardless of the possibility of establishing a clear cause-effect link between the goods and the accident.

Option 2: Non-regulatory approach

The non-regulatory approach – for instance, by using guidance documents - would not be efficient in dealing with the potential problems associated with these kind of products, because binding safety requirements could not be imposed using this option and the mandatory safety levels would remain unchanged.

Option 3 Regulatory approach; toys firmly attached to a food item

The reasoning that leads to ruling out the first two options points to the necessary search of a regulatory instrument that could reconcile sufficient protection with proportionality, as well as a reasonable balance of the relative benefits and costs of new measures, compared to the lack of action.

It is worth noting that the scarcity of solid data and scientific certainty means that a proper cost-benefit analysis of the impacts remains impossible. It seems logical to foresee that a proportionate tightening up of the current legal framework would raise the general safety of toys marketed in association with food, and thus lower the frequency of incidents.

One fundamental corollary of the precautionary principle implies that public health is paramount, *and* should be pursued regardless of how difficult the measurement of the effects of legislative measures may appear, as long as the potentially negative effects of lack of action cannot be discounted.

The requirements resulting from this assessment would be the following: the toy should be in a separate packaging, which is already foreseen in several (but not all) Member States. It would also be foreseen that the packaging/capsule should not present any choking hazard and should, therefore, pass the small parts cylinder test.

The proposal to prohibit small parts on all toys associated with foodstuff could be regarded as disproportionate. However, an outright ban seems in order for one special category of these products, namely for cases where the toy is firmly attached to a food product at the moment of consumption, in a way that the food product needs to be consumed in order to get direct access to the toy. These products present a choking hazard for all children independently of their age, since the toy is always put into the mouth.

It is foreseen that specific warnings for those products where a toy is not firmly attached but mingled with a food product is introduced ("adult supervision recommended").

The measures outlined above are likely to reduce the risk levels from toys in food to an acceptable level, whereas the cost of regulatory action to industry is likely to be minimal or non-existent, as over the recent years the commercialization of food items that need to be consumed to gain access to toys has become very limited. On the other hand, toys coupled with food items are almost invariably offered on sale within a separate package of dimensions that prevent swallowing, and contain no small parts. These conclusions appear consistent with the main principles of the precautionary approach, namely proportionality (as regulation is introduced only in respect of some precisely defined risks), and non-discrimination (because the new measures will apply to all toys throughout the EU, and to both EU-produced and imported products), as well as the examination of the relative benefits and negative consequences of action and lack of action.

The scientific knowledge that underlies these measures is limited, although a certain level of risk could not be ignored by the European regulators. It seems legitimate to draw the conclusion that, in view of the very modest costs that these measures would entail, and the fact that most economic operators have already incorporated precautionary features into their products, the new provisions on toys in food are justified and consistent with the precautionary principle.

7.2.9. Information on chemicals in the technical file

In addition to the three approaches under consideration in the revision of the chemical requirements (see 7.2.3), specific requirements for the technical documentation held by toy manufacturers and importers on chemicals in their toys has also been considered.

Option 1 No change scenario or non regulatory approach

The option of no change to the current requirements would imply that the difficulties the Market surveillance authorities have had to get sufficient information on the chemicals present in toys would continue. Therefore, this option has been disregarded at an early stage.

A non regulatory approach, such issuing as a recommendation to manufacturers/distributors on the information to be given on chemicals in the technical file, would most probably also mean that sufficient information on chemicals would not be available since those economic operators who have not been willing or able to give this information to the authorities in the past, are unlikely to do so on the basis of a measure that is not binding on them.

Option 2 Regulatory Approach

Three proposals concerning the content of the technical file were submitted to the specific impact assessment study on chemicals:

- Proposal 1: a detailed description of the design and manufacture, including the safety data sheets on chemicals used to be obtained from chemical suppliers.

- Proposal 2: a detailed description of the design and manufacture, including a list of components and materials used in toys as well as the safety data sheets on chemicals used to be obtained from chemical suppliers.

- Proposal 3: a detailed description of the design and manufacture, including substances contained in the toy, as well as the amount of the individual substances and the relevant Safety data sheets on chemicals to be obtained from chemical suppliers.

The table below summarises the costs and benefits associated with each proposal relative to the counterfactual of do-nothing that the consultant has obtained by consulting the economic operators. The table presents the central estimates that were obtained form the calculations presented in more detail in the study itself, and the calculations should not be taken more precise than is explained in the study (see chapter 5 of the study).

Table 4: Costs and benefits of the three proposals to update the technical file requirements (€ millions) 2008 – 2051

	Proposal 1	Proposal 2	Proposal 3
Costs			
NPV financial costs	126	126	159
Other economic	Enforcement and compliance costs Possible conflicts over IPR	Enforcement and compliance costs Possible conflicts over IPR	Enforcement and compliance costs Possible conflicts over IPR
Other social	None	None	None
Other environmental	None	None	None
Benefits			
Economic	Reduction in information asymmetries	Reduction in information asymmetries	Reduction in information asymmetries
Other social	None	None	None
Other environmental	None	None	None

As the table shows, the overall cost of each of the proposals is far lower than that of the chemical requirement revisions. As the table shows, proposals 1 and 2 have the same cost implications, with the proposal 3 generating an incremental of 33m euros over the period 2008 to 2051.

In addition to being more costly, proposal 3 also presents the handicap of not being workable in practise. To indicate all possible substances present in toys and their concentrations would be impossible in practise.

On these basis, proposal 2 emerges as the preferred option. It will have the benefit reinforcing market surveillance by permitting the surveillance authorities to have access to necessary information on chemicals and, in case of need, ask for more precision from the economic operator.

7.2.10. Affixing of the CE-marking

The CE marking implications go beyond the scope of the toys' safety regulatory framework because this mechanism is common to all the NA Directives in that the marking provides a presumption of conformity with the essential safety requirements of this Directive. This feature of the NA Directives is crucial to the (national) market surveillance authorities' duties and the effectiveness of their monitoring activities. As a consequence, this issue could not be considered in isolation, but against the backdrop of a current endeavour to upgrade and streamline some aspects of the regulatory framework that applies to the marketing of both industrial and consumer goods. Whilst the provisions that apply to products in general are

being dealt with within the scope of the so-called NA Package, the revision of the TSD provides the opportunity to consider the specific issues that are relevant to the toy safety framework and that could be addressed within the scope of this exercise. This issue is namely the affixing of the CE-marking (on the toy, packaging, label, leaflet, etc).

Option 1: no change scenario or non -regulatory approach

As regards the CE-marking, the first option to consider is to make no changes to the current requirements which foresee that the CE-marking is affixed either on the toy or on the packaging and in case of small toys alternatively on a label or leaflet. However, as indicated above, experience - as reported by the market surveillance authorities - has shown that the current rules do not provide a reasonable visibility for the CE-marking, either for the consumer or for the market surveillance authorities. Leaving the rules unchanged means that the problems persist and this option is, therefore, not a viable option.

Using non regulatory instruments such as guidelines would not achieve the objective pursued in an efficient manner since non binding rules would not change the current legally binding requirement, and manufacturers who have not taken care of ensuring enough visibility for the CE-marking in the past are highly unlikely to change their practise if no binding rules are laid down.

Option 2 Regulatory approach: affixing the CE-marking both on the toy and on the packaging

During the discussions in the Expert Group on Toys safety it has been proposed that the CE-marking should always be affixed both on the toy and on the packaging. However, the exception for small toys would remain.

This option was examined in the framework of the cost analysis performed by the consultant. The respondents in the consultation indicated that existing moulds and designs would need to be modified (for plastic toys) and text on labels and packaging amended in order to affix a CE mark for plush toys. Industry respondents were asked to quantify the costs of this requirement; the responses received are summarised in Table 1. The table indicates the percentage of respondents that agreed with different percentage changes in costs, by company size and annual turnover.

Table 1: Percentage of Respondents Agreeing with Different Cost Estimates for Changes in CE Marking Requirements

Change in Manufacturing Costs	**Large Firms (>€50mIy)**	**SMEs (<€50m/y)**
>100%Increase	11	6
50-100% Increase	0	6
25-50% Increase	0	20
<25% Increase	55	47
No Change	33	20

Total	**100%**	**100%**

The Table shows considerable uncertainty amongst respondents about the impacts of the proposed changes. This may represent genuine uncertainty about the impacts of the proposed modification. A high proportion of companies predicted no or little change in costs whilst a small proportion anticipated significant cost increases. The proportion of companies expecting significant cost increases was slightly higher for SMEs, with a third expecting manufacturing costs to increase by over 25%. This suggests that SMEs are less exposed to economies of scale compared with large companies.

The costs of the proposed modification are likely to be higher where toys require stamping with a CE mark, rather than using a label. Further consultation with company representatives indicated that, in some cases, completely new moulds might be required for plastic and metal toys, especially where a product is made up of intricate components. However, for the majority of toys, moulds can be modified to incorporate a CE mark. One industry respondent estimated the cost of modifying a mould at between €400 and €1,000 per mould. The cost of a new mould was estimated by industry at between €4,500 and € 150,000 depending on the nature of the mould. It should be noted that the estimates used in the case studies are at the lower end of the range provided by industry.

These costs are per mould; a typical toy is made up of more than one mould, but as only one visible component needs to be CE marked only one of the moulds needs to be modified. Similarly, moulds will need to be changed in any case after a certain volume of production, due to wear and tear and normal design changes. Thus the costs of adding CE marks to moulded toys could be minimal – and much lower that the figures above could suggest - if this is included at the same time as normal design modification or replacement of moulds.

The costs of these proposed modifications to the TSD can also be estimated for the case study companies. The costs arising from the proposed modifications on the CE-marking are presented in Tables 2 , 3 and 4.

Table 2: Costs of Proposed Modifications to the TSD to a Multinational Company			
Proposed Modifications	**Costs (€ 000)**		
	Low	**Medium**	**High**
CE Marking on toys	2,408	8,512	16,016

Table 3: Costs of Proposed Modifications to the TSD for a SME Company			
Proposed Modifications	**Costs (€)**		
	Low	**Medium**	**High**
CE Marking	71,250	238,125	442,500

Table 4: Costs of Proposed Modifications to the TSD for a Medium-sized Manufacturer and for an Importer			
Proposed Modification	**Costs (€)**		
	Low	**Medium**	**High**
Medium Manufacturer			
CE Marking	0	0	0
Importer			
CE Marking	114,000	381,000	708,000

During the discussions in the Expert Group, industry expressed concern, both in terms of costs and practical implication, about the impact of the proposed modification which would require that the CE marking has to be affixed both on the toy and the packaging. The impacts are most significant for plastic toys since adding a CE-marking would require modification of the mould which could incur significant costs. On the basis of the figures presented above, this requirement would put an important burden on industry, and would make the overall cost of the revision important to industry and enterprises, which could have great difficulties to transfer such costs to prices. There would also logistical considerations be significant, particularly for SME:s.

Furthermore, as far as the benefits flowing from this requirement are concerned, they are not expected to be significant. Both market surveillance authorities and consumer organisations consulted within the framework of the impact assessment study, concluded that there would be only a limited (indirect) impact on toys safety, if any. There would be benefits for the market surveillance (as well as consumer) in the form of a better visibility of the CE-marking, but this could be achieved by less stringent measures as explained below under option 3.Thus comparing the costs of this requirement which are likely not to be insignificant with these minor benefits leads clearly to the conclusions that it would put a disproportionate burden on industry.

Option 3 Regulatory approach: affixing the CE-marking on the toy or on the packaging + always on the packaging if not visible from outside (a transparent) packaging

However, strengthening the CE marking requirements appears essential to ensure confidence in the CE-marking and in the presumption of conformity with the essential safety requirements. On the basis of the above mentioned cost-benefit analysis and the discussions in the Expert Group, it has been concluded that best option would be to require that the CE-marking should, in principle, be affixed on the toy or on the packaging, as the current Directive foresees. In addition, will be required that if the CE-marking it is not visible from outside the (transparent) packaging, it should be always fixed at least on the packaging. The benefits of this foreseen change consist in particular in facilitating the market surveillance of toys, since the market surveillance authorities will be able to see in case of all toys

immediately – without opening the packaging – whether it contains the CE-marking or not. Since the market surveillance would become more efficient, toys safety should indirectly be improved also. Also consumers can benefit from the better visibility of the CE-marking.

The exact costs of this proposal were not analysed in the impact assessment study carried out by the consultant However, when consulted on this question by the Commission services, industry has indicated that the majority of toys bear the CE-marking on the packaging, which means that the costs of this measure are minimal according to industry. The costs of adding the CE-marking on a packaging in the (rare) cases where it did not exist before are necessarily much lower than the costs of adding a CE-marking on the toy itself when it did not exist (as would be required under option 2).Therefore and in view of the expected positive effect on market surveillance and on the safety of toys, it has been decided to retain this proposal - which was also largely supported by the public consultation in addition to the consensus it has received in the Expert Group of Toys Safety.

This proposal will contribute to the general improvement of market surveillance that is being sought by the Commission, through some general measures for industrial goods as well as specific initiatives in the area of consumer goods.

7.2.11. Conformity assessment procedures

As regards conformity assessment procedures, two changes have been envisaged: a) introducing an explicit obligation for the manufacturer to carry out a safety assessment (hazard analysis); b) mandatory third party verification for certain types of products.

a) Safety assessment (hazard analysis)

Option 1: No change in the current requirements

If the current rules are left unchanged, there is no specific mention of an obligation for manufacturers to carry out a safety assessment (hazard/risk analysis) in the Directive. However, carrying out an appropriate analysis of the hazards and risks that the toy may present is the very basis for ensuring the safety of the toy and carrying out adequately the conformity assessment of the toy. Leaving this obligation out of the Directive would offer a loophole for any manufacturer not fully committed to ensuring the safety of toys he produces. If no changes are introduced, the hazard/risk analysis does not either need to be kept in the technical file available for inspection, which makes it difficult for the market surveillance to carry out efficiently its tasks. This is likely to have indirect negative effect on the safety of toys.

In view of these problems, this option can be disregarded.

Option 2 non-regulatory approach, such as guidance documents

Using non binding instruments would not be effective if the objective is to ensure that all manufacturers carry out the hazard analysis and keep it in the technical file since it is unlikely that manufacturer not fully committed to ensuring the safety of toys he produces would change their practises on the basis of a non binding instrument. The problems mentioned above would clearly persist if only a non binding instrument was adopted.

Option 3 regulatory approach: explicit obligation to carry out a safety assessment (hazard analysis) and to keep it in the technical file

Under the proposed modifications, manufacturers would explicitly be required to carry out an assessment of the hazards that the toy may present before a toy is placed on the market and to include it in the technical file.

Industry has indicated in the impact assessment study that this proposed modification could lead to additional costs. When responding to the consultations within the framework of the impact assessment study, industry respondents were, however, not completely certain what was meant by this modification, that is, whether it would imply additional safety consideration on top of the safety requirements that are the rationale for the harmonised standards.

Because of this range of possibilities, the figures obtained in the impact assessment study are very variable (see sections 7.4.1. and 7.4.2 of the study). However, the intention of the proposed modifications is not to introduce a completely new requirement but to make it an explicit obligation which has to be documented and kept in the technical file. Since industry has stated that where the intention of the proposed modification is to refer to risk assessment that is already carried out, there are likely to be no cost at all or minimal costs as these are already being carried out, it does not appear useful to base an assessment on the figures given in the study.

It can, therefore, be concluded that given the positive effect on market surveillance activities - and as a result on toys safety in general and given that it is plausible that costs would be zero or minimal (more on administrative costs, see section 7.2.12), it appears justified and proportionate to introduce an obligation to carry out a hazard/risk assessment.

b) Mandatory third party verification for certain types of toys

Option 1 No change in the current requirements

This option would consist in keeping the current requirements on the choice of the conformity assessment procedures. Under the current Directive, the manufacturer has a choice between:

- Self verification of the product if he has applied the harmonised standards the reference number of which has been published in the OJ covering all the safety aspects of the toy;

- EC type examination by designated third party (the so called Notified body) if the manufacturer does not apply such standards.

This choice given to the manufacturer under the current directive relies on the basic concept of the directive which is to give the primary responsibility to the manufacturer for the safety of his toys and to rely on standardisation to set the technical requirements ensuring the safety of toys. However, this option has been criticized on the grounds that it does not guarantee that all manufacturers carry out a proper conformity assessment of their toys because there is no third party control. Therefore, it has been decided to analyse the opportunity to make changes to the current rules.

Option 2 Non regulatory approach

If it is considered that the current requirements are not appropriate and a change to the current situation is needed, issuing non binding guidance documents or recommendations would not be effective to solve the problem. This approach would not be efficient, because it would not oblige all the manufacturers to use the third party verification. In case a manufacturer does not

carry out the conformity assessment in a proper way under the current rules, it is highly unlikely that he would do in a better way if only non binding recommendations are issued.

Option 3 Regulatory approach Mandatory third party verification for certain types of toys

Imposing mandatory third party verification for certain categories of toys has been proposed in the Expert Group discussions by consumer organisations and by certain Member States. Responses from industry within the framework of the impact assessment study indicate that a number of manufacturers already undertake third party verification of toys conformity with harmonised standards, particularly due to requests from retailers. Respondents queried, however, whether this would result in increased safety or simply add further costs (which could be significant) and delays. Manufacturers contend that they have much greater experience of the potential risks associated with toys than external testing services.

One respondent indicated that investment in in-house testing expertise would be reduced, because of the additional cost of third party verification. This could have an adverse effect on the extent to which safety risks are addressed throughout the manufacturing process. It is, indeed, important to underline that third party certification does not mean that each product will actually be tested before being placed on the market, only the prototype is examined[24]. Therefore, deficiencies which might emerge at a later stage of marketing cannot entirely be excluded. Thus, not even the certification by an independent third party can offer a 100% guarantee that each product of a series is in conformity with the prototype – a problem well known to market surveillance authorities - and is unfailingly safe. Besides, manufacturing alterations and mistakes after the type examination may lead to non-conformity.

Most national and surveillance Authorities, Notified Bodies and consumer organisations considered that third party verification could have safety benefits, although it would be impractical for all toys. Respondents made a range of suggestions about the categories of toys that would benefit most from third party verification.

These suggestions are summarised in Table 1:

Table 1 Respondent Suggestions of Toy Categories for Third Party Verification

Authorities	**Notified Bodies**	**Consumers**
-infant/pre-school toys; **-electrical toys;** **-ride-ons;** **-dolls plush toys;** **and activity toys.**	**-toys used by children under 36 months;** **-toys where there is a significant risk of injuries; and** **-imported toys.**	**-toys containing chemical substances (e.g. chemistry sets);** **-complex toys with many components and** **-toys where there is a high risk of injuries (e.g. electrical toys).**

[24] Nor testing each and every toy prior to its being marketed would be an option, as it would result in de facto banning virtually all toys and introducing a system that would prove unmanageable and unenforceable.

To indicate the potential costs of mandatory third party verification, notified bodies were asked during consultation to provide typical costs for EC-type examination of a variety of different toy products. The percentage of responses for each cost range per toy (and the average cost of testing based on these responses) is given in Table 2:

Table 2 EC-type Examination Costs Estimated by Notified Bodies (% responses) by Product Type and Average Cost for Testing Various Toys By Category

Product Category	% Responses					Average Cost of Testing*
	€100 - €250	€250 - €500	€500 - €1,000	€1,000 - €2,500	>€2500	
Video	37.5	25	12.5	12.5	12.5	€900
Infant/Pre-school	60		30	10		€500
Activity Toys	36	36	18	9		€500
Games/Puzzles	45	27	27			€400
Dolls	31	38	15	15		€600
Vehicles	40	10	30	20		€700
Plush	41	33	17	8		€500
Action Toys	36	36	27			€400
Ride-ons	44		33	22		€700
Electrical Toys	21	14	36	21	7	€1,000
* All figures have been rounded to the nearest hundred						

The responses indicate that, for the majority of product categories, EC-type testing by Notified Bodies costs between €100 and €2,500 per product type. Electrical toys and video games appear to cost marginally more to test, at above €2,500 in around 10% of testing laboratories. The average cost per product type across all responses was calculated to be between €400 and €1,000, with action figure toys and games/puzzles at the lower end of the range and electrical toys at the top end of the range.

Industry responses suggest that only a few large companies currently use third party verification, with the majority of larger manufacturers carrying out self-certification using in-house resources. Responses from large manufacturers indicated that adopting third party verification would cost roughly the same as EC-type examination (estimated at around €1,000 per toy product on average).

By contrast, responses from SMEs suggest that a number of such companies already undertake third party testing, as they do not have the resources for testing and assessment of products in-house; it may be more cost effective for them to outsource this activity. Consequently, the costs of such a measure will be limited to the costs of the requirements under the proposals for tests not currently undertaken.

Mandatory third party verification for certain types of products would incur further costs, which could be significant in some cases, and delays. From a practical point of view, this option is also likely to cause problems of interpretation because it would be difficult to decide whether a particular toy falls within the categories listed as being submitted to the mandatory third party verification. This could then hamper the uniform application of the Directive in the Member States and lead to unequal treatment of economic operators.

Furthermore, it has been argued that mandatory third party verification does not make the products safer because companies which do not adequately test their products against the standards, would probably not use the third party verification either and the burden would thus be exclusively on "honest" companies.

Taking into account the expected costs of this requirement and that a mandatory third party verification for all or certain toys 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, if a harmonised standard covering all the safety aspects of the toy does not (yet) exist, a third party verification is deemed necessary since there are no common specific safety requirements enshrined in the standard and thus the involvement of a third party is necessary. The estimated compliance costs of such an approach will be very modest since virtually all toys are subject to harmonised standards.

7.2.12. Administrative costs

In accordance with the impact assessment guidelines of the European Commission, administrative costs are defined costs incurred by industry in meeting an obligation to provide information on their action or productions, either to public authorities or to private parties. Information is to be understood in a broad sense to include costs of labelling, reporting, monitoring and assessment needed to provide the information Changes in the manufacturing cots are typically not regarded as administrative costs. Whenever the measure is likely to impose significant administrative costs, the standard cost model as foreseen in the impact assessment guidelines is used to present the analysis of the impacts. That means that administrative costs are assessed on the basis of the average cost of the required action (price) multiplied by the total number of actions performed per year. The average cost per action will be generally estimated by multiplying a tariff (based on average labour cots per hour including prorated overheads). The quantity will be calculated as the frequency of required actions multiplied by the number of entities concerned. However, since it is difficult to estimate the number of entities concerned by the requirements in question, a calculation of the costs per company will be presented only.

In order to analyse the administrative costs of the foreseen revision, the industry has been asked to provide an estimation of the time needed to accomplish the new tasks. As regards the revision of the chemical requirements and changes to the technical file on the information to be provided in chemicals, the administrative cost calculation is presented above in section 7.2.3 and 7.2.9. The conclusion is that these administrative costs do not put a significant burden on industry.

As far as administrative costs of other major issues in the revision are concerned, industry has been able to provide data for the calculation of the administrative costs for the new requirements on toys in food (see 7.2.8). The new requirements do not appear to entail significant costs. Most of the products on the market include precautionary features that correspond to the new (mandatory) requirements on packaging and wrapping. The requirement to accompany toys in food products with a warning " adult supervision recommended" could according to industry amount to a one-time cost between 100.000 and 200.000 € per company, costs that are rather low.

As regards the administrative costs related to the proposed new warning requirements (that is, appropriate user limitations should accompany the toy, see more 7.2.4), industry has indicated that much of the information is already present on toys, although some companies need to spend additional time working out an appropriate age grade for the toy. However, for most companies the effect would be minimal as indicated by the analysis of the costs above in section 7.2.4. This is because of the short lifecycle of toys and the rapid changes in marketing strategies. One company has indicated that this amount to two working hours per day within a timeframe of 9 months. This would amount to costs of 27.200€ (2hrs/day x 170 working day for 9 months x 80€ per working hour).

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 the industry has indicated that this could amount to 3 working hours per day for one year. After this the changes should be fully incorporated. This could amount to a total of 48.000€ per company (3hrs/day x 200 working days x 80€/hrs).

Industry was also consulted on the administrative costs related to the introduction in the Directive of an explicit obligation to carry out an analysis of the hazards that the toy may present and to include it in the technical file. Since the companies are already carrying out the hazard analysis, their estimation is that this would not require any additional working time or generate, in most cases, new costs. In practical terms, small adaptations of the IT systems could be made necessary; their cost would be part of ordinary IT management and maintenance, and not necessitate new IT investment or significant extra expense.

Although the sector of toys is very diverse with different products and companies of different sizes and roles in the distribution chain, it is possible to present the above examples as an indication of the administrative costs related to the revision. It can be concluded that the administrative costs imposed by the revision should not put a significant burden on industry.

8. THE OVERALL IMPACT AND CONCLUSIONS

When drawing the conclusions, it is essential to bear in mind that the main objective of the Toys Safety Directive and of its revision is to ensure the health and safety of children. Ensuring that toys do not endanger the health or safety of children necessarily incurs costs to the economic operators. These costs are acceptable as long as they are necessary to attain the objective pursued and remain proportionate to the objective. As pointed out in section 3.2, the Commission has held intensive discussions on the revision in the Expert Group on Toys Safety with Member States and stakeholders and has carried out two impact assessment studies and in order to assess thoroughly the modifications in terms of proportionality so as to

not impose unnecessary burden and costs on industry, especially on small and medium sized enterprises, or administrations.

The cost-benefit analysis identified industry, national authorities and consumers as the stakeholders most likely to incur the costs and benefits from the proposed modifications to the Toy Safety Directive.

8.1. Costs

– The analysis attempted to quantify the costs of the TSD for all stakeholders, based on consultation responses and publicly available information. Since the complexity of the structure of the toy market (see Annex I) makes it impossible to develop meaningful aggregate estimates of the likely costs of the existing Toys Safety Directive, and proposed modifications to it, on the sector as a whole; the analysis of the costs of the revision have been approached through case studies. Two case studies (reflecting a multinational firm and an SME) were selected to identify the ranges of the costs that could be incurred by industry. Two further case studies were included (for a medium sized manufacturer and an importer) to identify an average cost scenario and to clarify issues raised in the analysis.

It is important to consider that since the estimate for the effects on costs relied on the consultation of the industry and its own estimates, this could have led to a liberal assessment of future costs the information in question comes from companies that have a vested interest in the proposed modifications rather than form an impartial third party.

The cost implications of the proposed TSD as analysed in the impact assessment study (excluding the chemical requirements) are summarised in the following table 1 as the percentage change in the production costs of each case study company. It is to be noted that this table includes also the costs of those proposals that were disregarded on the basis of the analysis presented in the previous sections (in particular the costs of affixing of the CE-marking both on the toy and on the packaging and the requirement to submit certain categories of toys to the third party verification

TABLE 1

Percentage Increase in Production Costs by Case Study Company and Cost Scenario

	Cost Scenario		
	Low	**Medium**	**High**
Modifications to the Proposed TSD addressing the Safety of Toys			
Multinational	+0.26%	+0.91%	+1.89%
SME	+1.6%	+4.6%	+8.9%
Other modifications to be included in the proposed TSD			
Multinational	+0.3%	+0.6%	+9.5%

SME	+0.7%	+1.9%	+3.6%

As regards the revision of the chemical requirements, the specific study summarises the cost implication of the preferred approach as follows:

TABLE 2

Change in ongoing costs of the proposed revision approach for chemical requirements (millions €) 2008 – 2051

Manufacturers	6.0%
Of which	
Multinational	4.8%
SME	7.6%
Importers	6.0%
Of which	
Multinational	4.0%
SME	6.0%

In general, the case studies indicated that the larger the company in terms of turnover, the lower the impact of the proposed TSD costs, suggesting that the burden of costs associated with the proposed TSD could fall disproportionately on smaller companies at least if certain of the most costly modifications had been maintained. The cost scenarios used include variations in each cost to account for the different levels of testing, assessment and labelling required by different companies, depending on current compliance with the proposed TSD.

A number of factors have been identified that can determine the extent of the costs faced, including:

- **product type**: a large disparity was found in the costs of CE marking between companies producing plush or wooden toys and toys that are manufactured from plastic or metal;
- **volume produced**: as with higher turnover, the higher the volume a company produces, the lower the cost impacts are likely to be, due to economies of scale in production; and
- **number of product lines**: the greater the number of different products produced, the greater the costs, as risk and conformity assessment procedures have to be carried out for each separate product.

However, the cost increases related to production lines may be seen with a more moderate angle, due to both the short life time of most of the products and to the marginal nature of mould costs, according to the information given by the industry itself. Consequently, the proposed measures for modification of the existing TSD, especially when having excluded the stringent requirement on the CE-marking from the proposal should not have but a minor/marginal impact on the production costs, and thus represent a proportionate approach.

It is conceivable that the stricter requirements for toys foreseen in the revision could impact household budgets via higher prices. The extent to which these costs will be passed on to buyers will depend on how competitive the market is, the extent to which costs can be absorbed, and the market flexibility margins. The market analysis (see Annex 1) points to an

EU market and industry which is sufficiently competitive and well structured; this should make it possible incorporating the changes into the current business models and strategies through the normal adaptation processes industry has to undergo anyway to cope with increasing global competition.

As for the likely costs to the Competent and Market Surveillance Authorities, they are expected to be minimal.

8.2. Benefits

The main benefits are likely to be experienced by consumers, particularly if the revised Toys Directive achieves its goals of a reduction in the number of toy-related accidents. Although one could assume that accidents will be reduced, current data makes it impossible to determine the extent of reduction in accidents that could arise as a result of the proposed modifications. The available data cannot be used to develop a statistical relationship between specific safety requirements and the number of toy-related accidents. Even if such a relationship could be developed, it is inherently difficult to value the human satisfaction gained from children playing with a safe toy or the pain suffered as a result of a major or a minor injury. Added to these aspects are reductions in health care costs (e.g. hospital visits) that might occur from reductions in accident numbers[23].

It is important to remember that the available statistics reflect only those accidents that result in a visit to a hospital. They do not include more minor accidents that are either dealt with within the home or involve a visit and treatment at a doctor's office. As a result, there could be a far higher number of minor (and very minor but still distressing) injuries that are not covered by the statistics. They may also not reflect any longer-term impacts on health, for example from chemicals contained within toys. In any case, it is important to note that when combined, the economic value of reducing the risk of fatalities, of major, minor and more minor injuries related to toys is likely in any case to be significant, and any reduction in the number of accidents justifies all related costs incurred that remain proportionate.

In addition to the safety benefits, in the form of reduced toy related accidents, expected from the revision, the new set of chemical requirements is expected to have significant health benefits in medium and long term. The prohibition/limitation of the use of certain harmful chemicals in toys will reduce the migration of chemicals in children from toys. This in turn will reduce the number of children developing diseases and other chemical-related harmful medium and long term effects (ie effects on the reproductive system). The specific impact assessment study on chemical requirements quantified the expected health benefits in terms of Disability Adjusted Life Years (DALYs). For the chosen option the NPV financial benefits would amount to €12,885 million (see section 7.2.3).

The direct benefits to industry of the revision of the TSD indicated by the consultations are:

- reduced legal uncertainty as the definitions and roles of economic operators and toys are more clearly laid out in the modified TSD. This suggests that future legal issues will be solved more easily and quickly reducing costs and confusion; and

- the clarification of competent and surveillance authority responsibilities in the modified TSD should also reduce the number of 'grey areas', thereby better protecting legitimate manufacturers, suppliers and distributors from counterfeit products and questionable imports.

These benefits cannot be quantified based on the available data. There is no readily available information on the number of legal cases brought against companies operating in the toy sector that would be avoided in the future.

Furthermore, significant benefits may arise to the EU toy industry if the proposed modifications (setting out the powers and obligations of Market Surveillance Authorities) reduce the level of counterfeiting that currently takes place within the EU market. The current costs of counterfeit toys to the industry is estimated at hundreds of millions of Euro in lost profits, thus, reducing the level of such activity by only a small amount will yield significant benefits The potential benefits associated with this are considerable. For example, TIE has indicated that one in every ten toys sold in Europe is counterfeit, with the sales of counterfeit goods accounting for 12% of total sales in the European toy market (OECD, 1998). TIE estimates that this relates to losses of €1.5 billion to the EU toy industry (TIE, 2003).

A study carried out by the Centre for Economic and Business Research for the Global Anti-Counterfeiting Group (CEBR, 2000) provides lower estimates of the impact of counterfeiting on the toy industry. The costs are still significant, though, with the study concluding that counterfeiting has the following effects on EU industry: it reduces the revenues realised through the sales of toys and sports equipment by €3,731 million annually; it reduces the profits realised by these sector by €627 million annually; and it reduces EU employment at a macroeconomic level by around 4,000 jobs (based on an extrapolation of the total reduction in EU employment and relative share of changes in revenues and profits for the toy sector).

These losses will also lead to reductions in national and EU Gross Domestic Product (GDP).Thus, the benefits of reducing the potential for counterfeiting of toys could be significant not only to the toy industry in the EU, but also to the EU economy more generally.

It is also plausible to claim that industry will benefit from enhanced safety requirements, by positioning EU producers and distributors at the forefront of innovation and showing a positioning responsive to consumer expectations. This reasoning can be expected as it is consistent with basic competitiveness conditions, but could not be estimated in reliably mathematical terms.

The responses given in the consultation clearly illustrates that Competent and Market Surveillance Authorities believe that they will observe significant benefits from the proposed modifications to TSD, including the modified definition of toys and economic operators; clarification of the roles and responsibilities of economic operators and public authorities; CE marking and referencing of other warning or directives; improved access to technical file, hazard and risk assessment of general safety and specific risks; packaging and labelling requirements and toys in food. The benefits of the modified TSD for Competent and Market Surveillance Authorities are purely qualitative as the majority of consultees agreed that they would outweigh any costs incurred through the adoption of the TSD, but gave no estimation of the potential benefits. They could include reduced surveillance and testing if the number of safety complaints from consumers or the number of accidents decreases. Other benefits include better understanding of responsibilities and roles of operator, reducing legal costs if a consumer or the relevant body takes an economic operator to court.

Finally, it is important to note that in general, as a result of the modification of the Toys Directive less low cost and low quality products will reach the EU market in the future. This development has a strong positive impact of the general safety level. Furthermore the long

term trend of increasing safety is likely to continue to improve both geographically in the EU and globally through improved knowledge of the safety standards.

9. MONITORING AND EVALUATION

In accordance with the proposal, every five years following the entry into force of this Directive, Member States shall send the Commission a report on the application of the Directive. This report shall contain an evaluation of the situation concerning the safety of toys and of the effectiveness of the Directive, as well as a presentation of the market surveillance activities performed by the Member State. The Commission shall draw up and publish a summary of the national reports.

The main objective of this provision is to reinforce the functioning of the current legal framework and to improve its enforcement and management. Therefore, the improvement of market surveillance and the control of notified bodies have a number of in-built mechanisms allowing national authorities, Member States and the Commission to closely monitor the implementation.

For market surveillance, information exchange systems provided for in the legal framework will give regular feedback on the level of implementation and on the effectiveness of this policy. Further information will be obtained in the context of the Expert Group on Toys Safety, and through the functioning of the Committee provided by the proposal.

ANNEX (1): Overview of the toys industry

In order to understand the potential impacts of the proposal, this annex provides an overview and characteristics of the market for toys over the last five years as well as its future trends.

The global toy market

The global toy industry is an economically important sector with an estimated annual turnover of over €50 billion.

While the traditional toys market has remained steady in the five years examined, the video games sector has experienced significant growth and expansion of market share in the same period.

The USA is the largest global toy market and the US toy industry employs around 32,400 people (60% of whom are employed in production). The labour intensive nature of the sector has resulted in US manufacturers combining high value-added domestic operations with overseas production in developing countries. In 2000, US toy imports were worth approximately $15.1 billion, of which over 70% ($10.7 billion) was produced in China (Keynote, 2002). This trend is becoming increasingly apparent in other western economies (including the EU)

The EU Toy Market

Market Structure and particular characteristics

Large international toy manufacturing companies (with headquarters in the USA, Japan and the EU), which export products worldwide, are predominant in the EU toy market. The six largest toy companies hold 50-60 percent of the total market share.

The manufacture of toys, toy components and related products (e.g. packaging material) consumed in the EU and world market is primarily located out in the Far East, with upwards 8000 suppliers in China. Due to economies of scale in production and the lower labour costs outside the EU, a number of large EU companies also produce their toys in the Far East, either directly in plants owned by the EU company or indirectly, under licenses. However, some skilled labour, such as research and development as well as marketing and administrative businesses is conducted within EU.

Most toy companies manufacturing within the EU are small and medium-sized enterprises (SMEs). TIE (Toys Industries of Europe) reports (2005) that only 4 percent of the toy companies have a turnover in excess of 40million euros and 85 percent of the toy companies have fewer than 50 employes. SMEs are involved in the production of traditional (and mainly plastic) toys, such as dolls, educational toys and some plush toys. Some SMEs produce toys independently (usually focussing on specific products or geographical markets), while others act as co-operatives, combining with other small firms in other countries to buy or manufacture in bulk. This is done so as to reduce (or spread) the high costs of production faced by this sector. In some cases, semi-manufactured parts or spare parts of toys produced in the Far East are used by EU manufacturers.

In contrast with SMEs in most other industries, toy-manufacturing SMEs are often involved in the supply chain in a number of other ways. Some act as direct importers, buying products

directly from overseas manufacturers either as own brand toys or as small to medium scale imports. These companies operate very differently from the mostly large companies that own or license out manufacturing, as they have little control over what is produced (except for own-branders who may have some control) and the price at which toys are sold at in the overseas market. Under the existing TOYS DIRECTIVE, companies that place a product on the EU market under their own name and/or trademark are directly responsible for the safety of the toy. Some SMEs (involved mainly in distribution and retailing) buy their products from major EU importers, who have already imported the toys into the EU. Other retailers are known to carry out their own supply chain management (importing products directly without going through an importer). In general, compared to other industries SMEs in the toy sector are much more involved in the global market than other SMEs.

Licensing[25] is especially frequent in the toy industry due to the creative nature of the industry at heart- It is required to structure the intellectual property rights and ensure sufficient level of profit. Licensing may occur at any level of the supply chain, from design to manufacturing to distribution and retail.

Once within the EU, toys reach the end consumer by a variety of means regardless of whether the toy was imported or produced within the EU. The market shares of the different distribution channels have changed little over the past five years. While consumers used to purchase most of toys from the traditional channels such as department stores and independent toy specialists, the emerging channels of hypermarkets, discounters and toy superstores are dominating toy sales today. The various distribution channels for toys (TIE, 2003) include:

toy specialists (around 30% of all toy sales)

hypermarkets and supermarkets (around 22% of all toy sales);

general merchandise: these are non-toy specialists and include book shops, city stores, grocery stores, etc. (around 14% of all toy sales);

department stores (around 7% of all toy sales);

mail order (around 6% of all toy sales);

other sources: these are non-toy specialists (e.g. catalogue showrooms) (around 20% of all toy sales).

Since the above data were published, one would expect the internet sales to have increased its share, but it should be noted that manufacturers rarely sell direct online, so toys sold online will be primarily trough retailer websites.

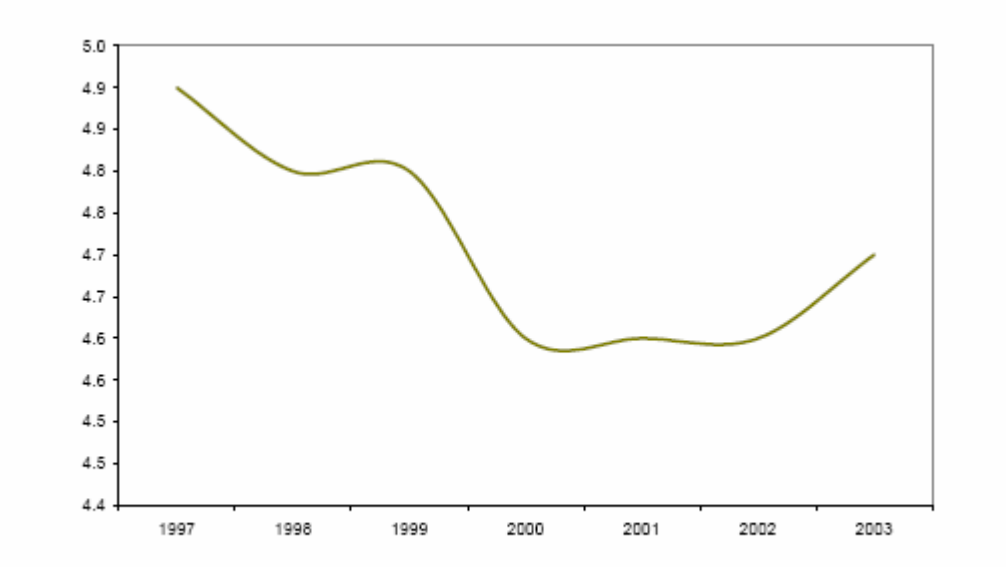
Production

[25] Licensing refers to the business of leasing the right to use a legally protected name, graphic, logo, saying or likeness, in conjunction with a product, promotion or service. Generally, the license is sealed by a formal agreement between the owner or agent of the copyright, trademark or patent (the licensor) and the prospective licensee who is either a manufacturer, supplier of services or an agent on behalf of them (TIA,2002).

The value of the European toy and games sector is significant, estimated at €4.7 billion for manufacturers and €17.3 billion for retailers (EC, 2004; TIE, 2004). The main producers of toys in the EU are Germany, Spain, Italy and France, with Germany accounting for over 20% of total production. The third largest toy company in the world is located in Denmark.

The following chart provides a summary of EU toy production from 1997 to 2003.

EU toy production (€ billion)



Source: Toy Industries of Europe, 1997-2003

The chart shows a temporary drop in output. Consultation responses suggest that this decline in production is a result of two main factors: First, the lower wages and economies of scale in Asia have made overseas manufacturing cheaper. Not only has this resulted in a slight decrease in domestic production and employment, but it has also somewhat reshaped the current structure of the toy and game industry: SMEs in the EU have shifted to occupy more specialised and niche oriented positions that enable them to add more value to the product. The second cause for the decline in EU production relates to the recent rise in global demand of electronic games and toys, which are (imperfect) substitutes for the traditional toys that are typically manufactured in the EU.

Sales picked up again in 2006. TIE attributes this to the growing demand for media-linked merchandise, such as toys modelled after film characters or cartoon personalities.

Imports

Imports of toys from outside the EU account for a significant proportion of the toy products sold in the EU, totalling between €6 billion and €9 billion. Between 2004 and 2005 EU imports increased by 21.8 per cent.

Dolls and accessories, soft toys, electronic toys and games, video games and boys' action toys are the main product categories imported into the EU. These imports originate primarily from Asia, of which imports from China constitute by far the greatest proportion.

Table Toy imports into EU (%)

Source	2003	2004	2005
ASIA/OCEANIA	**93.2**	**92**	**94.6**
China	78.6	78.2	79.4
Japan	6.2	4	7.3
Hong Kong	1.8	2.4	2.1
Taiwan	1.2	1.3	1.5
Thailand	1.3	1.3	1
NON-EU EUROPEAN COUNTRIES	**3.3**	**3.7**	**2.5**
Switzerland	1.7	2.2	1.5
Romania	1.2	1.1	0.7
Bulgaria	0.2	0.2	0.2
Norway	0.1	0.1	0.1
CIS	**0.1**	**0.1**	**0.1**
NORTH AMERICA	**2.7**	**3.3**	**2.1**
United States	2.3	2.8	1.9
Canada	0.5	0.4	0.2
MIDDLE EAST COUNTRIES	**0.4**	**0.5**	**0.5**
CENTRAL AND SOUTH AMERICA	**0.2**	**0.3**	**0.2**
OTHERS	**0.1**	**0.2**	**0.1**
TOTAL	100	100	100

Source: Toy Industries of Europe, 2006

It is, however, important to note that the toy industry in EU does not see imports as a major threat since a considerable part of it can be considered as 'friendly' and in fact either finished, semi-finished products or parts for assembly lines in the EU produced by EU and Western players in low-cost countries. In general all products needing high precision work are better done in Asia, and therefore produced in countries like China.

Exports

Exports from the EU to non-EU countries have been more or less stagnant after a period of steady increase (1988-2003). They represent a significant proportion of the turnover of EU manufacturers, with the most important trading partner being the USA. Exports from the EU amount to between €1 billion and €1.5 billion. Construction toys, board games, soft toys, baby toys, dolls and accessories are the main exports from the EU.

The following chart shows the main export markets from the EU (%)

DESTINATION	35.2	34.6	39
OTHER EUROPEAN COUNTRIES			
Switzerland	17.8	17.1	18.3
Norway	9.4	9.2	11
Romania	2.4	2.5	2.8
Croatia	1.5	1.6	1.8
Andorra	1.2	1.1	1.1
Bulgaria	0.8	0.6	0.8
NORTH AMERICA	29.7	23.5	22.3
United States	27.4	21.4	20.3
Canada	2.3	2.1	2
ASIA/OCEANIA	15.1	19.5	16.4
Japan	4.5	5.5	4.8
Australia	2.5	3.4	3.4
Hong Kong	2.9	2.6	3.4
South Korea	1.6	1.3	1.1
CIS	5.6	6.2	6.6
Russia	4.5	4.3	5.4
Ukraine	0.9	1.6	0.9
MIDDLE EAST COUNTRIES	5.9	6.2	6.6
Turkey	1.3	1.3	1.9
CENTRAL AND SOUTH AMERICA	5.3	4.9	4.9
Mexico	2.7	2.6	2.8
OTHERS	3.2	4	4.2
TOTAL	100	100	100

Source: Toy Industries of Europe, 2006

Consumption

The table below shows the market share of traditional toys in the EU in 2000. The Table does not include video games, which in principle do not fall within the scope of the TOYS DIRECTIVE. These are the single largest type of toy in terms of market share (23.2%), with the traditional toys accounting for 76.8%.

Market Shares of Traditional Toys in EU	
Activity toys	**14.1%**
Infant/Pre-school	**15.1%**
Games/Puzzles	**13.8%**
Dolls	**12.7%**
Vehicles	**10.7%**
Ride-ons	**5.5%**
Action Figures	**5.7%**
Plush toys	**8.4%**

Other toys	**14.0%**
Total	**100%**
Source: EC (2003)	

Changing consumer preferences, high impulse purchasing, concentrated seasonality and intensifying price competition all contribute to high demand uncertainty.

Employment

The EU toy industry employs over 100 000 people, 53 000 of whom work directly in production and 45 000 in research and development, retail, distribution and other services As stated above, most of the manufacturers are SMEs, 80% are small firms with less than 50 employees, while only 5% are large companies.

While overall direct employment (mainly production) has decreased slightly, due to strong movements in relocation of manufacturing to Asia, indirect employment (in R&D, marketing and distribution, retail) remains stable. The increasing automation of manufacturing and packaging processes in the EU toy industry, in line with technological progress and innovation, has also had an impact in reducing sector employment.

In line with the stable trend in demand for traditional toys and games, employment within the EU has remained steady according to data from TIE.

Future Trends in the Toy Sector

During consultation, 90% of all responses predicted that the EU toy market would remain stable during the next five years and that existing trends in production and demand will continue.

Market Trends

A key market trend identified analysts is the increasing importance of products attached to the promotion of sports, films and music in the toy sector. The increased use of character licensing and branding tied to film events is expected to contribute to secure and stable employment in the retail, marketing and distribution sectors of the industry until at least 2010. Coupled with the revival of classic toy brands and other retro characters and films, demand is expected to stay stable. This forecast is supported by the stable demand trends reported by consultees and by recent production figures.

Within the industry, it is expected that larger firms will continue to focus on internationally recognisable brands, whereas SMEs will increasingly focus on local tastes and niche markets, specialising in toys for particular age groups or a specific product line.

Other factors which will influence future trends include children's tastes, fads and fashions. Studies have indicated that children are growing up more quickly, enabling them to complete more complex tasks and develop greater social awareness at an ever younger age (TIA, 2002).

Combined with the rising incomes of many parents, it has forced toy manufacturers to adapt to these changes in product design, development and marketing, known as 'age compression'.

Industry Structure

Having already adapted to globalisation and taken advantage of outsourcing from abroad, the underlying structure of the EU toy sector is expected to remain stable. Despite the internet offering the manufacturers the potential to directly retail their toys to consumers, the consultations have revealed reluctance by large manufacturers to enter the retailing side. The focus of individual firms is also unlikely to change substantially from their manufacturing, supply, distribution or retail roles.

All electronic games and toys on the EU market are currently imported, mainly from China and Japan. The manufacture of electronic components and the assembly of electronic games and toys is carried out by Chinese companies, but EU companies tend to be responsible for their design. While some Chinese firms have began to register patents over parts of the manufacturing and design process, the consultations have revealed that, at least in the short term, Chinese firms are not expected to begin designing and manufacturing of toys (and electronic games) in their own right.

The EU is likely to retain the manufacture of certain toys that are currently being produced in the EU for non-economic reasons. Industry cites the example of board games which, for "obvious linguistic reasons", are mainly produced in Europe. EU toy companies are actively seeking opportunities to expand into Eastern European countries, particularly in Hungary, Poland and Czech Republic. If successful, this could make the production of toys in the EU more attractive to manufacturers.

In terms of future trends in employment, the fact that around 50% of industry respondents indicated that 100% of their products are manufactured in Asia, principally China, suggests according to the RPA study that direct employment (i.e. manufacturing) in the toy sector could continue to move outside the EU, except in the premium end of the market or in finishing, assembly and packaging. However, according to information from TIE, production costs are increasing in the Far East. During the last year, wages in China increased by + 18%. Many different industry sectors are competing for the labour force which pushes up the salaries. As a consequence the mobile Chinese labour force is moving easily from one sector to another one in which they are better paid. Therefore, the toy industry in China is, at the moment, suffering from a shortage of labour. According to TIE, this trend as well as the increase in transportation costs due to higher fuel prices means that the Far East starts to cease offering an interesting low production cost opportunity for the EU actors, and the production sites may start to be moving back to Europe.

ANNEX (2): Characteristics of the case study companies

Structure of the toy sector

Within the framework of the impact assessment study, manufacturers were sent a number of questions aimed at better characterising the nature of the companies operating in the sector, to provide the basis for quantifying likely costs and benefits. These questions focused on:

• the annual turnover of each company;

• the activities of each firm (manufacturer/supplier/distributor);

• number of full-time employees;

• number of products produced or supplied;

• cost estimates for proposed modifications;

• estimates of the costs of the existing TOYS DIRECTIVE; and

• import and export activities.

Responses to these questions enable a picture to be developed of the structure of the industry and provide a better understanding of companies' roles in terms of manufacture, supply and distribution, as well as the import and export of toys into and out of the EU. Table 1 presents data on the percentage of companies involved in different activities.

Table 1 Percentage of Companies involved in each Business Activity by Turnover			
	Large (>€50m)	**Medium (€10-€50m)**	**Small (€<lOm)**
Manufacture only	**40%**	**17%**	**0%**
Supply only	**20%**	**33%**	**36%**
Manufacture & Supply	**10%**	**0%**	**9%**
Manufacture, Supply & Distribution	**30%**	**50%**	**27%**
Supply & Distribution	**0%**	**0%**	**27%**
Total	**100%**	**100%**	**100%**
Import and Re-export of toys	**80%**	**50%**	**72%**
This Table is based solely on the responses received to questionnaires; the data may thus not be representative of the toy sector as a whole. They are, however, useful in interpreting and understanding the following analysis and conclusions.			

From Table 1, it appears that about 40% of larger multinational companies are involved solely in the manufacture of toys, whereas around 30% also undertake supply and distribution of toy products. In contrast, SME companies (those with a turnover below €50 million) are divided evenly between single activities in the supply chain and full integration of the production, supply and distribution process.

Normally, it could be expected that the more vertically integrated a company is, the more power it has to make an impact on the market. This is particularly the case when it is producing in large quantities. Thus, it could be expected that those firms that are more vertically integrated and produce toys in higher volumes will have greater market power to exert on downstream retailers and distributors. As a result, they may be better placed to pass on any increase in costs resulting from compliance with the proposed modifications to the Toys directive down the supply chain. Smaller manufacturers, with lower market power, may find that it is less easy to pass costs down the supply chain, because the retailer or distributor below them is large enough to switch to sourcing their toys from another company within or outside the EU. This could lead to smaller companies leaving the EU market. Alternatively, where the smaller manufacturer cannot pass on costs, it may have to reduce the range of toys it produces, leading to less choice for the consumer.

Table 1 also indicates that the re-export of toys imported into the EU can be important to the EU industry. Compliance with the revised Toys Directive for smaller enterprises may have a disproportionate impact on this part of the business, where the trading partners are countries where such stringent legislation is not in place. On the other hand, firms may benefit if future harmonisation of requirements takes place, so that all products (regardless of origin) are produced to the same standard and therefore are exposed to the same competitive pressures on costs.

Companies responding to the questionnaires were asked to indicate the number of different toy products that they produced or supplied to the EU market. As might be expected, larger firms produce a greater number of toys across all product categories than smaller firms. Responses suggest that larger companies, with a turnover greater than €50 million per annum, produce on average about 750 different toy product types, while smaller companies (turnover <€50 million) produce around 350 per year. This can be attributed to economies of scale in manufacturing as well as in marketing and administrative activities.

SME manufacturers also tend to focus production on a smaller number of product categories, producing more specialist toys for lower volume markets. For example, a small firm may produce 250 different activity books for children, whereas a larger firm might produce 250 different products across electrical, ride-on and vehicle categories in much higher volumes.

Case Study Companies

Based on responses to the questionnaires, case studies have been developed to illustrate the cost impacts of the existing Toys Safety Directive and of the proposed modifications. Where necessary, the data received from the questionnaires have been supplemented by publicly available information from different companies' annual financial reports for the financial year 2002/2003. The case studies are described in detail in Boxes 1 to 4 below.

The two main case studies relate to a large multinational company and a SME company. A range of assumptions have been made for these case study companies in order to estimate the impact of the existing Toys directive and proposed modifications. For example, it is assumed

that larger manufacturers experience economies of scale and will be able to achieve lower unit costs than SME companies. This applies particularly to any changes in fixed costs, such as those associated with hazard assessment and third party verification, and those requiring capital expenditure, such as CE marking existing toy moulds or replacing them with new moulds.

In addition, the complex and dynamic nature of the toy industry means that the implications of the TOYS DIRECTIVE will be different for importers compared to manufacturers and, similarly, will vary depending on the products produced. For example, a plastic product may require a CE mark to be incorporated into the mould, whereas a plush toy would simply require a modified or new label to be affixed, at a different cost to the moulded product. In order to account for such differences, two more case studies have been developed to clarify the issues raised and identify where costs will differ from the figures calculated in the two principal case studies. These case study companies are an importer and a medium-sized company.

All the assumptions made in the case studies are specified in Boxes 5.1 to 5.4. A summary of the structure of each case study company is presented in Table 2.

Table 2: Summary of Case Study Companies' Structure

Case Study Company	No. of Product Lines	Turnover (E million)	Total Production Costs (E million)
Large Multinational	**2,800**	**1,200**	**1,180**
Medium Manufacturer	**550**	**25**	**22**
Importer	**124**	**20**	**18**
SME	**75**	**8**	**7.7**

Box 1: Description of Multinational Case Study Company

Nature of the Company

• The company is a large manufacturer and importer of toys;

• Annual turnover is assumed to be over €1,200m (based on an actual firm's annual report);

• The company produces approximately 20 billion toy components that are used to construct 2,800 different toy products; and

• Total costs of production are assumed to be €1,l8Om.

Key Assumptions — Costs of Existing Toys Directive

• Conformity assessment costs associated with the existing TSD for this company were

estimated at between €300 and €5,000 per toy product. Questionnaire responses by larger enterprises supported this view, so the costs have been assumed to be €300 for the lowest cost, €1 ,000 as the middle cost and €1 ,700 at the high cost scenario; and

• Labelling and packaging costs are assumed to be between 0.1% and 0.5% of annual turnover, with 0.25% taken as the average.

Key Assumptions — Costs of Proposed Modifications

• It is assumed that only one visible component on each toy requires CE marking, therefore only 2,800 moulds will need to be altered (or replaced where designs are more complex). This accounts only for current production lines and does not include modification of moulds for past product lines that may be re-launched or reproduced in the future;

• Based on the figures derived in Table 5.9 (see below), the general view 0f higher turnover companies is that the proposed CE marking requirements are likely to increase total production costs by less than 25%;

• The cost of altering a mould is assumed to be between €400 and €800 per toy, with €600 as the medium cost scenario;

• The cost of replacing a mould is assumed to lie between €5,000 and €50,000 per toy product, with €25,000 per toy product as the medium cost scenario;

• It is assumed that 90% of moulds will need altering, with the remaining 10% requiring new moulds;

• Product moulds might need to be replaced anyway after a number of products are produced, due to general wear or modifications in design. The cost estimates do not include such changes and should therefore be regarded as an over- rather than an under-estimate of the potential increase in costs;

• Around 50% of the larger manufacturers that responded indicated that no further testing would be required for hazard analysis, as it is already undertaken. Around 25% of respondents said that they would need to make minor changes to the testing of toys, with one indicating a cost of €300 per product type, providing our medium cost scenario estimate. The remaining 25% of respondents suggested that major changes would be required, costing € 1,000 per product type, providing our high cost estimate;

• The costs of ensuring that warnings and references to other CE Directives are clearly visible on packaging have been estimated at between €1 ,000 and E2,500 per product to change the text on packaging, or €0.05 per toy produced. Due to the short product life-cycle of many toys, we assume that packaging needs to change rapidly to meet new product needs and marketing strategies. Thus, changing text and labels will impose minimal costs for larger manufacturers, setting our lower boundary at €500. The medium cost scenario is at €I,000 per toy product and upper boundary at €2,500 per toy product; and

• It is also assumed that the company will only need to modi1 around 50% of product types, with the remaining 50% changing due to other circumstances mentioned in the

previous bullet point.

Key Assumptions — Costs of Other Proposed Modifications

• Third Party Verification is assumed to cost €1,000, €1,500 or €2,000 per product depending on cost scenario; and

• Additional choking risk and hazard analysis is assumed to cost a similar amount to earlier assessment costs estimated to be between €400 and €2,000 as the upper and lower bounds, with € 1,000 per product as the average.

Box 2: Description of SME Case Study Company

Nature of the Company

• The company in question is a manufacturer of toys, an SME with a turnover of €8 million per year;

• The company is assumed to produce 75 different product types; and

• Total costs of production are estimated at around €7.7 million.

Key Assumptions — Costs of Existing TSD

• Conformity assessment costs associated with the existing TSD are estimated at between €300 and €5,000 per toy product. Questionnaire responses by small enterprises supported this view, so costs are assumed to be €1,000 on average (with €300 and € 1,700 as lower and upper bounds respectively);

• Labelling and packaging costs associated with the existing TSD are between 0.1% and 0.5% of annual turnover, with this range being confirmed by 75% of SME companies consulted. Some companies, however, provided estimates toward the higher end of this range and 25% responded that costs are higher, at around one or two percent of turnover. Accounting for these responses, the estimates used in this model are set between 0.25% and 0.75% of turnover with an average figure of 0.5% of turnover.

Key Assumptions Costs of Proposed Modifications

• As with the larger multinational, the proposed CE marking requirements would involve making modifications to all toy products, assumed in this case to number 75. This relates to current production lines and does not include past product lines that may be re-launched or re-produced in the future;

• The costs of altering an existing mould are assumed to range from €500, €750 to € 1,000 per mould;

• The same costs for a completely new mould are assumed to be the same as for the larger company case, respectively €5,000, €25,000 and €50,000 per mould;

• The percentage of moulds affected by each requirement is also assumed to be similar to

those for a larger company, with 90% of moulds to be altered and 10% to be replaced;

• From consultation, the lowest cost estimate for undertaking a hazard analysis appears to be around €400 per toy product rising to €2,000 per toy for those companies whose products would require major testing. The average estimate is therefore set at €1 ,000; and

• As with the multinational example, labelling and packaging costs are set at €500 per product at the lower boundary, to simulate the fast pace of product marketing and redesign, which results in packaging being changed regularly. The upper bound figure is set at €2,5 00, and the average set at €1,000.

Key Assumptions — Costs of Other Proposed Modifications

• Third Party Verification is assumed to cost €300, € 1,500 or €1,700 per product depending on cost scenario; and

• Additional choking risk and hazard analysis is assumed to cost a similar amount to earlier assessment costs estimated to be between €400 and €2,000 as the upper and lower bounds, with €1,000 per product as the average.

Box 3: Description of Medium-sized Case Study Company

Nature of the Company

• This manufacturer represents the average of our responses, as it employs less than 250 employees and has a turnover of under €50 million,

• It is assumed to have production costs of €22 million and an annual turnover of €25million;

• The company produces a total of 550 different toys composed of 400 types of plush toy and 150 wooden toys, with plans to expand into dolI production by the end of the year; and

• This case study aims to illustrate a middle value of costs, to compare and contrast with the two extremes of multinational and SME companies. It will also help identify future costs, in particular, those relating to the labelling on plush and wooden toys not represented in previous examples.

Key Assumptions Costs of Existing TSD

• All assumptions are carried over from the SME case study (Box 6.2)

Key Assumptions — Costs of Proposed Modifications

• All assumptions are carried over from the SME case study (Box 6.2)

• All other assumptions are carried over from the SME case study (Box 6.2).

Key Assumptions — Costs of Proposed Modifications

• All other assumptions are carried over from the SME case study (Box 6.2).

Box 4: Description of Importer Case Study Company
Nature of the Company **• A company solely involved in the import of toys from East Asia;** **• It currently imports 40 different activity toys, 20 types of doll, 4 plush toys, 50 different ride-ons and 10 types of electrical toy;** **• This case study will enable the degree to which costs can be passed down the supply chain and the impact of costs on each product type to be discussed in more depth; and** **• It is assumed that this company has an annual turnover of €20 million and production costs of El8 million.** **Key Assumptions — Costs of Existing TSD**