Study on the Impact of the Revision of the Council Directive 88/378/EEC on the Safety of Toys

Final Report

prepared for

European Commission
Enterprise Directorate General

RPA

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European Commission – Directorate General Enterprise

by

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Executive Summary

1. Background to the Study

The EU toy sector is regulated by the Toy Safety Directive (TSD)[1] (as amended[2]) which lays down safety criteria and essential requirements which toys must meet before being placed on the EU market. The safety criteria include protection against health hazards or physical injury in general, and risks associated with the physical and mechanical, flammability, chemical, electrical, hygienic and radioactive properties of toys in particular.

In May 2002, the Commission published its consumer safety policy for 2002 – 2006, which indicated that the TSD would be reviewed as part of its new strategy to improve consumer protection. This study has been commissioned by DG Enterprise to assess the impact of the planned modifications to the TSD on the safety of toys, for businesses (in particular small and medium-sized enterprises), consumers, public authorities, health and safety and the environment. The findings of this study are presented in this Report.

2. Economic Analysis of the EU Toy Sector

The European toy and games market is significant, estimated at €4.7 billion for manufacturers and €17.3 billion for retailers (EC, 2004; TIE, 2003). An analysis of production in the last five years shows that there has been a slight downward trend in overall production by value, from a peak of €4.9 billion in 1997 to a stable €4.6 billion from 2000 to 2002, which rose to €4.7 billion in 2003.

Imports of toys from outside the EU constitute a significant proportion of the value of all toy products sold in the EU, accounting for between €6 billion and €9 billion per year. 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, with imports from China constituting by far the greatest proportion.

Exports from the EU to non-EU countries are increasing and represent a significant proportion of turnover for EU manufacturers, with the most important trading partner being the USA. Exports from the EU account for between €1 billion and €1.5 billion annually.

There are over 2,000 manufacturers in the toy and games sector, employing over 53,000 people in the EU directly, with another 45,000 involved indirectly in research and

[1] Council Directive 88/378/EEC on the Approximation of the Laws of the Member States relating to Toy Safety.

[2] Council Directive 93/63/EEC of 22 July 1993 amending Council Directive 88/378/EEC on the Approximation of the Laws of the Member States relating to Toy Safety.

development, retail, distribution and other services. Most of the manufacturers are small and medium-sized enterprises (SMEs); 80% are small firms with less than 50 employees; while only 5% are large companies.

In the EU, while the traditional toys market has remained steady, the video games sector has experienced significant growth and expansion of market share in the same period.

3. Toy-related Accidents in the EU

An evaluation has been undertaken of the way in which the TSD is functioning with regard to ensuring that toys placed on the market are safe. This has involved an analysis of the types and trends in toy-related accidents in the EU prior to and during the life of the TSD. Based on the analysis, the following conclusions can be drawn:

- statistics indicate that the highest numbers of toy-related accidents are associated with soft toys and dolls; ride-ons, rocking and riding toys; small toys and small parts from toys and projectile toys. For soft toys and dolls, accidents may be linked to inconsistencies or human errors in production, and not necessarily the failure of legislation to address these risks;

- accidents involving children using outdoor toys, particularly ride-ons (i.e. rocking horses, scooters and cycles) are the most frequent. The number of such accidents has remained relatively steady across the years (i.e. there appears to be a constant baseline number of accidents for this category). This may be due to the (well understood) inherent risk of falling off or falling down while using these types of toys;

- accident data indicates that toddlers are the group of children at the highest risk of toy-related accidents in the EU, with estimates from the various Member States indicating that the majority of accidents occurring involve one to three year olds; and

- there are concerns about the adequacy of enforcement of the TSD, particularly in ensuring that all toys comply with the requirements of the TSD and in the assessment of the risks posed by new toys when they are first put on the market.

There may be scope for further action under the TSD to address some of these issues. However, there are certain types of accidents which, although involving toys, cannot be directly linked to or dealt with under the Directive. These include:

- children using products not intended as toys;
- toys which by their nature or the skill required for operation are inherently more risky;
- the impact of generational fashions and short lived crazes; and
- unforeseen circumstances.

4. Achievement of the Objectives of the Existing TSD

Consultees identified four main positive aspects of the Directive; these are:

- better manufacturer awareness of requirements for toy safety;
- reductions in the level of non-conformity amongst toys on the EU market;
- reductions in the number of toy-related accidents; and
- establishment of a harmonised framework (based on the New Approach) for ensuring that toys comply with the TSD's essential safety requirements and consequently, ensuring the free movement of toys.

The following were identified as areas where the TSD may not have achieved its objectives:

- the definition of toys;
- linked to this, the labelling of toys;
- the adequacy of harmonised standards and gaps in essential requirements; and
- enforcement.

Consultees suggested a number of actions that could be taken to address the areas for improvement of the Directive that they had identified. These covered:

- the definition of toys;
- the classification and labelling of toys;
- the scope of standards and requirements;
- assessment methods and information for consumers;
- updating the TSD in line with developments in the toy sector; and
- improvements in the quality and extent of enforcement.

5. Proposed Modifications to the TSD

The proposed modifications to the TSD cover:

- clarifications in the **definitions and scope** of the TSD;
- clarifications and additions intended to address the **safety of toys**;
- **other proposals** relating to the safety of toys which may be included in the proposed TSD; and
- clarifications on the duties of regulatory authorities and Notified Bodies.

Consultees were asked to give their views on the impact of the proposed modifications for them, and on the overall impact on trade and the competitiveness of the EU toy industry and on toy safety.

Many of the proposed modifications were considered to provide useful clarification of the TSD, without introducing significant new requirements. However, a number of the proposed modifications were highlighted as potentially giving rise to more major impacts.

These were:

- considering **reasonably foreseeable misuse** in assessing toy safety: manufacturers believed that this would not lead to changes in assessment procedures but that the scope for different interpretations of the phrase could leave them open to legal challenge and potentially result in unjustified withdrawal of toys from the market. However, consumer organisations believed that it could result in safety benefits;

- changes to **CE marking**, including reference to other Directives covered by the CE mark and inclusion of the mark on the toy as well as on the packaging. Industry was concerned about the practical difficulty of meeting these requirements and questioned their value for consumers. Adding a CE mark to a toy could be costly (for plastic toys where moulds would have to be modified) and cause practical difficulties (for example where SMEs purchased and imported part of a large manufacturing run, most of which was not destined for the EU);

- requirement to carry out **hazard analysis**: industry questioned the value of hazard analysis, as opposed to risk assessment. If the aim was that industry should carry out different procedures, these should be set out;

- **mandatory third party verification**, a proposed modification which has yet to be agreed or included, was viewed by industry as potentially increasing costs significantly whilst having limited safety benefits (although some manufacturers already undertake such verification for market reasons). Other consultees felt that the requirement could have significant safety benefits but would be impractical for all toys. Different suggestions were made as to which categories of toys should be covered;

- respondents were uncertain of the benefits of extending requirements for the assessment of **choking risks** to children **below 60 months** (from 36 months), as children above this age are less likely to put toys into their mouths. For industry, the suggestion (which has yet to be agreed or included) would be impractical. Few toys are specifically designed for children under 60 months and the suggestion would mean that toys such as small building bricks and dolls with changeable clothes, would no longer be available for this age group;

- while industry agrees that Annex II of the TSD addressing the **chemical properties of toys** must be upgraded to ensure that toys do not pose any risk of damaging children's health, there are concerns regarding how this is to be achieved, particularly for substances which are Category 1, 2 and 3 CMRs, which may be prohibited or restricted under the new proposals. Industry also noted the importance of combining modifications to the Directive with specific testing requirements. Where this is not done, testing laboratories will be left to develop their own approaches, and there will be no means of ensuring that the Directive is being complied with; and

- **location of Notified Bodies**: Notified Bodies were concerned that allowing some operations of Notified Bodies to be carried outside the Member State where they

were notified could lead to the transfer of jobs and toy safety expertise outside the EU.

Views on the impacts of the proposed modifications on international trade and competitiveness differed. Some industry respondents thought that they would increase costs, making the EU industry less competitive, leading to increased imports and loss of manufacturing jobs to the Far East. Others thought that the increased cost of meeting safety requirements would discourage imports of cheap toys into the EU. Views on the impacts on safety were also mixed. Around 40% of industry respondents, together with the majority of other stakeholders, believed that the proposed modifications would improve toy safety. The remaining 60% of industry respondents felt that toy safety would not be improved and that other measures, particularly better enforcement of the existing TSD, would be more effective.

6. Cost-Benefit Analysis of Proposed Modifications to the TSD

The cost-benefit analysis undertaken for this study identified industry, Competent/Market Surveillance Authorities and consumers as the stakeholders most likely to incur the costs and benefits from the proposed modifications to the TSD. Quantification of these costs has been undertaken using a number of case studies.

The cost implications of the proposed TSD for a multinational firm and an SME are summarised in Table 1 as the percentage change in the production costs of each case study company.

Table 1: Percentage Increase in Production Costs for a Multinational Firm and an SME

	Cost Scenario		
	Low	**Medium**	**High**
Proposed Modifications to the TSD Addressing the Safety of Toys			
Multinational	+0.3%	+0.9%	+1.9%
SME	+1.6%	+4.6%	+8.9%
Other Proposals which May be Included in the TSD			
Multinational	+0.3%	+0.6%	+9.5%
SME	+0.7%	+1.9%	+3.6%

In general, the larger the company in terms of turnover, the lower the impact of the proposed TSD costs, implying that the burden of costs associated with the proposed TSD may fall disproportionately on smaller companies. The cost scenarios included variations in each cost to account for the different levels of testing, assessment and labelling required by different companies depending on current methods of compliance with the proposed TSD.

However, a number of factors have been identified that can determine the scale of the costs faced, such as:

- **product type**: a large disparity was found in the costs of CE marking between companies producing plush or wooden toys and those producing 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 have to be carried out for each separate product.

It is expected, however, that setting out in detail the power and obligations of Market Surveillance Authorities under the proposed TSD could have a significant impact in reducing 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; reducing the level of such activity by only a small amount will yield significant benefits.

The likely costs to the Competent and Market Surveillance Authorities are expected to be minimal, and significant benefits are expected to be realised as a result of the improved clarity of the responsibilities and roles of economic operators, including improved access to technical files.

The main benefits are likely to be experienced by consumers, if the proposed TSD achieves its goals of a reduction in the number of toy-related accidents. However, current data make it difficult to determine the extent of reductions in accidents that could arise as a result of the proposed modifications.

CONTENTS

1. INTRODUCTION

1.1 Background to the Study

The EU toy sector is regulated by the Toy Safety Directive[1] (as amended[2]) which lays down safety criteria and essential requirements which toys must meet before being placed on the EU market. The safety criteria include protection against health hazards or physical injury in general, and risks associated with the physical and mechanical, flammability, chemical, electrical, hygienic and radioactive properties of toys in particular.

The Toy Safety Directive (TSD), like most EU sectoral directives for product safety, is based on the 'New Approach'. The New Approach was introduced to remove the technical barriers to trade in the internal market due to the use of national standards, through the active encouragement of a system of European standards. The TSD includes mandatory essential safety requirements, conformity assessment procedures, provisions on CE marking, notification procedures and market surveillance, with more specific requirements given in the harmonised standards under the Directive (EN 71). All toys marketed in the EU are expected to have a CE mark, which indicates the conformity of the toy with the provisions of the Directive.

In May 2002, the Commission published its consumer safety policy for 2002 – 2006 (CEC, 2002), which indicated that the TSD would be reviewed as part of its new strategy to improve consumer protection. This study has been commissioned by DG Enterprise to assess the impact of the planned revisions to the TSD on the safety of toys, for businesses (in particular small and medium-sized enterprises), consumers, public authorities, health and safety and the environment.

1.2 Objectives of the Study

As set out in the Technical Specification, the objectives of this study are to:

- analyse the results of the way in which the TSD is functioning, with regard to ensuring that toys placed on the market are safe and that the internal toy market is functioning smoothly;
- identify the fields where the legislation may not have achieved its objectives or where it may be possible to improve the achievement of objectives;
- identify actions likely to improve the achievement of the Directive's objectives;

[1] Council Directive 88/378/EEC on the Approximation of the Laws of the Member States relating to Toy Safety.

[2] Council Directive 93/63/EEC of 22 July 1993 amending Council Directive 88/378/EEC on the Approximation of the Laws of the Member States relating to Toy Safety.

- assess the costs and the benefits of this action for economic operators, consumers and public authorities, together with its impact on the environment; and

- assess the costs and the benefits of the proposed changes to the Directive for economic operators, consumers and public authorities, together with its impact on the environment.

1.3 Organisation of the Report

Following from the objectives of the study, the remaining sections of this Report are organised as follows:

- Section 2 sets out the main elements of the existing TSD, as part of the 'New Approach';

- Section 3 analyses the functioning of the internal market for toys based on the main economic indicators (e.g. production, import and export, employment, etc.) and the future trends within the EU toy market. It also assesses the impact of the existing TSD on the functioning of the internal market;

- Section 4 discusses the impact of the existing TSD in ensuring that toys placed on the EU market are safe. It identifies (a) areas where the existing TSD has achieved its objectives; (b) areas where the existing TSD may not have achieved its objectives; (c) areas where it may be possible to improve the achievement of objectives and (d) how these improvements could be achieved;

- Section 5 identifies the proposed modifications to the TSD which are intended to improve the achievement of its objectives and summarises the views of stakeholders on the implications of these changes;

- Section 6 provides an assessment of the costs and benefits of the proposed changes to the TSD for businesses, regulatory authorities and consumers;

- Section 7 presents our conclusions for the study; and

- Section 8 provides a list of references used for this study.

1.4 Approach to the Study

At the Steering Group meeting held in January 2004, an approach to the study was agreed that involved consultation with the relevant stakeholders in the EU toy sector. As part of this consultation process, competent authorities, market surveillance authorities, notified bodies, consumer organisations as well as manufacturers, suppliers and distributors of toys in the EU were asked for their views on the impacts of the TSD. This was undertaken through the use of questionnaires (the content of which was agreed in

advance with the Commission services and the Steering Group) which were sent by email to the stakeholders and to which responses were invited either in written or electronic form.

The consultation process was undertaken in two phases. Phase I focussed on assessing the impacts of the existing TSD, and questions concerned: the positive impacts of the existing TSD; areas where the objectives of the Directive may not have been achieved or where improvements could be made; actions likely to improve the achievement of the Directive's objectives; and the costs and benefits associated with the Directive.

Phase II focussed on assessing the impacts of the proposed modifications to the TSD. The issues addressed in these questionnaires concerned:

- the clarifications in the scope of the proposed TSD;
- the clarifications and/or additions to the TSD intended to address the safety of toys;
- other proposals relating to the safety of toys which may be included in the proposed TSD;
- the clarifications in the duties of public authorities;
- impacts of the proposals on innovation and competitiveness; and
- the overall effectiveness of the proposed TSD.

Consultation with companies (SMEs or otherwise) for this study has relied mainly on trade associations (as the intermediary), although in some cases, relevant companies were approached directly to seek additional information. Input from Chinese manufacturers supplying the EU market was also sought.

For the trade associations, responses to the questionnaires were received from the following countries: UK, Germany, Spain, France, Sweden, Denmark, Netherlands and Poland. In some cases, national trade associations referred (or deferred) to the EU trade association, mostly because they were satisfied that their interests were adequately covered by the EU trade association.

Based on the responses to the questionnaire, follow-up through direct contact has been undertaken with a sub-set of respondents. The reasons for such follow-up included the wish to gather information outside the scope of the questionnaire, seeking clarification of questionnaire responses or discussion of particular aspects in more detail. The consultants also met with the members and representatives of two national trade associations and an EU trade association to discuss some of the key issues for this study in greater detail.

2. DIRECTIVE 88/378/EC - A NEW APPROACH DIRECTIVE

2.1 Scope of the TSD

The existing TSD defines a toy as 'any product or material designed or clearly intended for use in play by children of less than 14 years of age'. The existing TSD excludes 21 products from its scope and these products are listed in Annex 1 to the Directive. The list in Annex 1 includes products not designed or intended for children (e.g. detailed scale models for adult collectors), products that present a particular risk not covered by the Directive (e.g. sports equipment) or products which require supervision or special conditions of use. The European Commission has also published guidance documents[3] on the application of the TSD for grey zone products.

The existing TSD is based on the New Approach, a legislative technique which is defined in the Council Resolution on a New Approach to Technical Harmonisation and Standardisation[4]. The New Approach was devised to facilitate the achievement of the Internal Market and to develop flexible and technology-neutral legislation by moving from detailed product specific technical requirements to defining the essential requirements for types of products, thus promoting innovation and competitiveness. More than 20 Directives are currently based on the New Approach, and a number of other Directives rely on the principles of the New Approach.

The main elements of the New Approach, which apply to the TSD, are:

- the definition of **mandatory essential requirements** within the Directive, which must be uniformly enforced by Member States;
- the preparation of **harmonised standards**, compliance with which is presumed to imply compliance with the essential requirements;
- the definition of appropriate **conformity assessment procedures** for manufacturers;
- the introduction of **CE marking**; and
- an obligation on Member States to take all appropriate **enforcement measures**, to ensure that non-conforming products are withdrawn from the market.

These are discussed in detail below.

2.2 Mandatory Essential Requirements

A fundamental aim of the New Approach is to limit legislative harmonisation to the essential requirements that products placed on the Community market must meet. The essential requirements thus define the results to be attained, or the hazards to be addressed by the Directive, but do not provide the detailed technological solutions or manufacturing specifications to be adopted by the manufacturer. The essential

[3] The guidance documents are available at http://europa.eu.int/comm/enterprise/toys/eg_guidance.htm

[4] OJC 136/1, 4.6.1985

requirements must thus be worded in terms which can be uniformly enforced by Member States and are mandatory. They must also enable Notified Bodies to assess the conformity of products with essential requirements and standardisation bodies to develop standards that ensure, partly or completely, the fulfilment of those essential requirements.

The TSD sets out (in Annex II to the Directive) the essential requirements (or safety criteria) which toys must meet during manufacture and before being placed on the market. These include protection against health hazards or physical injury in general, and risks associated with the physical and mechanical, flammability, chemical, electrical, hygienic and radioactive properties of toys in particular.

The existing TSD requires that users of toys must be protected against health hazards and risks of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children. Furthermore, the degree of risk present in the use of a toy must be commensurate with the ability of the children, and where appropriate, their supervisors to cope with it. This applies in particular to toys which are intended for use by children younger than 36 months. The TSD requires that there must be a minimum age for users of a toy and/or a warning specifying that the toy must only be used under adult supervision, where appropriate.

2.3 Harmonised Standards

Harmonised standards are European standards drawn up by European standardisation bodies (e.g. CEN, CENELEC and ETSI) on the basis of the 'essential requirements' of the Directive, following a mandate issued by the European Commission after consultation with Member States. Products that comply with harmonised standards, references to which have been published in the Official Journal of the European Communities, are presumed to meet the corresponding essential requirements. Compliance with harmonised standards is voluntary and the manufacturer is allowed to apply any other technical specifications to meet the essential requirements.

The relevant harmonised standard for the safety of toys is EN 71 and it consists of the following parts:

- Part 1: Mechanical and physical properties;
- Part 2: Flammability;
- Part 3: Migration of certain elements;
- Part 4: Experimental sets for chemistry and related activities;
- Part 5: Chemical toys (sets) other than experimental sets;
- Part 6: Graphical symbol for age warning labelling;
- Part 7: Finger Paints - requirements and test methods; and
- Part 8: Swings, slides and similar activity toys for indoor and outdoor family domestic use.

EN 50088 on the safety of electrical toys also applies to toys, while Parts 9, 10 and 11 of EN 71 are currently 'under approval' to address organic chemical compounds[5].

In the absence of harmonised standards or where the standards do not cover all aspects relating to the toy, the manufacturer is allowed to apply any appropriate specifications that meet the essential requirements of the TSD and the toy must be submitted for EC-type examination by an Approved Body.

2.4 Conformity Assessment

Under the New Approach, before a product can be placed on the market, the manufacturer must subject the product to a conformity assessment procedure provided for in the applicable Directive. This is intended to prove the conformity of the toy with the essential requirements of the Directive and the harmonised standards through examinations and compliance tests. Manufacturers may choose between different conformity assessment procedures provided for in the relevant Directive.

Under the TSD, there are two modules for conformity assessment:

- **self-certification**: this module can only be used when the manufacturer has followed the harmonised standards which cover all the safety aspects of the toy. In self-certification, the relevant compliance tests and examinations are performed by the manufacturer; he then draws up a design dossier and describes the means by which he has ensured the conformity of the product, after which he affixes the CE marking, his name and address on the toy or on the packaging before placing the toy on the market; and

- **EC-type examination**: this module must be used when the manufacturer has not applied the harmonised standards covering all the safety requirements for the toy or where such standards do not exist. Under this module, the intervention of third party conformity assessment bodies, known as Notified Bodies, is required. The manufacturer submits the model of the toy as well as a design dossier to a Notified Body. The Notified Body examines the toy and, if satisfied that the toy meets the essential requirements of the TSD, issues an EC-type examination certificate. The manufacturer then uses the approved model to ensure the conformity of his production, after which he can affix the CE marking, his name and address on each toy or on the packaging before placing the toy on the market.

The results of the conformity tests must be documented and the manufacturer or importer must be able to prove the conformity of the product with the requirements of the TSD. The manufacturer is thus required to keep the following information available for inspection:

[5] Part 9: Organic chemical compounds - Requirements; Part 10: Organic chemical compounds - Sample preparation and extraction and Part 11: Organic chemical compounds - Methods of analysis.

- a description of the means (such as the use of a test report or a technical file) whereby the manufacturer ensures conformity of production;
- the address of the places of manufacture and storage; and
- detailed information concerning the design and manufacture.

2.5 CE Marking

Under the New Approach, CE marking was introduced as a declaration by the manufacturer, or his authorised representative, that the product conforms to all the harmonisation provisions that apply to it and that the product has been the subject of the applicable conformity assessment procedures. It is addressed to, and is protected by, the authorities of the Member States and is not a commercial quality mark (EC, 2003).

Under the existing TSD, all toys prior to being placed on the market, must be affixed with the CE mark (on the toy or its packaging) by the manufacturer or his authorised representative. Member States shall presume that toys bearing the CE marking comply with the Directive's provision and as such, shall enjoy free circulation in the EU (except where the toys are likely to jeopardise the safety and/or health of consumers).

2.6 Enforcement

The operation of the New Approach requires that national authorities carry out their responsibilities for the protection of safety or other interests covered by the relevant Directive. Appropriate enforcement measures, including market surveillance, are thus essential to ensuring that the objectives of the Directive are achieved.

The existing TSD places an obligation on Member States to take all necessary measures to ensure that sample checks are carried out on toys which are on their market, so as to verify their conformity with this Directive. Where a non-conforming toy is found, the manufacturer (or his authorised representative) shall be required to make the product conform. Where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product.

2.7 Other Directives Applicable to Toys

As New Approach Directives are intended to cover a specific product type and/or a defined hazard, it is often the case that the essential requirements of other Directives may be applicable to a given product at the same time to ensure consumer safety. Some of the other Directives which certain toys have to comply with include:

- 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; and
- Council Directive 76/768/EEC on Cosmetic Products.

In some cases, regulatory requirements (from other Directives) which differ from those used in 'standard' New Approach Directives may be used. For instance, certain obligations of the manufacturer and certain procedures under the General Product Safety Directive (GPSD) apply to the toys sector, as the existing TSD does not contain comparable post-sale safety obligations[6].

Under the GPSD, if a manufacturer identifies a safety risk in a product already on the market, he will need to inform its distributors and also immediately inform the relevant authority both of those risks and the actions taken to protect consumers. Member States also have the authority to impose a recall of such products. When a Member State restricts a product from the market, orders a withdrawal from the distributor, or requires a recall, the Member State is required to notify the European Commission through the RAPEX procedure (Article 12). If the same product is likely to be on the markets of other Member States, those other Member States are also notified. It should be noted that the RAPEX procedure applies only in cases where a product poses a serious risk[7].

This process is different from the safeguard clause notification procedure under the TSD.

[6] Article 2a of the GPSD states that the provisions of the GPSD shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned.

[7] According to the GPSD, 'serious risk' means any serious risk, including those of which the effects are not immediate, requiring rapid intervention by the public authorities.

3. ECONOMIC ANALYSIS OF THE EU TOY SECTOR

3.1 Introduction

This Section provides an overview of the market for toys in the EU over the last five years, setting out the key characteristics of the sector. The aim is to ascertain whether the internal toy market is functioning smoothly through analysis of economic indicators such as production, employment, productivity, the number of undertakings and commercial trade data. Consideration of these economic indicators will enable the identification of the key trends in the sector and the implications of potential future trends on the EU, particularly with regard to production, import and export markets.

The market figures used are based on information obtained from Eurostat, EU and national trade associations, published data in trade journals, market reviews, import/export reports, as well as consultation with EU manufacturers, suppliers and distributors.

3.2 Overview of the Global Toy Market

The global toy industry is an economically important sector with an estimated annual turnover of over €50 billion. Table 3.1 below provides an overview of the world market for toys by region.

Table 3.1: Overview of World Market for Toys by Region

Regions	**1996**	**1997**	**1998**	**1999**	**2000**
	US Dollars (million)				
Traditional Toys Markets (Toy Sales at Retail Prices)					
North America	19,513	21,444	22,283	24,117	24,215
Europe (inc. Eastern countries)	14,121	13,793	13,693	13,368	12,506
Asia	13,795	13,883	14,040	13,323	13,249
Latin & South America	2,390	2,630	2,566	2,515	2,523
Middle East	829	829	832	832	762
Oceania	1,109	1,181	1,130	1,163	1,085
Africa	315	339	354	326	402
Sub-Total	**52,073**	**54,099**	**54,898**	**55,645**	**54,742**
Video Games (Toy Sales at Retail Prices)					
Video Games	9,372	11,913	14,553	15,445	14,752
Total	**61,448**	**65,012**	**69,451**	**71,088**	**69,493**

Source: ICTI - WTF (2001)

Table 3.1 shows that, 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, as discussed below).

3.3 Overview of the EU Toy Market

3.3.1 Market Structure

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 manufacture of toys, toy components and related products (e.g. packaging material) for the EU and world market is primarily located out in the Far East, especially 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. These companies, however, retain their research and development, as well as marketing and administrative businesses within the EU.

Most toy companies manufacturing within the EU are small and medium-sized enterprises (SMEs) involved in the production of traditional (and mainly plastic) toys, such as dolls, educational toys and some plush toys. They are located particularly in regions such as Bavaria (Germany), Alicante (Spain), Rhône-Alps (France) and around Milan (Italy). 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 addition to the manufacture of toys, SMEs in the toy industry are 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 to be marketed and distributed within the EU. 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 TSD, 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, small companies in the toy sector are more involved in the global market than small firms in other sectors.

Licensing[8] plays a major role in the toy industry. This can take various forms, ranging from design licensing (where a company which designs a toy sells the licence for mass production of the toy to another company) through manufacturing licensing (in which a manufacturer can sell the production rights to a toy to one or more companies) to distribution and retail licensing (in which a company can sell the licence to distribute and sell a particular product to various companies located in various countries and/or areas of the world).

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 various distribution channels for toys (TIE, 2003) include:

- toy specialists: these are the main distribution channel for toys in the EU, accounting for around 30% of all toy sales;
- hypermarkets and supermarkets: these currently account for around 22% of all toy sales;
- general merchandise: these are non-toy specialists and include book shops, city stores, grocery stores, etc. and these currently account for around 14% of all toy sales;
- department stores: these currently account for around 7% of all toy sales;
- mail order: these currently account for around 6% of all toy sales; and
- other sources: these are non-toy specialists (e.g. catalogue showrooms) which currently account for around 20% of all toy sales.

The market shares of the different distribution channels have changed little over the past five years. Retailers have significant power and impact on market share in the toy industry today, as they are able to act across the supply chain in a variety of ways (i.e. as producers, importers and/or distributors).

3.3.2 Production

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.

Table 3.2 provides a summary of EU toy production from 1997 to 2003.

[8] 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).

Table 3.2: Total EU Toy Production (1997-2003)	
Year	**Value (billion €)**
1997	4.9
1998	4.8
1999	4.8
2000	4.6
2001	4.6
2002	4.6
2003	4.7
Source: TIE (1998), TIE (2000), TIE (2003) and TIE (2004)	

Table 3.2 shows a slight downward trend in overall production by value, from a peak of €4.9 billion in 1997 to a stable €4.6 billion from 2000 to 2002, which rose to €4.7 billion in 2003. Consultation responses suggests that this decline in production is a result of two main factors:

- the first is a significant increase in the production of toys and games in Asia, particularly in China, where a combination of lower wages and economies of scale makes manufacturing of toys much cheaper. This has resulted in an alteration in the structure of the European toy industry from a mass production manufacturing base towards a predominantly marketing and sales-based business. This leaves a large number of mainly small and medium scale manufacturers in niche and high value-added market sectors, a trend repeated in many manufacturing industries in the EU. However, research and development activities still take place predominantly in the EU; and

- secondly, the fall in EU production is part of a global trend in reduced demand for traditional toys and increased demand for electronic toys and games.

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.

3.3.3 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. 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 3.3 shows the origin of toys imported into the EU by value. Figures 3.1 and 3.2 show the percentage and type of toys imported to the EU respectively based on data from the EU trade association, Toy Industries of Europe (TIE).

Table 3.4: Value of Toys Imported to the EU by Country						
Source Country	**1998 (million €)**	**1999 (million €)**	**2000 (million €)**	**2001 (million €)**	**2002 (million €)**	**2003* (million €)**
China	3,187	-	5,100	-	5,630	5,949
Japan	1,298	-	852	-	1,567	378
USA	199	-	309	-	189	194
Switzerland	181	-	195	-	158	150
Total Imports	**6,036**	**6,691**	**7,787**	**7,925**	**9,003**	**7,882**
Source: TIE (2004) * Exchange rates ($/€) significantly influence the trade volume.						

3.3.4 Exports

Exports from the EU to non-EU countries are increasing and 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. Table 3.4 shows the main export markets. Figures 3.3 and 3.4 show the percentage and type of toys exported from the EU respectively.

Table 3.6: Value of Toys Exported from the EU by Country						
Destination Country	**1998 (million €)**	**1999 (million €)**	**2000 (million €)**	**2001 (million €)**	**2002 (million €)**	**2003* (million €)**
USA	319	-	357	-	341	241
Switzerland	142	-	164	-	221	198
Norway	62	-	82	-	119	108
Hungary	-	-	56	-	111	60
Poland	-	-	51	-	53	56
Total Exports	**1,126**	**1,356**	**1,378**	**1,440**	**1,545**	**1,332**
Source: TIE (2004) * Exchange rates ($/€) significantly influence the trade volume.						

Figure 3.1: Imports from Non-EU countries into the European Union

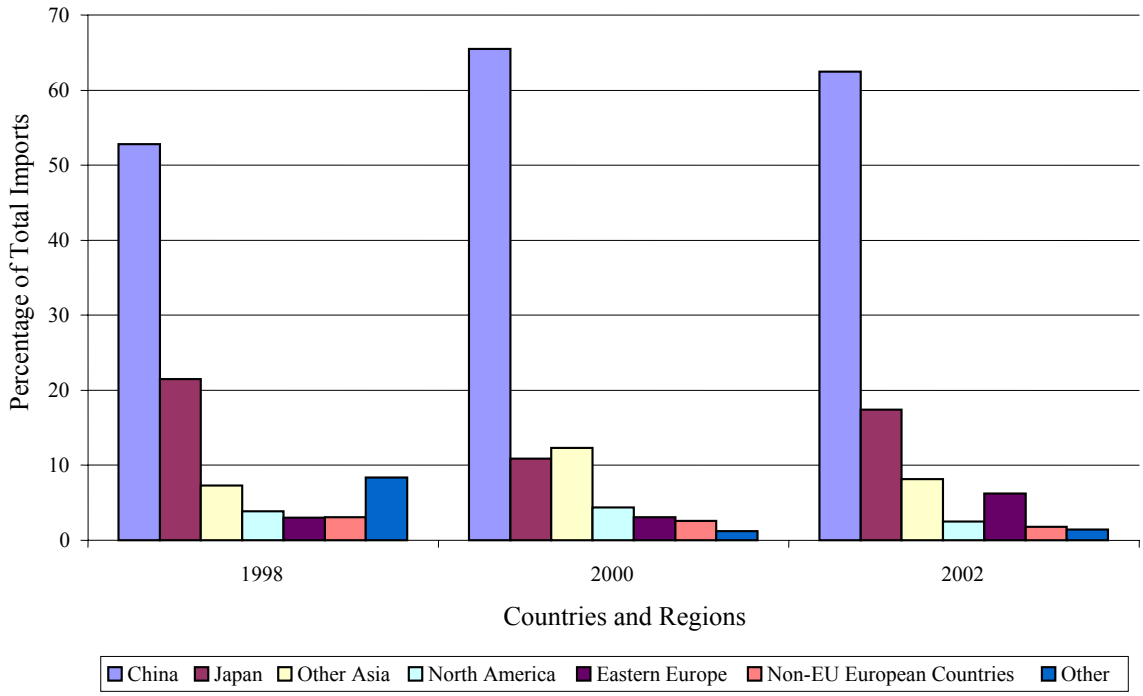


Figure 3.2: Total Imports by Type of Toy

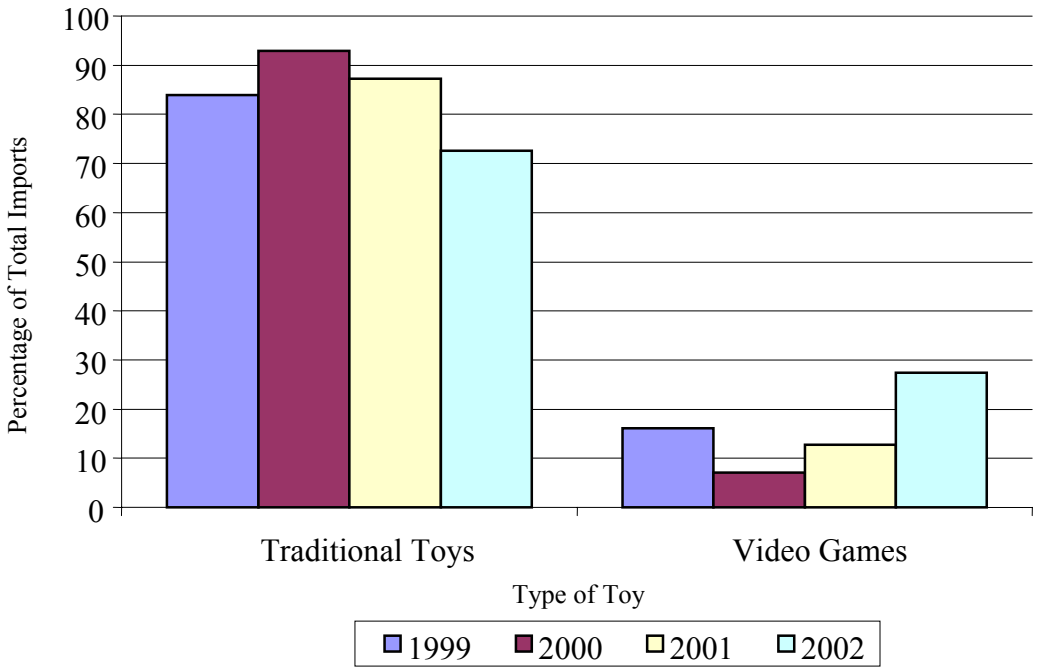


Figure 3.3: Exports from the European Union to Non-EU Countries

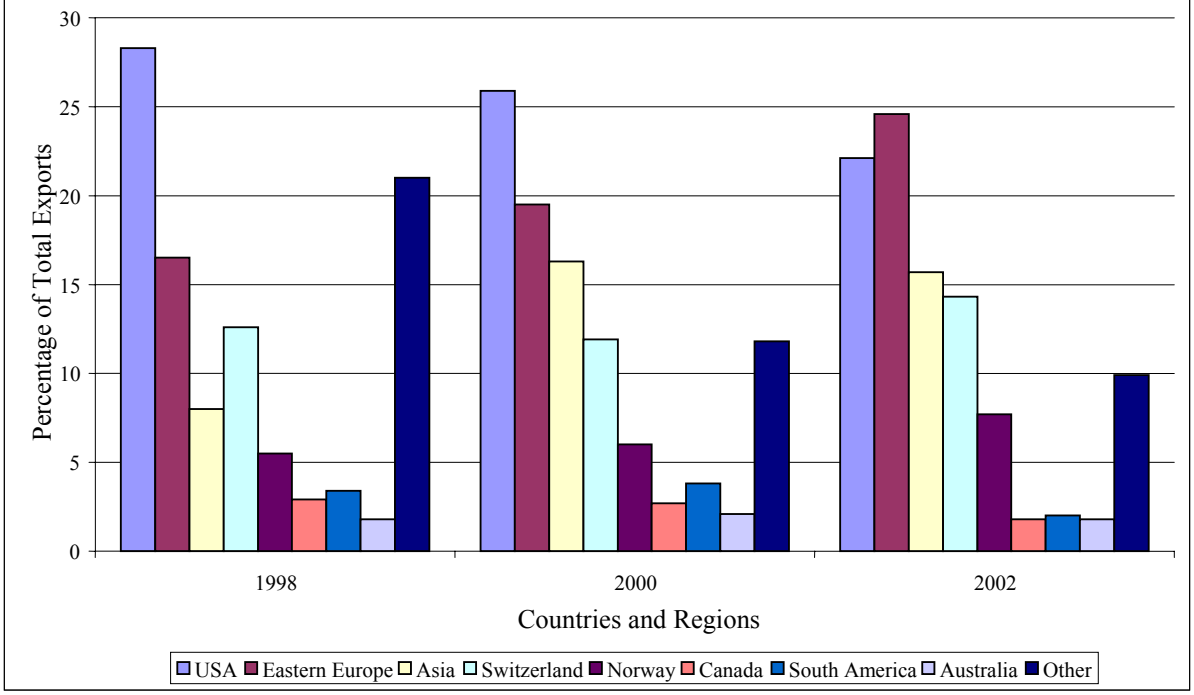
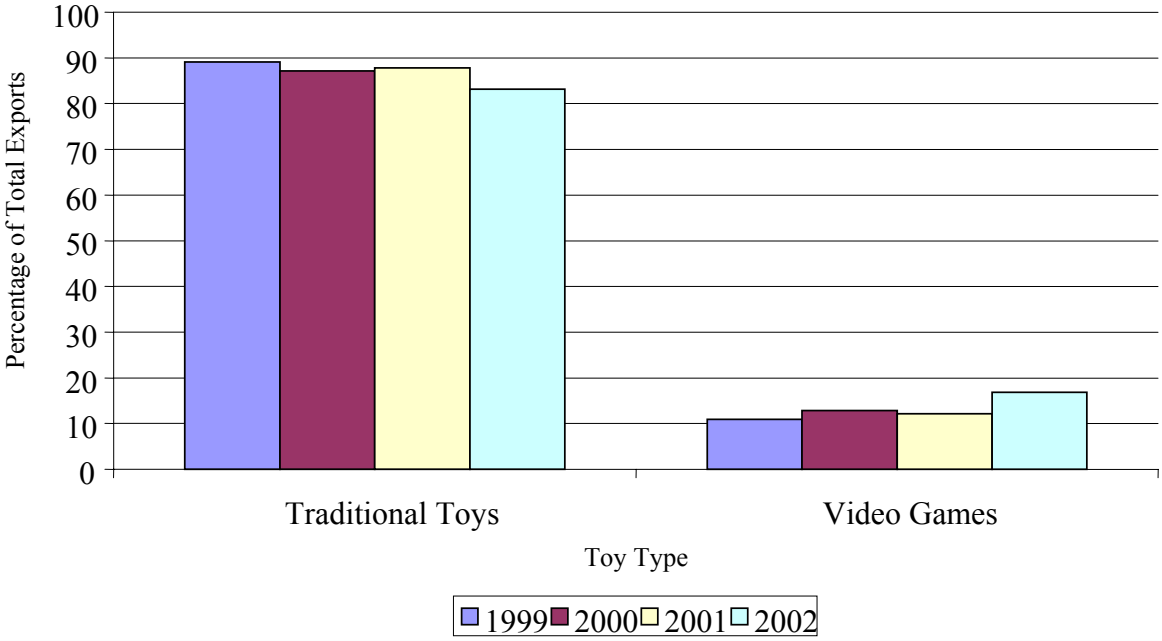


Figure 3.4: Total Exports by Type of Toy



3.3.5 Consumption

Table 3.5 shows the market share of traditional toys in the EU in 2000. The Table does not include video games, which generally do not fall within the scope of the TSD. These are the single largest type of toy in terms of market share (23.2%), with the traditional toys accounting for 76.8%.

Table 3.5: 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)	

3.3.6 Employment

In 2003, there were over 2,000 manufacturers in the toy and games sector, employing over 53,000 people in the EU directly with another 45,000 involved indirectly in research and development, retail, distribution and other services . Germany has the highest direct employment, while the United Kingdom has the highest level of indirect employment (in retail and marketing). 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.

3.3.7 Future Trends in the Toy Sector

Market Trends

A key market trend identified in the literature is the increasing importance of products attached to the promotion of sports, films and music in the toy sector. Increased character licensing and branding, to include the advertising and merchandising of tie-in products that encourage children and parents to seek out certain products and brands,

should secure stable employment in the retail, marketing and distribution sectors of the toy industry in the next five years. This forecast is supported by the stable demand trends reported by consultees and by recent production figures. Another recent market trend is the revival of toy 'classics', with many toy companies re-launching past successes. More products are also being developed from retro characters and films.

With the larger firms concentrating on the global market and producing internationally recognised brands, an increasing number of small and medium-sized firms are growing rapidly in localised and niche markets, specialising in toys targeted at specific ages or product types. This trend can be expected to continue in the near future. A possible cause for concern, though, is the static and sometimes negative growth in the traditional toy industry (as shown by Table 3.1 and 3.2).

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

The underlying structure of the EU toy sector (particularly with regard to traditional toys) is unlikely to change substantially, as it has adapted to globalisation and the advantages of overseas production. The focus of individual firms is also unlikely to change substantially from their manufacturing, supply, distribution or retail roles, unless the Internet allows manufacturers and distributors to take a significant proportion of retail sales.

Multinational companies tend to produce toys for a large number of market segments, allowing the full exploitation of the firms' licensing and branding investments. Consultation responses also show that more than 50% of total turnover from multinational firms is sourced from narrow groups of products that are globally recognised, such as dolls, action figures, games and puzzles. This is due to the reduced costs associated with the economies of scale utilised in the production of such globally recognised toys in high volumes. This trend is unlikely to change in the near future.

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 may be responsible for their design. Industry associations indicate, however, that some Chinese companies have patented part of the design and manufacturing processes; it is believed that, in time, Chinese companies will move to outright design and manufacturing of electronic games and toys 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 (although some components may be imported). 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 that direct employment (i.e. manufacturing) in the toy sector is likely to continue to move outside the EU, except in the premium end of the market or in finishing, assembly and packaging.

If Internet sales increase in conjunction with increased sales by the major hypermarket chains, however, employment in the retail sector could change dramatically. The Internet may also benefit small and medium-sized firms as market knowledge and accessibility improves, allowing for increased market coverage and choice for the consumer. The retail sector is therefore likely to be the most volatile in terms of its structure and employment.

3.4 Impact of the TSD on the Functioning of the Internal Market

The consultation exercise indicated that the establishment of a harmonised regulatory framework under the TSD/New Approach was seen as a positive achievement by Competent Authorities, consumer organisations and manufacturers. Competent Authorities and consumer organisations commented that the Directive makes it possible for Member States to test products on a comparable and consistent basis. It provides a good structure for supervising and enforcing the safety of toys on the EU market and harmonised standards (based on the New Approach) also mean that toys on sale across the EU meet the same safety standards.

Manufacturers indicated that the Directive had improved access to markets (in Europe and elsewhere); one manufacturers' association and two major toy companies felt that the Directive had reduced competition from manufacturers based outside the EU. Manufacturers and Industry Associations also considered the presumption of conformity under the harmonised framework to be a positive benefit.

3.5 Counterfeiting

Industry, consumer organisations and Competent Authorities have expressed serious concerns regarding the increasing problem of the sale of counterfeit toys and games in the EU. Consumers buy these toys believing that they are entirely safe for children to play with and that they will last; in practice, this is often not the case. Indeed, many such toys may present health and safety risks, as they usually do not comply with TSD.

While the toy industry is committed to tackling the counterfeiting problem, many manufacturers have indicated that they are restrained by the lack of appropriate legislation for three main reasons:

- the fast moving nature of the toys and games market often means that, where a product suffers counterfeiting from its first day on the market, the short product life cycle means that trying to tackle the problem after it has already begun is not effective (it takes a long time to obtain the appropriate protection);

- the cost of protecting numerous products in different European countries can be prohibitive; and

- existing patent protection is not appropriate, given that new toys are innovations to improve entertainment or educational value and not inventions in the traditional sense.

Industry has indicated that it requires quick access to protection and adequate enforcement in the EU. By closing the loopholes noted above, it is likely that fewer counterfeit toys and games would be produced and enter the EU market. This would also improve the safety of toys, as well as help to secure investments and jobs in the EU.

4. IMPACT OF THE EXISTING TSD ON TOY SAFETY IN THE EU

4.1 Introduction

The Toy Safety Directive (TSD) lays down safety criteria and essential requirements which all toys must meet before being placed on the EU market.

This Section evaluates the functioning of the TSD in ensuring that toys placed on the market are safe, through an analysis of the nature and trends in toy-related accidents in the EU prior to and during the life of the TSD (i.e. 1988 to 2004). The analysis is based on statistical data obtained from Injury Surveillance Systems (ISS) databases (across the EU and in Member States), published data on toy-related accidents in research journals and data reported in publications by consumer and academic groups involved in product safety research.

The Section concludes by identifying the following (based on responses to consultation undertaken for this study):

- areas where the TSD has achieved its objectives with regard to toy safety;
- areas where the TSD may not have achieved its objectives with regard to toy safety or where it may be possible to improve the achievement of objectives; and
- actions to improve the achievement of the TSD's objectives.

4.2 Trends in Toy-related Accidents in the EU

4.2.1 Overview

The term 'toy-related accidents' as used in this Report refers to accidents where toys have been cited as a factor and which have required admission to Accident and Emergency (A&E) departments or some form of hospitalisation, as such admissions are the main source of data on accidents. It does not necessarily imply that the responsibility/blame for the accident lies with either the toy or its manufacturer, as information on the exact cause of accidents is not readily available from sources of accident data. The discussion on the statistics is not intended to (and cannot) properly reflect all extraneous factors (e.g. demand for certain toys, market trends, fads, etc.) which may account for any changes in statistics. These have, however, been highlighted where possible.

To assess the impact of the TSD on toy-related accidents, one would ideally compare the numbers and trends in accidents prior to the introduction of the TSD in 1988 with those after the introduction of the Directive. However, only three injury surveillance systems with the potential ability to provide such analyses were in operation in EU Member States prior to the introduction of the Directive. These were the UK DTI's Home Accident Surveillance System (HASS), the Netherlands Consumer Safety Institute's 'PORS' and Danish National Institute of Health's all-injury surveillance system. From these three databases, it has only been possible to find an adequate run of annual statistical reports for the UK HASS, the results of which are discussed in Section 4.3.5.

In addition, a review of the relevant literature relating to toy-related accidents has failed to provide sufficient information to enable any practical comparison or analysis. No published retrospective analyses of the impact of the TSD on toy-related accidents, or time series analyses of accident statistics before (and after) the introduction of the TSD, have been identified in any of the relevant literature. It has thus not been possible to provide a direct statistical comparison of EU-wide data on toy-related accidents pre-1988 and post-1998.

Accident data from some Member States, however, are considered in detail below, supplemented by accident data obtained from the EU ISS (formerly EHLASS). It should, however, be noted that the EU ISS is primarily an indicative and quantitative source of information on domestic and leisure accidents. It represents the number of cases resulting in admissions to Accident and Emergency (A&E) departments in hospitals sampled in the various Member States (and not national estimates). Thus, where references are made in this Report to data obtained from the EU ISS, these are potentially significant underestimates of the number of toy-related accidents in the countries involved. The UK data (in Section 4.3.5), however, represent national estimates of toy-related accidents.

A problem with the interpretation of toy-related accident data is related to what (and who) is included within the sample definition. This problem is particularly significant because:

- the 'toy' products involved in the largest numbers of accidents include cycles, roller-skates and skateboards (and more recently scooters) - all of which are also used by teenagers and some adults above the 0-14 age range covered by the Directive[9]. Data on toy-related accidents from the Netherlands show that approximately 30% of the accidents in 1999 involved adults (i.e. people more than 14 years of age);

- while industry practice and/or published standards usually distinguish between models for children and models for adults (e.g. by a size measurement), this does not necessarily correspond to the body size of 14-year olds, but to a considerably (but not consistently) younger dividing line. Moreover, many of the models of these products bought for and used by children (sometimes from as young as seven years) have been designed for adults[10]. It does, however, make it impossible for accident records to distinguish reliably between children using 'toy' cycles, scooters, roller-skates or skateboards and children using adult models; and

- articles such as swings and slides are involved in accidents both in domestic gardens and in public parks, but the (more demanding) requirements for the latter are not within the scope of the TSD or its associated standard.

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9 In practice, the published tables in the HASS annual reports do not provide a breakdown of the ages of patients for each specific product (or product category). Thus, for roller-skates and skateboards, it has not been possible to distinguish between accidents to children and accidents to older teenagers or adults. For toys, garden play equipment, child cycles and child scooters, it may be reasonably assumed that the majority of injuries would have involved children less than 14 years of age.

10 This need not put the children at greater hazard and is part of the increasing use children make of adult products as they grow up (particularly sports and IT equipment).

In general, all injury statistics should be interpreted taking into account the variations in exposure to the risks. These variations (in the case of toys) could include:

- the average length of time children spend playing with each type of toy;
- the numbers of children in each age cohort (since birth-rates have varied considerably over the past 20 years in some countries); and
- the duration of exposure to the toy[11] (although this is rarely measured, some effect can be gauged from considering sales figures).

Social trends have also probably contributed to children spending more time indoors and more time watching television, playing video games and (for 10-14s) engaging in activities that involve using non-toy products. In addition, the toy market is particularly prone to generational fashions and short-lived crazes, and this may affect the statistics.

4.3 Toy-related Accidents in Member States

4.3.1 Toy-related Accidents in Belgium

A breakdown of the accident data from the EU ISS of accidents involving children in Belgium for 1999 showed that 18% of all cases requiring admission to A&E departments involved children (ages 0-14) playing with toys. Table 4.1 below shows the number of admissions to A&E departments in Belgium resulting from toy-related accidents from 1992 to 1999 with a breakdown of the type of toy involved in the accident.

Table 4.1: Breakdown of Toy-related Accidents in Belgium According to Type of Toy Involved

Type of Toy	1992	1994	1996	1998	1999	Total	%
Modules[1]	58	41	31	32	33	**195**	**28**
Outdoor Toy[2]	60	77	24	71	43	**275**	**39**
Indoor Toy[3]	45	42	37	26	28	**178**	**25**
Mobile Toy[4]	9	19	11	7	8	**54**	**8**
Total	**172**	**179**	**103**	**136**	**112**	**702**	**100**

Definitions of Toy Categories:
[1] Modules: Swing or seesaw, slide, etc.
[2] Outdoor toys: Ball, skipping rope, elastic band, boomerang, baseball bat, frisbee, racket, etc.
[3] Indoor toys: Toy car, building block, marble, ball, weapons, arrows and darts, doll, soft toy, etc.
[4] Mobile toys: Pedal car, tractor, rocking horse, go-kart, tricycle, child's bicycle
Source: CRIOC (2002)

Table 4.1 shows that there was a significant reduction in the number of accidents after 1994. This has been explained as being partly due to the implementation of Belgian regulations on the safety of products and the safety of toys in 1994[12] (CRIOC, 2002).

[11] The general increase in toy sales (in the early 1980s) was a feature of increasing affluence in families accompanied by (possibly) decreasing numbers of children. The children had more toys, but consequently could not play with each of them as long as previous generations had.

[12] Loi du 9 février 1994 relative à la sécurité des consummateurs.

The Table also shows that outdoor toys (particularly balls) were most frequently involved in accidents, followed by modules (playground equipment, specifically swings or see-saws and slides found in private gardens) and then indoor toys (toy cars, marbles and miscellaneous building blocks)[13]. Accidents involving indoor toys accounted for a quarter of all toy-related accidents between 1992 and 1999. A breakdown of the indoor toys involved in accidents indicates that marbles and beads were involved in the significant majority (31%) of all accidents, followed by small toys (28%), building bricks (11%), weapons (7%) and dolls (4%) (CRIOC, 2002).

In discussing the impact of the TSD on toy-related accidents in Belgium, it could be suggested based on Table 4.1 that the TSD may have contributed to a noticeable reduction in toy-related accidents in Belgium. It has not been possible, however, to substantiate this view with the relevant authorities.

4.3.2 Toy-related Accidents in Denmark

According to the Danish National Institute of Public Health, there were over 4,000 reported cases of toy-related accidents involving children in 1997 (ISO, 2000). Table 4.2 provides a breakdown of the type of toy involved in toy-related accidents in Denmark for 1996 to 1998 based on data from the EU ISS.

Table 4.2: Breakdown of Toy-related Accidents in Denmark According to Type of Toy Involved

	1996	**1997**	**1998**
Toys carrying the weight of a child (i.e. Ride-ons and rocking horses)	79	84	66
Toy boxes	20	18	25
Toy weapons	0	0	19
Models and construction kits	9	2	47
Marbles, bricks and beads	2	1	140
Soft toys, dolls and action figures	1	0	7
Sports, games and other toys	332	424	182
Unspecified toy	81	68	63
Total	**524**	**597**	**549**

Source: EU ISS (2004)

Table 4.2 shows an increase in the number of toy-related accidents, from 524 in 1996 to 597 in 1999. However, there is variability in the number of accidents involving sports and game related toys, which increased from 332 (in 1996) to 424 (in 1997) and then fell to 182 (in 1998). While the number of other toy-related accidents remained steady between 1996 and 1997, there was a significant increase in the number of accidents involving toy weapons, models and construction kits, marbles, bricks and beads in 1998. While the reason for this increase is unclear, it is possible that changing trends in the demand for certain toys, particularly sports and game related toys, may provide an explanation.

[13] The trend was reversed in 1996 with more accidents involving indoor toys than outdoor toys, but no explanation has been proffered for this.

4.3.3 Toy-related Accidents in the Netherlands

A survey by the Dutch Consumer Safety Institute has indicated that home and leisure accidents account for up to 65% of all fatal injuries occurring due to external causes for children between 0 and 4 years of age (EC, 1999).

Of non-fatal injuries due to external causes treated in a hospital, 92% are home and leisure accidents involving children. For children between 5 and 14 years of age; these account for approximately 64% of all accidents. This means that in the Netherlands, over 120,000 children between 0 and 4 years of age and 280,000 children between 5 and 14 years of age are treated annually by a general practitioner for injuries caused by home and leisure accidents (EC, 1999). The Dutch Consumer Safety Institute (DCSI) estimates that, of these, about 5,500 children are admitted to emergency rooms each year because of accidents involving toys.

Data were extracted from the EU ISS for toy-related accidents involving children in the Netherlands for 1996 to 1999. Table 4.3 provides a breakdown of the type of toy involved in the accident, while Table 4.4 shows the percentage distribution of accidents involving a visit to hospital by age.

Table 4.3: Breakdown of Toy-related Accidents in the Netherlands According to Type of Toy Involved

	1996	**1997**	**1998**	**1999**
Toys carrying the weight of a child (i.e. Ride-ons and rocking horses)	16	19	7	4
Models and construction kits	17	23	7	3
Toy boxes	9	8	0	0
Marble, beads and bricks	5	6	0	0
Soft toy, dolls and action figures	4	8	3	5
Sports, games and other toys	21	5	0	0
Unspecified toys	82	82	48	39
Total	**154**	**151**	**65**	**51**

Source: EU ISS (2004)

Table 4.4: Toy-related Accidents Involving a Visit to Hospital by Age of Child

Category (Age)	**Percentage Injured**
Babies (0-12 months)	21%
Toddlers (1-3 years)	16%
Pre-school (3-5 years)	26%
Children (5-7 years)	11%
7 upwards	26%
Total	**100 %**

Source: EU ISS (2004)

Table 4.3 shows that toys carrying the weight of a child (e.g. ride-ons) were involved in the highest number of accidents in the four years examined. Also, the percentages of

children affected by toy-related accidents in Table 4.4 are consistent with the general trend in toy-related accidents (discussed in Section 4.4.1), in which children under three years are at the highest risk.

In discussing the impact of the TSD on toy-related accidents in the Netherlands, two isolated sets of statistical tables for the Netherlands (SceV, 1990; SceV, 1996) suggest that accidents numbered about 5,200 per year in 1988-89 and around 3,200 in 1995. This appears to be similar to the percentage decline in accidents involving all toys in the UK between those dates (against an underlying upward trend over the long-term). As the current average accident rate from toys estimated by the DCSI is 5,500 children per annum, the trend would appear to have reversed since 1995. This does not, however, take into account any variability in the two sets of data and consequent lack of comparability.

Information received from the Dutch Market Surveillance Authorities indicates that toy-related accidents increased from 3,119 (in 1999) to 3,681 (in 2000) and 5,428 (in 2001). No explanation was proffered for this increase.

4.3.4 Toy-related Accidents in Sweden

The Swedish Consumer Agency (SCA) indicates that Sweden has traditionally had a low incidence of accidents involving children, with the rates of children killed in accidents the lowest in the world.

Hospital surveys of injuries in the mid-1980s and in 2001 suggest similar levels of toy-related accidents. In 1986, there were approximately 4,300 toy injuries for all ages, while in 2001 there was the same number of injuries (4,300) but involving only children 0-14 years of age. While there are considerable difficulties in providing a comparison of this data with present-day EU ISS data, the above data provide no indications of a significant reduction of the number of injuries involving toys. A comparison of consumer complaints about hazardous toys registered at the SCA showed that, while there were around 34 complaints in 1987, there were 48 complaints in 2003. This does not necessarily provide a reliable picture, however, as it is thought to be much easier to make complaints today (e.g. through email) than in 1987 (pers. comm.).

In assessing the impact of the TSD on toy-related accidents, therefore, a comparison of the results of the 1980s survey with those of a similar survey carried out in 2001 would suggest that there has not been a significant decrease in toy-related accidents. It has been pointed out by the Swedish authorities, however, that, compared to 25 years ago, the general quality of toys has improved significantly due to the TSD and the associated EN standards.

4.3.5 Toy-related Accidents in the UK

As noted above, the UK had an injury surveillance system in operation prior to the introduction of the TSD. Data from the UK HASS indicates that over 40,000 children per year are affected by toy-related accidents, with the majority of these accidents involving one to three year olds (CAPT, 2002).

The Royal Society for the Prevention of Accidents (ROSPA) examined data from the UK Home & Leisure Accident Surveillance Systems (HASS/LASS) for toy-related accidents involving children aged 0-14 years old, over the period 1990-1999. The results from the HASS showed very little change over the ten years, with the national estimate for accidents involving all types of toys running at about 30,000[14] . The results from LASS showed a slight decrease over the same period, with national estimates ranging from 12,000 in 1990 and dropping to 7,800 in 1999[15]. This change, however, is thought to be the result of changes in data collection rather than a reflection of the relative safety of toys (pers. comm.).

Table 4.5 below provides a three-year trend analysis of data from HASS/LASS for accidents involving toys and children between 0-14 years old, over the period 2000-2002.

Table 4.5: UK Toy Accident Data for 2000-2002 for Children Aged 0-14 years

Article	Year		
	2000	**2001**	**2002**
Ride-ons (car, rocking-horse etc.)	6,705	6,516	6,766
Toy vehicles (car, plane, boat)	5,286	4,373	3,998
Box for toys	3,921	3,124	2,973
Small game/toy part	3,034	2,410	1,928
House to enter (including Wendy House)	3,157	5,338	5,782
Dolls, soft toys etc.	2,146	1,749	1,764
Other toy model	2,005	2,963	2,686
Toy with projectile	1,366	285	288
Marble	1,189	678	636
Percussion cap toy	88	18	-
Other toy weapon	657	1,696	1,743
Costume mask	266	142	308
Construction kit	1,259	1,053	677
Other toy replica	443	232	369
Chemistry set etc.	53	89	21
Table or board game	426	197	390
Other game	550	446	431
Unspecified games	195	36	103
Other toy	6,688	6,658	7,688
Unspecified toy	9,810	9,531	8,857
Total	**49,244**	**47,534**	**47,408**

Source: UK HASS (2002)

[14] Some years showed slight peaks and troughs, the peaks were generally due to a major craze such as the folding scooters entering the market.

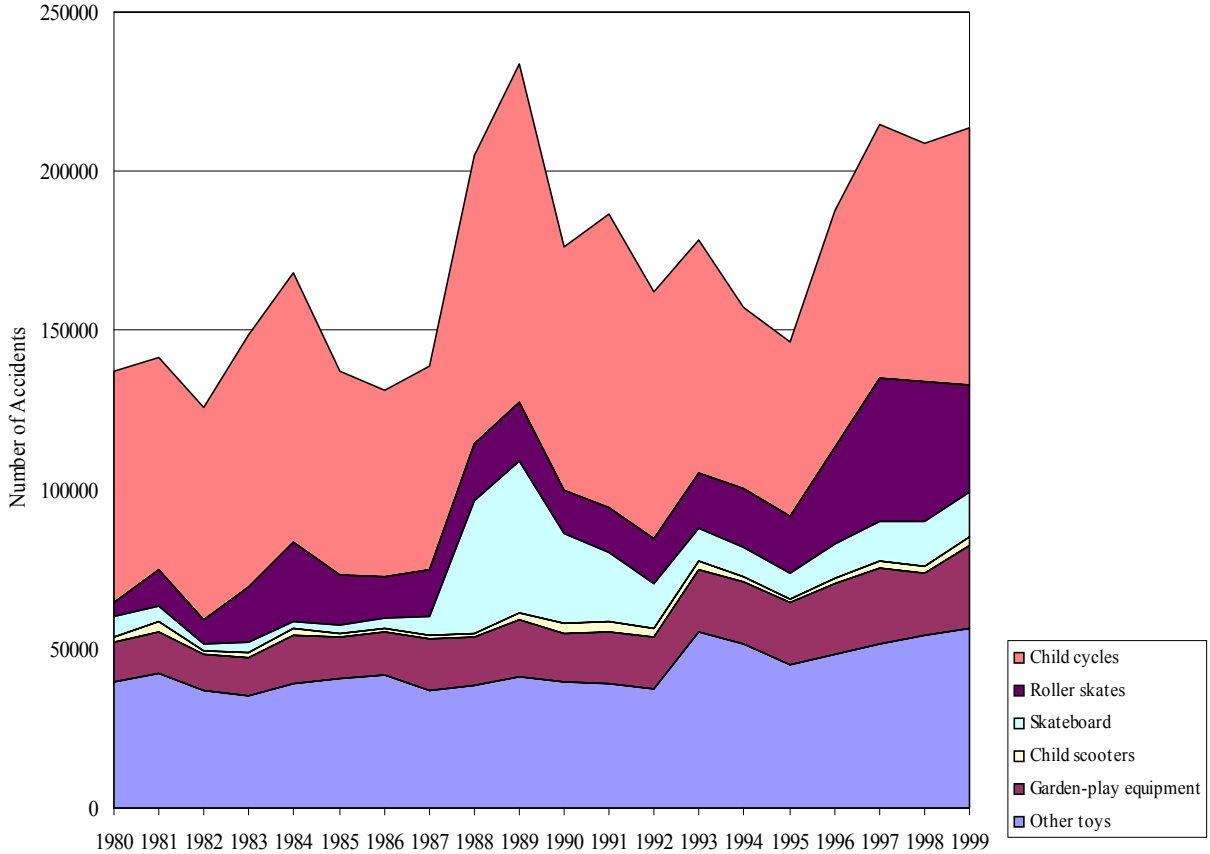
[15] The results indicate an average of over 40,000 toy-related accidents from both HASS and LASS data.

The data for 2000 - 2002 do not show any major deviations in trends compared to the previous ten years. In the time period examined, there is a slight drop in the number of accidents involving toy vehicles, toy boxes, dolls, construction kits, small games/toy parts and toys with projectiles, while there is a slight increase in accidents involving toys to enter (i.e. Wendy houses) and toy weapons. The reasons for these changes are not clear, although they are probably linked to social changes (i.e. changes in trends and preferences for toys).

An interesting aspect of the UK accident data is that the number of toy-related accidents has hardly changed since the introduction of the TSD in the UK, in 1990. Figure 4.1 presents the results (best estimates) of a twenty-year time series assessment of the accidents involving toys treated in UK hospitals before and after the 1988 Directive, highlighting the contribution of various categories of toys.

The HASS data has had to be manually analysed to produce comparable data over a twenty-year time scale. This is due to the changes over the past twenty years in the categories of products into which toys are classified. In addition, corrections have had to be made to take account of the extension of the sample in 1987 from sampling only home accidents in England and Wales to sampling home and leisure accidents across the UK.

Figure 4.1: Contribution of Selected Categories of Toys to Hospitalised Home and Leisure Accidents in the UK (for all ages of patients)



The main points arising from the Figure 4.1 (and discussed in detail below) are:

- the slow but steady upward trend in accidents involving other toys from 1992;
- the predominance of outdoor toys, particularly ride-ons such as child cycles in accidents; and
- the impact of generational fashions and crazes (e.g. skateboards and roller skates) on accident data, as shown by the peaks in the Figure.

An analysis of the data presented in Figure 4.1 above demonstrates the effects of these social variations (particularly generational fashions and short-lived crazes) on toy-related accidents from specific toy products. For instance:

- roller-skate accidents peaked around 1994 and more strongly around 1997-98, when new designs and (particularly in-line skates) made a long-established children's toy suddenly fashionable;
- skateboard accidents peaked sharply around 1988-89 in between these two roller-skate crazes (earlier HASS data had monitored a previous peak in skateboard accidents when they first hit the market around 1978);
- child scooter accidents remained consistently low throughout the 20 years, because folding 'micro-scooters' did not become common presents for children until slightly later in the UK and France (Thelot & Nectoux, 2003); and
- child cycle accidents appeared to peak in synchronisation with both roller skates and skateboard accidents. It is not clear whether this was due to a relationship between trends in exposure (e.g. the crazes temporarily increasing outdoor play generally or years with better weather) or whether it coincided with fashions in sales of child cycles (e.g. BMX-like designs). However, there were clearly considerable variations in child cycle accidents that have a major effect on the overall trends in numbers of accidents involving toys.

In contrast, accidents involving garden-play equipment (i.e. domestic climbing frames, swings, etc.) show a steady increase throughout the 20 year period. During this period, such products steadily became available in much greater numbers and at lower prices than before. Unrelated to any specific trend or fashion in exposure, accidents involving 'other toys' remained relatively level from 1980 until 1992, after which a short-lived peak was followed by a low but steady upward trend.

Based on the above analysis, it has not been possible to draw any overall conclusions about the direct impact of the TSD on toy-related accidents in the UK immediately after its introduction in 1988. The variability of exposure of children to different toys in both long and short-term periods remains a key problem in interpreting such data.

The UK data suggest that the safety requirements under the TSD have substantially reduced the numbers of fatal accidents involving toys[16]. It is clear, however, that numbers of non-fatal injuries (and the risks of serious and fatal injury) can increase substantially when new toys appear on the market (e.g. skateboards, roller blades, micro scooters and yo-balls). As with some other rapid-innovation sectors, the risks posed by new toys is likely to be due less to failings in the Directive (since this gives only very generally expressed essential safety requirements), than that hazards in their mode of use have not been fully anticipated by their designers, type approval laboratories or toy standards drafting committees. Even in cases where the hazards have been fully anticipated by the manufacturers, it may still be difficult to reduce certain types of accidents as some toys are inherently dangerous because of the skill required to use them, e.g. skate boards and roller-skates.

It is important to note that mandatory toy safety regulations and voluntary standards had been in force in the UK for many years prior to being replaced by the 1988 Directive and the related common European standard EN 71. Thus, a significant majority (though by no means all) of the requirements of the existing TSD were already being enforced in the UK. Thus, the TSD may be expected to have had less impact in the UK than in Member States with less (or no) pre-existing national requirements[17]. In addition, detailed toy safety requirements had been in force in the USA for several years. The global nature of the toy market will therefore have required many international toy companies to ensure that all their toys meet these requirements.

4.4 Impact of Various Factors on Toy-related Accidents in the EU

This Section discusses the types, trends and issues arising from toy-related accidents in the EU, analysing the impact of the age of the child, the type of toy, the origin of the toy and the type of risk on toy safety within the EU. The objective is to provide an overview of the areas where the TSD may not have achieved its objectives or where it may be possible to improve the achievement of its objectives with regard to toy safety.

4.4.1 Impact of Age of Child on Toy Safety

In determining the risk posed by a toy, the ability of the user (the child) must be taken into consideration and, where required, the toy must have a label that specifies a minimum age of the user.

Accident data from ISS indicates that toddlers are the group at the highest risk of toy-related accidents in the EU, with estimates from the various Member States indicating that the majority of accidents occurring involve one to three year olds. Accidents which

[16] It should be noted that the published HASS reports provides limited data on fatal accidents involving toys in the home, although such data are unlikely to be available for any other European country.

[17] It should be noted that other Member States (such as Sweden) had strict safety requirements relating to toys prior to the introduction of the TSD. As such, the TSD may be expected to have had less impact in such Member States.

are particularly associated with this age category include choking incidents and serious burns from toys catching fire. A survey of accidents involving children in Spain found that over 60% of the choking incidents and serious burns in Spain involved toddlers (OCU, 1999). In another study by the UK DTI of choking incidents, 40% of toy chokings involved children under 36 months (babies and toddlers), with a further 45% occurring in the next 36 months (DTI, 1996). In another UK study, toys (or parts of toys) were involved in an average of 167 choking incidents per year, of which 139 (84%) involved children under three (DTI, 1999).

Indoor toys (e.g. toy cars, marbles, building blocks, etc) are also primarily associated with accidents involving children aged between zero and five years, with a sharp drop in accident frequency from the age of six years. One theory on the reason for this is that children play less often with indoor toys beyond the age of six years. On the other hand, accidents involving mobile toys (i.e. ride-ons) tend to remain constant throughout different age groups, but the type of toy changes. For younger children, for instance, tricycles and pedal cars are usually involved while for older children, go-karts or carts attached to bicycles are most frequently involved (CRIOC, 2002).

Accident statistics also indicate that the body part affected in toy-related accidents varies according to the age of the child. Table 4.6 below shows the body distribution of toy-related accidents in a survey of children in Spain. The Table shows that a significant proportion of all toy-related injuries are to the head area, which includes injuries to the face, eyes, mouth and ears, with babies and toddlers being at the highest risk.

Table 4.6: Effect of Age on Body Part Impacted in a Toy-related Accident

Part of Body Injured	0-12 months	1-4 years	5-14 years
Head	70 %	55 %	24 %
Arms	10 %	9 %	5 %
Trunk	10 %	27 %	34 %
Legs	10 %	9 %	37 %

Source: OCU (1999)

There appears to be no direct statistical relationship between the implementation of the TSD and decreases or increases in accidents involving particular age groups. Consultation has indicated, however, that serious accidents involving toddlers (particularly from the ingestion of small toy pieces) have decreased significantly compared to their incidence prior to 1988. The Choke Hazard Test (or small cylinder test), specifically designed to reflect the size of gullet in a child of three years, has been said to have dramatically reduced the incidence of choking on small items, although there are indications that certain toys which have passed the choke hazard test have still resulted in choking incidents. The report published by the UK DTI (1999) concerning the choking of children under four years of age in the UK showed that:

- overall, toys account for only a small proportion of choking cases. Food was responsible in 51% of cases, non-food items (excluding toys) were responsible for

32%, toys or parts of toys were responsible for 6% of cases and the remaining 11% were caused by unknown objects;

- only 2% of accidents were caused by large objects which would not fit completely within the small parts test cylinder. The figure is 3% after excluding the 33% of cases where the size could not be estimated;
- toy-related accidents decline steadily with age; and
- recorded choking incidents (fatal and non-fatal) to children under 4 years old involving toys declined by an average of 3% per year over the 10 years (1987 to 1996).

In assessing the age distribution of accidents involving toys, it should be noted that the use of toys by the wrong age group results in a significant proportion of all toy-related accidents. Parents have been found either to ignore or to misunderstand the warnings relating to age on toys. For instance, parents sometimes interpret age warnings as age gradings (i.e. the toy warnings are assumed to refer to a 'normal' three year old child's intellectual awareness, interest or physical ability and some parents may consider their children to be more intelligent or larger than the average three year old). Consumer bodies and toy associations have produced a range of guidance for consumers on toys that may be considered safe for the various age groups. An example of such toy categorisation is shown in Table 4.7. Such guidance may provide a means of reducing the number of toy-related accidents resulting from use by wrong age groups, as such accidents cannot be specifically addressed under the TSD. Awareness programmes by government and consumer bodies may also be of value.

Table 4.7: Toys Considered Safe for Different Age Groups

Category (Age)	**Type of Toy**
Babies (0-12 months)	Rattles, squeaky toys, ball, chimes and bells.
Toddlers (1-3 years)	Pull along toys, soft toys, dolls, finger paints and large crayons.
Pre-school (3-5 years)	Hand puppets, construction kits, train sets and puzzles.
Children (5-7 years)	As well as all the toys listed above, bat and ball games, pencil sets, colouring kits, craft and hobby kits and musical instruments.

Source: BTHA (2004)

4.4.2 Impact of Type of Toy on Toy Safety

Accident statistics from within the EU suggest that the highest numbers of toy-related accidents are associated with the following categories:

- soft toys and dolls;
- ride-ons, rocking and riding toys;
- small toys and small parts from toys; and
- projectile toys.

Soft Toys and Dolls

Children under three are at the highest risk from these types of toys, with accidents resulting mainly from ingestion of small parts such as eyes, buttons or pieces of stuffing. Although there are specific safety requirements for soft toys in the EU, there are still a significant number of soft toys that do not meet the specified standards.

In 1993, for instance, the Swedish Consumer Agency carried out a study in which 15 different retailers were visited. Six soft toys that failed to fulfil the safety requirements were identified. In a subsequent survey carried out in 1997, 26 out of the 37 soft toys that were tested (72%) failed the tests (SCA, 2001).

In October 2000, another survey was undertaken in which a number of soft toys were purchased from various Internet retailers. Out of the 72 soft toys tested, there were problems with 35 (49%) of the tested toys; 18 (25%) of these toys were incorrectly made and did not fulfil requirements in Part 1 of the EN 71 standard[18]. The tests showed that eyes, noses, bells, buttons and other small parts that posed a risk of choking to a child broke loose from 14 of the tested toys. Three toys were packed in plastic packaging that was too thin while one teddy bear failed to fulfil the flammability requirements (burning too rapidly when tested). Five of the toys that had already failed these tests, along with 17 others, also failed to display relevant information required by the Toy Safety Act. Some toys did not carry the CE mark while others did not specify the name of the importer to Europe or other applicable importer, supplier, wholesaler or retailer. Significantly, many of the toys tested carried warnings which stated that the toy was not suitable for children under the age of three (SCA, 2001).

The survey indicated, however, that the texts and markings displayed on the tested toys have shown a slight improvement and that the current safety requirements for soft toys have resulted in a significant improvement in the quality of soft toys compared to those available in the 1980s.

Ride-ons, Rocking and Riding Toys

Ride-ons refer to toys that support a child's weight, such as cars, bicycles, scooters and rocking horses. These toys account for some of the highest numbers of injuries in the EU (as shown in Table 4.8), with injuries sustained ranging from bruises to cuts and fractures when children fall over toys. In the UK, ride-ons accounted for approximately 15% of all toy-related accidents from 2000 - 2002, while in the Netherlands, approximately 35% of all toy-related accidents (reported on the EU ISS) in 1999 were from ride-ons[19], with two-thirds of such incidents resulting in head/skull injuries as shown in Table 4.9. Standards are currently being developed under the existing TSD (e.g. EN 71 Part 8) to address some of these accidents.

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[18] The soft toys were tested according to SS-EN 71-1 (1989) Safety of toys - mechanical and physical properties and SS-EN 71-2 (1993) Safety of toys – flammability.

[19] The high number of accidents involving ride-ons may be related to the high level of use of bicycles in the Netherlands.

Table 4.8: Numbers of Toy-related Accidents Involving Ride-ons				
	1996	**1997**	**1998**	**1999**
Austria	0	3	1	2
Belgium	13	5	5	3
Denmark	79	84	68	-
Finland	20	17	6	-
France	15	14	16	23
Germany	9	-	-	-
Greece	0	30	0	19
Ireland	3	8	8	-
Italy	0	6	5	-
Luxembourg	2	1	0	1
Netherlands	16	19	7	4
Portugal	23	19	5	-
Spain	1	7	1	2
Sweden	8	20	13	8
UK	-	-	174	97
Total	**189**	**233**	**309**	**159**
Source: EU ISS (2004)				

Table 4.9: Distribution of Injuries to Children Involving Ride-ons (Netherlands)	
Body Part	**% of Injuries**
Skull and Head Injuries	66 %
Arms	17 %
Legs	17 %
Total	**100 %**
Source: EU ISS (2004)	

Small Toys and Small Parts from Toys

This group of toys includes items such as model cars, planes, trains, marbles, beads and toy bricks, and these account for a significant proportion of all toy-related accidents (as shown in Table 4.10 below).

Table 4.10: Toy-related Accidents Involving Small Toys and Small Parts from Toys				
	1996	**1997**	**1998**	**1999**
Austria	0	1	0	0
Belgium	2	2	2	0
Denmark	9	2	27	0
Finland	3	6	7	-
France	3	4	2	2
Germany	0	-	-	-
Greece	147	2	135	6
Ireland	0	0	0	-
Italy	3	3	2	-

Table 4.10: Toy-related Accidents Involving Small Toys and Small Parts from Toys				
	1996	**1997**	**1998**	**1999**
Luxembourg	0	0	0	0
Netherlands	17	23	7	3
Portugal	12	15	4	-
Spain	0	0	0	2
Sweden	2	2	16	8
UK	-	-	138	133
Total	**198**	**60**	**340**	**154**
Source: EU ISS (2004)				

The majority of accidents involving such toys occur in children under three, and are caused when small parts are ingested, resulting in choking (obstruction of the gullet). Overall, it is estimated that 5% of all choking incidents involve toys (DTI, 1996). A significant further proportion of accidents involving these toys also occur when children trip over them, usually after leaving them on stairs or steps.

Projectile Toys

Projectile toys include toy guns, bows and arrows, water pistols and catapults (catapults are not considered as toys under the TSD). These could also come in more sophisticated forms, such as fashioned rubber dart guns, foot-bellows-powered rocket launchers, mechanical windup or string powered hand launchers for flying dolls, or more powerful dart guns, slingshots or crossbow-like toys.

The majority of projectile and flying toy-related injuries occur when a child is struck by the toy. Projectile toys can cut skin, blind or injure a child who is struck in the eye or ear. Eye injuries caused by projectile toys have been reported in the EU as well as in the USA, where rocket toys intended for 3-6 year olds have resulted in eye injuries (PIRG, 2002).

The Swedish Consumer Agency (SCA) has recently conducted a test of projectiles according to the SS-EN 71-1 (1999) Safety of Toys-Part 1 Mechanical and physical properties. In all, 70 projectile firing toys were tested. Three of these broke before or during the test phase; eight failed to meet safety regulations according to EN 71, Part 1 and 23 did not carry the warning text that is required for toys that have kinetic energy that exceeds 0.08 J, but which is under the limit of 0.5 J.

4.4.3 Impact of Origin of Toy on Toy Safety in the EU

Based on the data presented in Section 3, imports from non-EU countries represent a significant proportion of toys in the EU. It is thus to be expected that a significant proportion of toy-related accidents will involve imported toys.

Nevertheless, information received from various Competent Authorities and Market Surveillance Authorities indicates that the number of toys resulting in accidents,

withdrawn from the market or requiring consumer alerts from the Far East and Asian countries may be disproportionate to their market share. The toys of concern are typically those found in significant numbers at the cheaper end of the toy market, e.g. low price shops, discount stores, street market places or given away as free gifts. Many unsafe toys are also found in souvenir shops and, in some case, are labelled as not being toys so as to circumvent the TSD requirements (i.e. there would be no need for a CE marking on such toys). These unsafe toys rarely involve major brand name manufacturers who produce toys in the Far East.

While statistical data to back up these assertions have not been provided, a number of Member State surveillance authorities have identified certain types of toys imported from Asian countries, particularly China, as being a significant majority of all unsafe toys. For instance, the Swedish Authorities indicate that most of the soft toys that were found not to comply with the Directive were imported by companies that are not members of the Swedish branch organisation for such products. Information received from the new Member States suggests that toy imports from Asia are also an issue with regard to toy safety in those countries. One Competent Authority indicated that in a trade inspection of 9,000 batches of toys, 15% were found to contain irregularities and the majority were of Asian origin (particularly China and Taiwan).

This does not, however, imply that all toys from the Far East and Asian countries are dangerous. One Competent Authority has indicated that the large market in the EU has encouraged a lot of manufacturers in the Far East to improve the safety of their toys. Industry also highlights the fact that since China (and Asian countries in general) supply most of the EU (and world) toys, the percentage of non-complying toys originating from these countries will inevitably be high. Industry also noted that major brand companies manufacturing in the Far East apply high safety standards to all their products, wherever these are manufactured.

In addition to dubious imports from outside the EU, one Competent/Market Surveillance Authority has noted that even responsible EU importers have been found to rely solely on the fact that they have ordered CE marked toys. No further assessment of the safety of these toys, additional risk assessment or in-house testing is carried out by the importer. Tests have shown that a number of imported toys which are CE marked do not pass all the required tests. One Competent Authority also noted that many toys originating in the USA have no CE mark, for example toys given away with children's meals.

In relation to the impact of the origin of toys on the risk posed by a toy, some consultees have noted that the increasing number of toys sold via the Internet raises a new issue for toy safety. The information required to enable a consumer to make a safe purchase does not necessarily appear on sales websites. A survey conducted by the authorities responsible for product safety in the five Nordic countries (Iceland, Denmark, Norway, Sweden and Finland) under the Nordic Cooperation Forum for Product Safety found that websites selling toys on-line provided only limited information about the safety or use of the toy. Information that a certain toy was not intended for, and might be dangerous to, children under 36 months was missing on nearly all the websites visited (NCFPS, 2002).

4.4.4 Other Accidents Involving Toys and Toy-like Products

An overview of the types of accidents shows that a number of toy-related accidents are caused by:

- children using products not intended as toys, e.g. ones with child-appealing decorative features;
- toys with other uses, e.g. promotional items;
- unforeseen circumstances, e.g. falling over the toys on the stairs; and
- toys which by their nature or the skill required for operation are inherently more risky and would require protective equipment (e.g. skateboards, bicycles and scooters).

Such accidents also include those resulting from lack of proper supervision, in cases where the manufacturer has made the product to the required safety standards but specified that it cannot be used without adult supervision. Lack of supervision can transform a safe toy into a dangerous one, in circumstances that may not be foreseen by the manufacturers or even the parents.

As well as accidents associated with the toys themselves, injuries can occur when children and adults trip on toys. The most serious of these accidents occur when toys are left on stairs or steps. This may in part account for the higher number of leg injuries observable in toy-related accidents involving adults. Some of the above accidents, although involving toys, cannot be directly linked to or dealt with under the TSD and such accidents may constitute a significant proportion of all accidents. The exact proportion, however, is not known.

Information on such accidents would be useful in drawing conclusions from the statistics on toy-related accidents about the effectiveness of the Directive in achieving its objectives. Unfortunately, a number of databases do not permit distinctions to be made between accidents associated with factors that can be addressed under the TSD and those which cannot. This could only be achieved through an appropriate and robust EU home and leisure accident surveillance system.

Other products, which are not defined as toys according to the existing TSD, are known to cause accidents when children play with them. Examples of such products include CDs, crayons, scissors, confetti, fireworks, toy boxes, buttons, tokens, coins, batteries etc (CRIOC, 2002). Others, such as fashion jewellery, which are excluded from the list of toys, are also known to be used by children. There are also products, which may have child equivalents, where the models bought for and used by children (sometimes from as young as seven years) have been designed for adults e.g. cycles, scooters, roller-skates and skateboards. The use of such products makes it difficult to distinguish between accidents resulting from children using toy models and children using adult models. This is of particular significance where there is an increase in particular types of accidents resulting from certain toys. For instance, the increase in the number of accidents resulting from roller-skates, skateboards, cycles and scooters in the UK in the 1990s (as discussed in Section 4.3.5).

4.5 Areas where the Existing TSD has Achieved its Objectives in Relation to Toy Safety

4.5.1 Introduction

As part of the consultation process Competent Authorities, Market Surveillance Authorities, Notified Bodies, consumer organisations and manufacturers were asked for their views on the impacts of the current Toy Safety Directive in ensuring that toys placed on the EU market are safe. Although responses varied, similar issues were identified by the different groups of consultees. This Section therefore summarises the findings of the responses received from the various stakeholder groups.

Consultees identified a number of positive aspects of the Directive:

- better manufacturer awareness of requirements for toy safety;
- reductions in the level of non-conformity amongst toys on the EU market;
- establishment of a harmonised framework (based on the New Approach) for ensuring that toys comply with the TSD's essential safety requirements and, consequently, ensuring the free movement of toys (see Section 3.4); and
- reductions in numbers of toy-related accidents (discussed earlier in this Section).

Respondents were not unanimous, however, in their evaluation of the positive impacts of the Directive.

4.5.2 Better Manufacturer Awareness of Safety Requirements

One Competent Authority identified better awareness of safety issues amongst toy manufacturers in the EU as a significant benefit of the Directive. This was supported by a number of notified bodies, which indicated that major manufacturers understood the requirements of harmonised standards well and designed toys with these in mind. As a result, most toys submitted for initial testing already complied with the standards. Some manufacturers' associations however noted that their member companies had been well aware of the need to ensure the safety of toys before the Directive was introduced.

Another Competent Authority believed that the Directive has also had a significant role outside the EU, for example in making manufacturers in the Far East improve toy safety in order to retain access to the important EU market.

4.5.4 Reductions in the Level of Non-Conformance

There were mixed views on the extent to which the Directive had reduced the level of non-conforming toys on the EU market. Some Competent Authorities and consumer organisations believed that it had resulted in fewer unsafe toys being placed on the EU market than in the past, with this being linked to a stringent enforcement regime. A manufacturers' association was of the view that there is a direct correlation between the level of enforcement in a Member State and the level of non-compliant toys on the Member State's market.

Other consultees felt that there had been no areas of significant improvement and that there were still many non-compliant toys on the market. One manufacturers' association noted that the expectation that 100% conformance with the Directive could be achieved was unrealistic.

One Competent Authority noted that the range of toys in regular toyshops was safer than 25 years ago, but there were still problems with cheap imports. Several consultees supported the view that the cheaper end of the market was the one posing most compliance problems. An industry association noted, however, that toys in general are inexpensive, whether they are imported or not. Thus the perception that imported toys are 'cheap and nasty' is not relevant today. The association notes that the growth of brands and licensing and the need to preserve a good reputation, as well as the European standards, the TSD and greater awareness of toy safety, have resulted in improved safety standards in Far East countries.

4.6 Areas Where the Existing TSD May Not Have Achieved its Objectives in Relation to Toy Safety

4.6.1 Introduction

Consultees were asked to identify areas where the objectives of the Directive may not have been achieved or where improvements could be made, covering both the safety of toys and compliance with the Directive by manufacturers. Again, a number of different issues were identified, although one manufacturers' association noted that experience with the Directive had generally been positive. Issues included:

- the definition of toys;
- linked to this, the labelling of toys;
- the adequacy of harmonised standards and gaps in essential requirements; and
- enforcement.

4.6.2 Definition of Toys

Confusion over the definition of toys was identified by a number of Competent Authorities, Market Surveillance Authorities and consumer organisations. Several Competent Authorities noted that whether a product met the definition of a toy, and was thus subject to the Directive, was the most frequent source of queries from manufacturers. Manufacturers' associations also indicated that determining whether or not a product was a toy (and as such, whether it should carry the CE mark) caused difficulties.

Other frequent queries to Competent and Market Surveillance Authorities included the suitability of toys for children under three years of age. Two Competent Authorities also identified gaps in the Directive definition, excluding certain types of items used by children when playing, for example products for school use.

Consumer organisations have also highlighted the need for a more flexible approach to modifying the list of products not considered as toys (listed Annex 1 of the TSD) which would not require the revision of the Directive.

4.6.3 Labelling of Toys

A significant problem identified by Competent and Market Surveillance Authorities was the practice of labelling products that were obviously toys as "not suitable for children", apparently in order to circumvent the requirements of the Directive. One Competent Authority cited the example of soft toys labelled as "executive toys". Examples were also given of toys clearly designed for children under three years labelled as not suitable for them.

Other problems with labelling identified by respondents related to manufacturers' awareness of their responsibilities under the Directive. Some Competent Authorities believed that manufacturers equated meeting the labelling requirements with compliance with the Directive. They did not appear to realise in all cases that CE marking implies responsibility for the safety of the toy. Several Competent Authorities cited examples of CE marked toys that did not comply with the essential requirements of the Directive, and there were also examples of fraudulent or incorrect labelling.

One Notified Body believed that Asia/Pacific manufacturers appeared to have little knowledge of the requirements for CE marking; while a Competent Authority noted that importers did not necessarily check the safety of toys themselves but just relied on the CE mark affixed by the manufacturer. Linked to this, one Notified Body indicated that there were sometimes problems of clarity over the definition of "authorised representatives" of overseas manufacturers under the Directive, while a Market Surveillance Authority had experienced unclear paper-trails where manufacturers were based outside the EU.

4.6.4 Adequacy of Harmonised Standards and Gaps in Essential Requirements

Several respondents raised the problem of harmonised standards not adequately covering the essential requirements of the Directive and of gaps in the coverage of potential safety issues. These included lack of provisions on maximum noise levels, drowning risks and choking incidents with toys larger that the size specified in standards. The risks posed by the chemical properties of toys were identified as a gap in requirements by a number of Competent Authorities. Another Competent Authority believed that the lack of coverage of environmental issues was a shortcoming.

More generally, one Competent Authority raised the point that standards were not able to address newly-identified hazards in a quick way; instead, authorities had to wait for incidents to happen before they could take action. Other Competent Authorities, and manufacturers, identified problems with the differing interpretation of standards by notified bodies. Meanwhile, a Notified Body claimed that the gap between the self-certification/harmonised standards approach and type approval was too large, with a full type approval process having to be undertaken if one small aspect of a toy was not covered by the appropriate standard.

4.6.5 Enforcement

Inadequate enforcement of the Directive was recognised as a significant problem by many respondents, resulting in non-compliant toys remaining on the EU market. A consumer organisation commented that the extent of enforcement activity had reduced markedly over the past 15 years. Manufacturers' associations believe that lack of enforcement undermines the efforts made by responsible toy manufacturers to ensure the safety of their products and reduces consumer confidence.

Effective enforcement was seen as essential to the proper functioning of the Directive, particularly in cases of self-certification of compliance with harmonised standards. One Competent Authority commented that self-certification did not work, because of the perceived low risk of any infringements being caught. Another noted that the CE self-certification procedure must be foolproof to operate effectively, including proper enforcement. A Notified Body commented on the variation in enforcement practices in different Member States, which was reflected in the extent of testing that manufacturers undertook before placing toys on the market in particular countries.

One Competent Authority noted that administrative cooperation between Member States needs to be improved, particularly with regard to notifications. Under the Low Voltage Directive, Member States exchange information on dangerous products by uploading it to the CIRCA system. This means that, theoretically, dangerous products can be identified by other Member States within hours of being reported. The Competent Authority suggested that the CIRCA system may be particularly useful for recording problems regarding grey zones (pers. comm.). One Manufacturers' Association also noted that an improvement in administrative cooperation between Member States Market Surveillance Authorities would be useful.

4.7 Actions to Improve Achievement of the Directive's Objectives

4.7.1 Introduction

Consultees suggested a number of actions that could be taken to address the areas for improvement of the Directive that they had identified. The suggested actions covered:

- the definition of toys;
- the classification and labelling of toys;
- the scope of standards and requirements;
- assessment methods and information for consumers;
- updating the TSD in line with developments in the toy sector; and
- improvements in quality and extent of enforcement (discussed in Section 4.6.5 above).

4.7.2 Definition of Toys

In response to the problems identified in relation to the definition of toys, respondents suggested a number of potential actions. These included clarifying the list of items not considered to be toys and providing further clarification of the grey area between toys and non-toys. One respondent suggested specifically including items used by children in schools within the scope of the Directive. In general, manufacturers' associations believed that clarifying definitions and the scope of the Directive were the key areas for improvement.

4.7.3 Classification and Labelling of Toys

On labelling, suggestions for action were focused on safety warnings. Competent Authorities and consumer organisation suggested that the requirements for presentation of warnings could be made more precise, particularly in relation to the size and detail of warnings. One consumer organisation felt that safety warnings could get lost amongst the large amount of information provided on labels, particularly those using a number of languages, and suggested that the development of pictograms could be a way to address this problem.

4.7.4 Scope of Standards and Requirements

Most suggestions for action in relation to the scope of standards and requirements concerned the chemical composition of toys. One Competent Authority called for the requirements relating to chemical composition to be revised completely; a consumer organisation suggested that the long-term effects of certain chemicals had not been adequately addressed and should be. Other actions suggested by Notified Bodies and Competent and Market Surveillance Authorities include limit values for the content and migration of chemicals and an indication of the chemical composition of toys on labels.

4.7.5 Assessment Methods and Information for Consumers

One Market Surveillance Authority suggested that the content of technical reports and methods of assessing compliance could be improved as a means of improving compliance. A consumer organisation believed that better information for consumers on the meaning of CE marks could have a similar effect.

4.7.6 Updating the TSD in Line with Developments in the Toy Sector

Most stakeholders indicated that there should be the possibility to add, modify or specify in detail essential requirements in a flexible way after adoption of the Directive so as to reflect modern toy trends. The speed of introducing modifications to harmonised standards also needs to be rapidly increased. Currently, the fad for a particular toy can be over before the standards are updated. The possibility of using the comitology procedure to ensure that the essential requirements of the TSD are in line with developments in the toy sector should be explored. This may potentially address the issue of counterfeiting (discussed in Section 3.5) as obtaining quick access to regulatory protection and adequate enforcement is potentially part of the solution.

5. PROPOSED MODIFICATIONS TO THE TSD

5.1 Introduction

The discussions in this Section are based upon draft proposals (setting out the proposed TSD) which were made available to the Consultants by the Commission's services for this study.

The proposed modifications to the TSD cover:

- clarifications in the **definitions and scope** of the TSD;
- clarifications and additions intended to address the **safety of toys**;
- **other proposals** relating to the safety of toys which may be included in the proposed TSD; and
- clarifications on the **duties of regulatory authorities and Notified Bodies**.

The impact of each of the proposed modifications is discussed in detail below. The assessment of impacts is based on consultation with the following stakeholders:

- EU manufacturers, suppliers and distributors of toys and their trade associations (at Member State and EU levels);
- Competent Authorities and Market Surveillance Authorities in EU Member States (including the new Member States);
- Notified Bodies based in the EU; and
- consumer organisations based in the EU.

5.2 Clarifications in the Definition and Scope of the TSD

5.2.1 Nature of the Proposed Modifications

The proposed modifications to the definition and scope of the TSD are set out in Table 5.1. They cover:

- the definition of toys;
- definition of economic operators;
- responsibilities of economic operators; and
- the scope of the TSD.

Table 5.1: Proposed Modifications to the Definition and Scope of the TSD

Toys are defined as "products designed or intended, whether or not exclusively, for use in play by children under 14 years of age".

Definitions of **economic operators** are clarified:

- *manufacturer* means the natural or legal person who: a) designs and manufactures a toy or who has a toy designed and manufactured, with a view to its placing on the market under his own name or trademark; or b) places a toy on the market under his own name or trademark;
- *importer* means any natural or legal person other than the manufacturer established in the Community who places a product from a third country on the Community market; and
- *distributor* means any natural or legal person in the supply chain who takes subsequent commercial actions after the toy has been placed on the market in the Community.

Responsibilities of economic operators are clarified; *manufacturers* of toys are responsible for meeting the requirements of the TSD only if they are established in the Community. Otherwise, the responsible person is:

- the manufacturer's *authorised representative*, if one has been appointed, for the tasks that he has been mandated to carry out; or
- the *importer* of the product, if there is no authorised representative to carry out the task in question.

The **scope** of the TSD is clarified. It will not apply to:

- automatic playing machines, whether coin operated or not, intended for public use in areas accessible to the public;
- electronic equipment, such as PC and game consoles, used to access interactive software and associated peripherals, if these associated peripherals are not specifically designed for and targeted at children and have a play value in their own right, such as specially designed key boards, joy sticks or steering wheels; and
- interactive software, such as computer games, and their storage media**,** such as CDs.

5.2.2 The Definition of Toys

The proposed modification would define toys as "products designed or intended, *whether or not exclusively*, for use in play by children under 14 years of age".

The aim of the proposed modification is not to change or widen the scope, but only to clarify it, especially in relation to certain new products. The words "whether or not exclusively" mean that all products which fulfil the definition of a toy (set out above) are covered by the TSD, regardless of whether they have another intended purpose apart from playing, or are used by adults. This is only meant to confirm present practice.

Views of stakeholders on the impacts of this modification were varied. Some consultees felt that it would result in little change compared with the current TSD, some felt that it provided a useful clarification of the existing definition whilst others felt that it created new areas of uncertainty about which products were included within the scope of the TSD.

Few industry or Notified Body respondents believed that the change would increase the number of products covered by the TSD, although a small group of specialist toy manufacturers thought that the number of toys covered by the TSD could increase by 10%. By contrast, a significant majority of Competent and Market Surveillance Authorities felt that the change would increase the number of products subject to the TSD, although 30% of such respondents already interpreted the TSD in line with the proposed modification. This indicates that the modification may result in a more consistent interpretation amongst Competent and Market Surveillance Authorities of the definition of a toy.

Since it is evident that the TSD cannot define its scope exhaustively, a number of respondents suggested further ways in which the type of products subject to the TSD could be clarified, including:

- guidance for retailers on what is and is not a toy (examples were given of existing guidance); and
- lists of toys and non-toys, not necessarily comprehensive but updated periodically, to provide guidance to Notified Bodies.

Some respondents also proposed a simplified definition, such as "products for use in play by children under 14 years".

5.2.3 Definition of Economic Operators

The proposed modification provides a series of definitions, intended to provide clarification of the economic operators with responsibilities under the TSD. Respondents welcomed the fact that the definitions provided clarity and harmonisation with other New Approach Directives, but felt that they would result in little or no practical change.

5.2.4 Responsibilities of Economic Operators

Following on from the definitions, a change is proposed to the responsibilities of economic operators under the TSD. The proposed modification clarifies that manufacturers are only responsible for meeting the requirements of the TSD if they are established in the EU. Where manufacturers are based outside the EU, responsibility for meeting the requirements of the TSD would be borne by:

- the **manufacturer's authorised representative**, if the manufacturer has appointed one, for the tasks that he has been mandated to carry out; or
- the **importer** of the product, if there is no authorised representative to carry out the task in question.

In addition, **distributors** whose activities may affect the safety properties of the toys must make sure that the toys they are distributing comply with the essential safety requirements and that they only distribute toys bearing the CE mark and identification of the manufacturer.

Most respondents felt that the change provided a useful clarification of responsibilities, but would make little practical difference to the current situation. Two consumer organisations, though, felt that it would emphasise the importance of toy safety to those in the supply chain, with benefits for consumer safety.

Some Competent and Market Surveillance Authorities noted that there were difficulties in identifying authorised representatives and in obtaining relevant information from them, particularly if they are located in another Member State. Two authorities currently hold importers of toys into their country responsible for the safety of toys and felt that these importers should be responsible for contacting the authorised representative or manufacturer to obtain they relevant information. However, importers did not agree but insisted that the authority should contact the EU manufacturer or authorised representative directly [20]. This appears to be an issue of enforcement policy, though, rather than a reflection on the requirements of the TSD.

One Competent Authority noted that, if distributors tamper with a toy in such a way that the safety is affected, it may not be appropriate or fair for the toy to bear the name of the manufacturer. Instead, it should bear the name of the distributor.

5.2.5 Scope of the TSD

The proposed modifications clarifies the material scope of the existing TSD. It is proposed that the TSD shall **not** apply to:

a. **automatic playing machines**, whether coin operated or not, intended for public use in areas accessible to the public;
b. **electronic equipment,** such as PC and game consoles, used to access interactive software and associated peripherals**,** if these associated peripherals are not specifically designed for and targeted at children and have a play value in their own right, such as specially designed key boards, joy sticks or steering wheels; and
c. **interactive software**, such as computer games, and their storage media**,** such as CDs.

Most respondents agreed that the proposed modification would have few practical implications and would not significantly affect the number of toys subject to the TSD.

One trade association (representing producers of game consoles and related software) indicated that its members were worried about proposals (b) and (c). However, it did not provide any further information as it indicated that it was in negotiation with the Commission on these proposals.

[20] Section 5.4.5 sets out an alternative proposal to the above proposal, in which it is mandatory for manufacturers outside the EU to have an authorised representative in the Community. Under this (alternative) proposal, the importer cannot be held directly responsible for meeting the requirements of the TSD.

5.3 Safety of Toys

5.3.1 Nature of the Proposed Modifications

The proposed modifications in relation to the safety of toys are set out in Table 5.2. They cover:

- reasonably foreseeable misuse of toys;
- CE marking – reference to other Directives;
- CE marking – on toys and packaging;
- toys at fairs;
- hazard analysis;
- production of technical files;
- warnings on toys;
- asphyxiation risks;
- choking risks for children above 36 months;
- chemical properties of toys; and
- toys intended for children under 36 months or intended to be put in the mouth.

Table 5.2: Proposed Modifications to the TSD to Address the Safety of Toys

The essential requirement on the safety of toys will be extended to include protection of health hazards and risk of physical injury during "**reasonably foreseeable misuse**" of toys as well as their use as intended or in a foreseeable way.

Toys that are covered by other Directives that require CE marking are required to **reference these other Directives** in the documents accompanying the product or on the packaging, and in the EC declaration of conformity.

CE marking and the name, or mark and address of the manufacturer, authorised representative or importer must be marked **on the toy** and on the packaging, unless the CE mark is visible from the outside.

Member States shall permit toys not CE-marked and not complying with the TSD to feature in **trade fairs and exhibitions**, provided they are clearly signed as such and are not for sale or for distribution free of charge.

Manufacturers (or authorised representatives/importers) must carry out **analysis of the hazards** that a toy may present before placing it on the market.

When market surveillance authorities request production of a technical file or a translation from it, a **deadline** of 15 days (or less) is now proposed for presenting that information. If the manufacturer does not meet this obligation, he may be required to have a test performed by a Notified Body to verify compliance.

Two changes are proposed for **warnings** on toys:

- where appropriate, warnings must specify minimum or maximum ages for users of toys and maximum or minimum weight of the user and ability of users as well as the need to ensure that the toy is used only under adult supervision; and
- all required information shall be readily visible, noticeable, clearly legible and prominently displayed at the point of sale.

Toys, and their parts, and the packaging in which they are contained for retail sale must not present a risk of **asphyxiation** caused by strangulation or suffocation.

Choking risks should be covered for toys intended for children above 36 months or for toys intended, likely or enticing to be put in the mouth.

5.3.2 Reasonably Foreseeable Misuse of Toys

The proposed modification would amend the requirement in relation to the essential safety of toys as follows:

'users of toys as well as other persons 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, including the reasonably foreseeable misuse of the toys'.

Respondents had a number of concerns about the impacts of this proposed modification. These primarily related to the potential for different interpretations of this requirement, related to differences in culture and habitats as well as technical considerations, leading to uncertainty for industry, Market Surveillance Authorities and Notified Bodies.

Industry was particularly concerned that the phrase could result in increased litigation against manufacturers over toy-related incidents, even when toys were complying fully with harmonised standards (current harmonised standards have not been developed to take account of misuse of toys). The concept of addressing misuse in assessing safety is not found in other product safety directives (although Notified Bodies indicated that misuse was taken into account when testing products under other Directives, for example on machinery).

There were differing views amongst industry respondents on the cost implications of the proposed modification. Most respondents believed that the change would not affect procedures for assessing safety, as these are already extensive. In contrast, some industry respondents believed that the lack of coverage of misuse in harmonised standards would mean that every toy had to go through type approval. It could also increase insurance costs (because of the likelihood of increased litigation). It might also result in the withdrawal of toys from the market. The reasoning behind this is that, once any toy is involved in a single incident, the cause of the incident has to be investigated and the hazard posed by the toy assessed. If the accident has resulted from misuse of the toy, this then becomes a 'foreseeable misuse' that would have to be addressed in future.

Consumer organisations were generally satisfied with the increased emphasis placed by the proposed modifications on the manufacturers' responsibility to ensure that the often unpredictable behaviour of children is taken into account when designing their products.

The other main concern of consumer organisations was the meaning and/or interpretation of 'normal' in the TSD, as this could be interpreted in many different ways. However, this wording is a feature of the current TSD and no modifications to it have been proposed.

5.3.3 CE Marking – Reference to Other Directives

Under the proposed modification, toys that are covered by other Directives which require the affixing of the CE marking are required to reference the other Directives which also apply to that toy in the documents accompanying the product or on the packaging, and in the EC declaration of conformity.

In general, respondents indicated that there would be few, if any benefits for consumers from this modification. Consumers have limited understanding of the significance of a CE mark and reference to other Directives could be confusing. The majority of surveillance authorities believed that the modification would bring benefits, but some argued that these benefits could be achieved through the inclusion of a reference to other Directives in the declaration of conformity rather than on the toy or packaging.

Whilst 25% of industry respondents thought that the proposed modification would not impose additional costs, others said that the need to modify packaging design, in order to accommodate the additional text, could result in significant costs. There could also be practical problems in adding additional text to small packages. Consumer organisations agreed that adding further text to packaging could be confusing for consumers.

5.3.4 CE Marking on Toys and Packaging

The second proposed modification regarding CE marking is a requirement that the CE marking and the name or mark or address of the manufacturer, authorised representative or importer shall be marked on the toy and on the packaging unless the CE marking is visible from the outside. Exceptions for small toys will remain.

Surveillance authorities indicated that the requirement for markings to be placed on both the toy and the packaging could make their work simpler and more efficient, especially in relation to toys that are not new and which may have become separated from their packaging. However, warnings are seen as more important than the CE mark and surveillance authorities envisaged that the modification would only have limited impacts on toy safety. This reservation was shared by consumer organisations, which believed that greater consumer awareness of the meaning of the CE mark is required for it to play a significant role in consumer choice.

Industry expressed considerable concern about the impacts of this proposed modification, in terms of both cost and practical implications. The impacts are most significant for plastic toys; adding the CE mark and manufacturer's name would require modification of the moulds used to make the toys, which could incur very significant costs.

There are also logistical considerations, particularly for SMEs. SMEs often buy-in part of a major production run of toys from non-EU manufacturers to sell on the EU market. In many cases, the majority of the production run may be intended for non-EU markets and thus the manufacturers are unlikely to be willing to modify the mould to meet EU requirements. This would remove an important source of products for the EU industry. Adding further information onto a toy may also raise difficulties in terms of the space available on a toy and the aesthetic impact of adding further information. The impacts are less significant for plush toys, as the information could be added simply by replacing current labels; it is not clear how the requirements would be met for wooden or (non-moulded) metal toys.

One further issue is that the complexity of the toy supply chain, as described in Section 3 of this Report, means that the manufacturer of a toy does not necessarily know who the

importer of the toy into the EU will be. Toys manufactured by one company may be imported into different EU markets by different importers. In this case, it would be impossible for the manufacturer to mark the toy with the correct name of the importer. If the importer had to add this information to the toy, this might require the removal of packaging in which the toy was imported, addition of a further label to the toy (if practically possible) and re-packaging. As well as imposing significant costs, this would lead to increased generation of packaging waste.

5.3.5 Toys at Fairs

The proposed modifications make clear that toys which do not carry a CE mark, and which do not comply with the provisions of the TSD, can be exhibited at trade fairs and exhibitions. However, they must be clearly indicated as not complying with the TSD and not sold or distributed free of charge.

Industry respondents indicated that this proposed modification effectively clarified current practice.

Competent and Market Surveillance Authorities, and consumer organisations expressed some concern about the proposed modification, mainly because they did not understand why toys that would not be permitted on the EU market would be exhibited in the EU. (This comment appears to stem from a lack of understanding of the complexity and international nature of the toy industry). There was also some concern that the provision could result in non-compliant toys being sold or given away at the end of the fair or exhibition, although this would clearly not be in compliance with the Directive.

5.3.6 Hazard Analysis

Under the proposed modifications, manufacturers would explicitly be required to carry out a hazard analysis before a toy is placed on the market. Industry comments on this requirement mainly concerned what was meant by hazard analysis, as opposed to the risk assessment that is specified in harmonised standards. Industry believes that risk assessment is a more appropriate approach to adopt to ensure product safety.

If the intention of the proposed modification was to require a different approach, the TSD should specify what hazard analysis entailed and what additional information should be included in the technical files. In the absence of such clarification, the impacts of the proposed modification were difficult to determine.

5.3.7 Production of Technical Files

When a market surveillance authority requests production of a technical file, or translation of it, from a manufacturer, the proposed modification specifies that this should be presented in 15 days (or less). If this obligation is not met, the manufacturer may be required to have compliance of the toy verified through testing by a Notified Body.

Industry did not believe that this proposed modification would have significant impacts, provided that the request for technical files was justified. Clarification of when a period less than 15 days could be required was requested.

A significant majority of Competent and Market Surveillance Authorities indicated that this requirement would make carrying out their duties easier and more efficient. They did raise concern, however, about the need to make clear to manufacturers that compliance with the TSD related to the whole production line and that all toys, not simply the prototype tested for conformity, must be safe and meet the essential requirements of the TSD. One Competent Authority wanted the phrase 'by a notified body' removed from the proposed modification, so that testing could be carried out by any accredited laboratory.

5.3.8 Warnings on Toys

The proposed modifications include two changes in relation to warnings on toys:

- 'Where appropriate, warnings must specify minimum or maximum ages for users of toys and maximum or minimum weight of the users and ability of users as well as the need to ensure that the toy is used only under adult supervision'; and

- 'All required information shall be readily visible, noticeable, clearly legible and prominently displayed at the point of sale'.

Industry responses were mainly concerned with the interpretation of the requirements and their practicality. Some respondents were concerned that the phrase 'where appropriate' could be open to different interpretation by Market Surveillance Authorities. They considered that guidance was needed on how to evaluate the minimum and maximum ages and weight, and the ability, of users as well as an indication of the types of toys to which such indications applied. There were also practical issues with adding further information in the limited space available at the point of sale (and questions over how this requirement would be met for mail order, catalogue and internet sales). Some Notified Bodies expressed similar concerns.

Most Competent and Surveillance Authorities, and consumer organisations, considered that the proposed modification would benefit the consumer by ensuring the safety of toys for a particular child, as well as making enforcement easier and more efficient. The first requirement covered warnings that are already required by standards, such as 'not for children that weigh more than 20 kg'. The second requirement would make it easier to ensure that warnings are presented in such a way that they can be identified and read reasonably easily by purchasers, rather than hidden in a mass of multi-language text.

5.3.9 Asphyxiation Risks

The proposed modifications require that toys, their parts and packaging should not present a risk of asphyxiation caused by strangulation or suffocation.

In general, industry did not believe that the modification would have any significant implications, as it is similar to the position of the existing TSD and harmonised standards. However, some respondents expressed concern that the requirement could be interpreted as restricting the use of packaging such as shrink wrap, which is generally discarded before toys reach young children, or the sale of toys such as skipping ropes which could cause strangulation if misused.

Competent and Market Surveillance Authorities believed that the modification should result in a reduction in the number of unsafe toys. Notified Bodies agreed that the change was important, and two noted that they would need to identify an objective test to verify the risk as well as carrying out more tests on packaging.

5.3.10 Choking

The proposed modifications would extend the requirements relating to choking risks to toys intended for children above 36 months in age that are intended, likely or enticing to be put in the mouth.

Industry considered that this requirement would result in very significant impacts. The term 'enticing' was seen as problematic, as it is open to different interpretations by enforcement authorities. Industry indicates that this could be crucial in determining liability for toy-related accidents. Respondents noted that younger children tended to open toys using their teeth, even when this was not the intention of the manufacturer. In industry's opinion, the introduction of a specific reference to the risk of choking for children above 36 months would be workable only if strictly limited to 'other toys which are clearly intended to be put in the mouth'. Some Notified Bodies agreed that the requirement was unclear and open to different interpretations.

Most Competent Authorities, though, foresaw few problems in interpretation or enforcement of the requirement. One respondent considered that the modification would increase the safety of toys whilst another noted that it would bring the TSD into line with the size requirements of EN 71-1 standards; this was also noted by consumer organisations. One authority noted, however, that the modification does not take account of the role of parents in ensuring that the toys given to children are safe to play with.

5.3.11 Chemical Properties

Discussions on the chemical properties in the Expert Group on Toys Safety have covered the following issues:

- **manufacturers are expected to ensure that toys are designed and constructed so that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations**. One industry respondent noted that, because the regulation of chemicals is a complex area with often varying and opposing views regarding the safety of a substance or product, it may be useful to insert a caveat so that the point refers to '…no *proven* risk of adverse effects…';

- **toys shall in all cases comply with relevant Community legislation relating to the prohibition of use of certain dangerous substances and preparations, including Directives 76/769/EEC, 67/548/EEC and 1999/45/EC**. One Competent Authority requested that references to the Classification and Labelling Directive (1999/45/EC) should be clarified. An industry respondent asked whether nitrosamines used in the latex balloon industry would be affected by these proposals and, if so, how this would be addressed. Information received from industry indicates that, while it is aware of concerns about the possible effects of nitrosamines within latex balloons, no technology is currently available to eliminate nitrosamines completely from the latex balloon at point of sale. If the proposed TSD is based on an absolute prohibition, the European latex balloon manufacturing industry would face major impacts, and could even be shut down;

- **the use in toys of the following substances shall be prohibited: substances that are classified as carcinogenic, mutagenic or toxic for reproduction, category 1 and 2 (CMR) according to Directive 67/548/EEC, substances that are classified as causing skin sensitisation according to Directive 67/548/EEC, substances such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic (PBT) properties or very persistent and very bioaccumulative (VPVB) properties**. Industry questioned whether the prohibition of PBTs and vPvBs applied only to chemicals listed in Directive 67/548/EEC. If it extended to chemicals outside the Directive, it would be difficult for manufacturers to keep track of what they can and cannot use, and are consequently unlikely to comply with the Directive.

  There were differing views among Competent and Market Surveillance Authorities on Category 3 CMRs. Two authorities believed that Category 3 CMRs should not be permitted in toys and supported a blanket prohibition, while three authorities opposed a blanket ban on Category 3 CMRs, noting that, until further scientific evidence is available, these substances should be treated on a case by case basis. Other Authorities called for the prohibition of substances with allergenic properties (in line with the Cosmetics Directive), substances classified as causing respiratory tract (inhalation) sensitisation or substances fulfilling the criteria for R43;

- **cosmetics, including fragrances and preservatives, used in toys shall comply with the Cosmetics Directive**. Further clarification on the type of cosmetics (i.e. cosmetic products in toys or cosmetic toys) being referred to may be required; and

- **bioavailability of chemicals resulting from the use of toys must not exceed specified levels**. Two Authorities were of the view that, in addition to bioavailability, there should be specific requirements concerning the content (not the migration/release) of substances, in particular heavy metals. There should also be some requirements regarding organic chemicals.

Industry has made comments on the following issues:

- **proposals that toys may not contain substances meeting the criteria for classification as 'toxic', 'harmful', 'corrosive' (above a certain concentration limit, e.g. 0.1%) according to the provisions of Directive 67/548/EEC unless the Scientific Committee has performed an evaluation (and found the use to be acceptable in toys)**. According to industry, while it does not use materials which are classified as toxic according to Directive 67/548/EEC, the finished materials used to make a toy may contain impurities from the manufacturing process which, as isolated substances, would be classified as hazardous. Industry thus believes that it is more appropriate to require that the relevant substances should not be *released* in amounts that could be harmful to health than to prohibit their presence. Industry also highlighted that the Scientific Committee is explicitly mentioned with a given task only in Annex II, and this is not consistent with the rest of the TSD. Under the existing TSD, Notified Bodies are currently required to deal with these issues and industry supports Notified Bodies undertaking this task;

- **a complete ban on CMRs Categories 1 and 2 (without the possibility of an authorisation)**. As with the previous proposal, industry notes that, while the finished materials used to manufacture a toy are not classified as Category 1 and 2 CMRs, they may contain impurities of substances from their manufacturing process which could be Category 1 and 2 CMRs. Industry also emphasised that it is the intentional use of Category 1 and Category 2 CMRs to make toys that should be banned, not their presence as impurities/residuals. In industry's view, a complete ban of all Category 1 and 2 CMRs, would result in most plastics being banned and potentially 80% of all toys disappearing from the market. Importers and retailers, however, may require guidance on how to fulfil relevant requirements for technical files;

- **for CMRs Category III, it is proposed that they be banned in principle but with a possibility of authorisation under certain conditions after a risk assessment provided by the manufacturer and evaluation by the Scientific Committee**. Industry indicates that a default ban is unacceptable, as it would affect numerous substances which have been used safely for many years and for which toxicological information is currently incomplete. There was also concern that this part of the Directive could become very confusing, particularly for suppliers who are expected to be able to demonstrate compliance; and

- **for substances that are skin sensitisers and respiratory tract sensitisers, it is proposed that they be banned, but with the possibility of an authorisation under certain conditions after a risk assessment provided by the manufacturer and evaluation by the Scientific Committee. An alternative proposal is that 'they should not be used in toys in such a way that they come into contact with skin or are released in the air'. The same requirements would apply to fragrances/preservatives**. Industry comments were similar to those made in response to the previous proposal. It was noted that sensitisers are ubiquitous by nature and that a number of natural sensitisers would be covered by the ban.

In general, industry agrees that the chemical section of the TSD must be upgraded to ensure that toys should not pose any risk of damaging children's health. However, there are concerns about how this is to be achieved. One respondent was concerned that, by failing to develop specific norms and testing for toys, the industry could end up with disproportionate testing requirements developed for other sectors, which are left to individual interpretation. This could result in significant costs for industry. Industry also noted the importance of combining modifications to the Directive with specific testing requirements. Where this is not done, testing laboratories will be left to develop their own approaches, and there will be no means of ensuring that the Directive is being complied with.

5.3.12 Toys Intended for Children Under 36 months or Intended to be Put in the Mouth

Under the proposed TSD, toys intended for children under 36 months, or intended to be put in the mouth are expected to comply with the food contact materials legislation as well as regulations setting maximum levels for certain contaminants in foodstuffs.

The main points raised with regard to this proposal include:

- while the upper limit of the food contact legislation is generally quoted as a specific migration level (which defines how much of a substance may be transferred from packaging to 1kg of a foodstuff prior to consumption), substance transfers from toys put in the mouth are not comparable with transfers from food packaging;

- the food contact legislation is only appropriate for certain specific toys and will require the development of an application "concept", including testing methods (migration), as the tests in the regulations have been developed for a different type of application. An industry respondent noted that food-grade plastics are very expensive compared with other plastics, so that if their use was required costs could increase significantly. The alternative, of testing each material in line with the food contact legislation, would also be expensive and not necessarily appropriate (for example, the olive oil test); and

- risk assessments for food contact materials are different from those for toys intended for children under three years.

  Industry was also not in favour of having **positive/negative lists of these substances in the TSD, with the possibility of updating these fairly**. In its opinion, positive lists are design-restrictive and are not in line with the New Approach. Industry also considered that CEN TC52 has made a good start on this issue. Responding companies noted that it would be useful, if not common regulatory practice, to have a list of banned and/or restricted substances. It was pointed out that the industry often deals with suppliers that cannot guarantee the absence of particular substances. The only way to ensure they are not present is to perform tests; industry thus needs to be provided not only with the list of banned substances, but also the list of tests to be performed.

5.4 Other Proposals

5.4.1 Nature of the Proposals

The proposed modifications include a number of other proposals relating to the safety of toys, which may be included in the TSD. These proposals are summarised in Table 5.3 and cover:

- third party verification;
- choking in children over 36 months;
- toys in food;
- modification of the role of the authorised representative;
- the new EU chemicals policy (REACH); and
- other proposals.

The potential impacts of these changes are discussed below.

Table 5.3: Other Suggested Changes to the TSD

Mandatory third party verification for certain categories of toys.

Increasing the age limit for choking risks from 36 to 60 months.

Addressing the issue of toys in food.

A provision requiring manufacturers established outside the EU to have an authorised representative.

It is intended that the new EU chemicals policy (REACH) will apply to toys when/if it is adopted in the future.

Other measures:
- limiting the speed of electrically-driven ride-on vehicles;
- requiring toys to be designed and constructed so that sound from them cannot damage children's hearing;
- adding the caveat 'unless essential to proper functioning of the toy' to the requirements on burning risks;
- a requirement to construct activity toys so as to create no risk of crushing or trapping body parts or clothing and to reduce risks of falls, impacts and drowning; and
- permitting electrical toys to deviate from the 24 volt limit if it can be ensured that the voltages would not lead to any risk of harmful electrical shock.

5.4.2 Third Party Verification

The introduction of mandatory third party verification for certain categories of toys has been suggested as a possible modification to the TSD.

Responses from industry indicate that a number of manufacturers already undertake third party verification of toys' conformity with harmonised standards, in response to market pressures (particularly 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.

Most Competent 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 5.4.

Table 5.4: Respondent Suggestions of Toy Categories for Third Party Verification

Authorities	Notified Bodies	Consumers
- infant/pre-school toys; - electrical toys; - ride-ons; - dolls and 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).

5.4.3 Choking

The current TSD requires choking risks to be addressed in toys intended for children under 36 months of age. One proposal would be to extend this requirement to children under 60 months.

Industry respondents indicated that this requirement would be impractical, since very few toys are currently intended solely for children below 60 months. Such a modification would mean that children under 60 months would not be able to play with dolls with changeable clothing, small building bricks, small puzzles or activity toys with detachable parts. This would severely limit the developmental benefits of play. Industry respondents also indicated that the modification would have little impact on safety, as the risks associated with choking were considerably reduced above 36 months.

Other respondents, from authorities, Notified Bodies and consumer organisations, were uncertain about the advantages and disadvantages of the suggested modification. Some favoured the change on safety grounds and felt that it would incur few additional costs. Others noted that few children over four years tended to put things in their mouths, so the safety benefits would be limited, and that the change would also require amendments to harmonised standards

5.4.4 Toys in Food

The question of toys in food has also been raised in discussions on the amendment of the TSD, focusing on whether there is a need for special requirements and/or whether this problem should be addressed in the context of the age limits only or by specific warnings.

Most industry respondents felt that toys in food should be addressed within the TSD.

There was some disagreement on the definition of such toys; for example, should the definition include toys embedded in food, toys outside the food but packaged with it (e.g. cereals) or toys that make food? Notified Bodies had similar views, with one respondent suggesting the need for a specific test for toys that came into contact with food, addressing issues such as migration of substances from the toy into food. One Notified Body already carries out such tests, based on the requirements of the Directive on contact with foodstuffs.

Until recently, Commission-level discussions concerning food products containing inedibles (FPCIs) have fallen under the remit of the Emergencies Committee of the General Product Safety Directive (92/59/EEC). In May 2000, the Committee concluded that:

"In light of the information available to date, the risks associated with non-food products accompanying food products in a separate packaging seem to be no different to those presented by small toys in general or by toys containing small parts in general… the Committee considers that particular attention should be paid to every new development and fresh information making it possible to pinpoint any specific risk resulting from the association of food with non-food products in a separate package. In this context, a specific assessment should be conducted whenever new and relevant information occurs, to examine the possibility to establish European Standards specifically covering non-food products accompanying food products in a separate packaging."

A recent report for the European Parliament supported this view, finding that although the causal link between eating the food product and a subsequent incident is not proven, the risks associated with FPCIs are demonstrably low (RPA, 2003).

Most Competent and Surveillance Authorities felt that toys should be specifically addressed in the TSD, although 15% felt that other legislation, such as the General Product Safety Directive, covered the issue adequately. Consumer organisations noted that 'toys embedded in food' are prohibited in the USA and this should also be the case in the EU. They suggested that the present requirements concerning choking hazards for children below 36 months have not prevented fatal accidents; any part of a toy associated with a food item should be subject to the cylinder test in standard EN 71-1.

5.4.5 Role of the Authorised Representative

It has been suggested that the role of the Authorised Representative be modified as follows:

'Any manufacturer who places toys on the market under his own name shall notify the Competent Authorities of the Member State in which he has his place of business of the address of the registered place of business. Where a manufacturer who places his toys on the market under his own name does not have a registered place of business in a Member State, he shall designate an authorised representative. The authorised representative shall notify the competent authority of the Member State in which he has his registered place of business of the address of the registered place of business'.

The main point of this proposal (which is an alternative to the proposal presented in Section 5.2.4) is that manufacturers outside the EU would be required to have an authorised representative in the Community who would responsibility (rather than the importer) for ensuring compliance with the TSD.

Industry responses indicated that the proposed modification did not have any significant implications for the toy sector. Industry was, however, keen to stress that the proposal should take into account the complex structure of the toy industry. For instance, a number of major retailers (such as supermarkets) place toys on the EU market, either under their own brand name or trademark, or under another recognised brand name. In this case, it is the decision of the retailer (and not the brand name manufacturer) to place the toy on the EU market.

5.4.6 REACH (New EU Chemicals Policy)

It is intended that all manufacturers and importers of toys ensure that their products comply with REACH, the proposed Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, when it is adopted.

Industry noted that compliance with REACH may have significant impacts for the toy industry, particularly given the complexity of the supply chain, which may make it difficult to establish the full chemical content of toys. In safety terms, however, it is not the chemicals used in a toy that are important but the availability of these to children.

5.4.7 Other Measures

Speed of Electrically-Driven Ride-Ons

A suggestion that the speed of electrically-driven ride-ons should be limited, to minimise the risk of injury, received mixed responses from industry. Some respondents thought it could have significant positive benefits, although the implications would need to be assessed in detail; others considered that it was the location in which the toys were used, rather than the speed, which gave rise to risk. One respondent noted that too low a limit could make electrically-driven ride-ons unattractive to children, reducing the market significantly.

Preventing Damage to Hearing

Overall, respondents supported the suggestion that toys should be designed and constructed so that sound from them cannot damage children's hearing. Around 90% of respondents were in favour of such a requirement, although there were some concerns about the potential cost. One respondent noted that there was no objective evidence to indicate what level of sound would damage a child's hearing, so that that judgement of volume is subjective.

Modified Requirements on Burning Risks

No respondents envisaged benefits to either safety or cost from the suggested change.

Requirements for Activity Toys

Most respondents believed that the requirement would have a positive impact on safety; however, they were concerned about the potential costs of the resulting modifications to product design and manufacture.

Deviations from 24 Volt Limit

Industry respondents again believed that this suggestion could have a positive impact, without affecting safety. One manufacturer noted that technical advances in electrical devices should ensure that products above 24 volts could be used safely; US experience demonstrated that the current limit restricted design without benefiting safety.

One Competent Authority disagreed, as the proposed wording would set no limit on voltage. A Notified Body also argued that the limit should be retained, as a limit is easier to measure and interpret than an electrical risk, although another noted that it is the amperage not the voltage that is important.

5.5 Duties of Regulatory Authorities and Notified Bodies

5.5.1 Competent and Market Surveillance Authorities

The proposed modifications to the TSD set out in detail the powers and obligations of Market Surveillance Authorities. These are described in Table 5.5.

Table 5.5: Powers and Obligations of Market Surveillance Authorities
1. Member States shall ensure that the market surveillance authorities may, at least, take the following measures in respect of any toy placed on the market: (a) organise appropriate checks on an adequate scale, up to the final stage of use or consumption, in order to verify that toys comply with this Directive (b) require all necessary information from manufacturers, importers or distributors, in particular the presentation of the technical file (c) take samples of toys and subject them to safety checks (d) obtain access, on request, to the place of manufacture or storage (e) require from notified bodies any information on EC-type examination certificates that they have issued, withdrawn or refused, to the extent that this is necessary for effective market surveillance
2. Member States shall ensure that in respect of toys which may compromise the health and safety of persons market surveillance authorities may: (a) restrict or forbid their placing on the market (b) order or organise their actual and immediate withdrawal from the market (c) alert consumers of the risks they present (d) order or co-ordinate or, if appropriate, organise together with manufacturers and distributors their recall from consumers and their destruction in suitable condition
3. In addition to the powers provided for in paragraphs 1 and 2, the market surveillance authorities shall be empowered to: a) take preventive action to ensure that non-compliant products are not placed on the market b) apply dissuasive penalties (provided in another Article) to manufacturers, importers or distributors who do not comply with their obligations under this Directive c) take, where appropriate, any other measure provided in Article 8 of Directive 2001/95/EC (General Product Safety Directive)
4. When the surveillance authorities take any measures as provided for in paragraphs 1, 2 or 3 those measures shall be subject to the provisions of Article 8(2) and (3) of Directive 2001/95/EEC.
5. Measures taken by the market surveillance authorities under paragraphs 1, 2 or 3 shall be addressed, as appropriate, to (a) the manufacturer, his authorised representative or the importer, as appropriate (b) within the limits of their respective activities, distributors and, in particular, the party responsible for the first stage of distribution on the national market (c) any other person, where necessary, with a view to cooperative action to prevent risks arising from a product
6. In order to ensure effective market surveillance of toys, Article 9 of Directive 2001/95/EC shall apply.

The overall view of Competent and Market Surveillance Authorities was that setting out their powers and obligations brought benefits, even if some of these powers and obligations reflect current practice. One respondent noted that the reference to the General Product Safety Directive was particularly beneficial as harmonised provisions make enforcement easier. Some authorities indicated that additional costs might be incurred in meeting some of the requirements, in particular:

- organising appropriate checks on an adequate scale, up to the final stage of use or consumption, in order to verify that toys comply with this Directive; and
- taking samples of toys and subject them to safety checks.

5.5.2 Notified Bodies

The proposed modifications include four relating to Notified Bodies. These are summarised in Table 5.6.

Table 5.6: Proposed Modifications Relating to Notified Bodies

Location of Notified Bodies	The notified body must be established on the territory of the notifying Member State. It may have activities or personnel outside the Community, provided that it informs the notifying Member State accordingly and assumes full responsibility for any such activities or personnel.
Approval of Notified Bodies	The notified body, its director or the assessment and verification staff shall not be the designer, manufacturer or supplier of toys or the authorised representative of any of those parties; they shall not become directly involved in the design, production or marketing of toys or represent the parties engaged in these activities. They shall not provide consultancy within their conformity assessment activities, without prejudice to the exchanges of technical information between the manufacturer and the notified body.
Conformity Assessment Procedures	Before placing the toys on the market, manufacturers shall use the conformity assessment procedures identified in paragraphs 2 and 3 to demonstrate that the toys comply with the provisions of this Directive. They shall draw up the EC declaration of conformity in one of the languages of the Community in order to certify the compliance of identified individual products.
Activities to be Performed as part of EC-type Examination	Clarifies the activities to be performed as part of an EC-type examination as follows: • when a notified body carries out the EC-type examination, it shall evaluate, if necessary, jointly with the manufacturer, the analysis performed by the manufacturer of the hazards that the toy may present; • the EC-type examination certificate shall comprise a list of Directives applied, colour image of the toy and the number of the relevant test report; • the certificate shall be reviewed at any time and, where necessary withdrawn, in case of a safety problem with the product covered by the certificate; and • the file and correspondence relating to the EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to the notified body.

Location of Notified Bodies

The proposed changes permit Notified Bodies to have activities or personnel outside the EU, provided they inform the notifying Member State and take full responsibility for activities performed elsewhere. This is intended only to confirm present practice, as this option has always existed even if it has not been explicitly mentioned in the TSD.

The majority of responding Notified Bodies expressed concern about this proposed modification, fearing that it could lead to the transfer of much examination work outside the EU, resulting in a loss of employment and expertise within the EU. They also

believed that such a transfer could reduce the level of control over the process of safety evaluation. However, two Notified Bodies supported the proposed modification.

Approval of Notified Bodies

The aim of the proposed change is to emphasise that Notified Bodies must be fully independent of those with responsibility for placing the toys that they are testing on the market.

Most Notified Bodies supported this clarification and felt that it was very important for them. Two respondents, though, requested further clarification on what was meant by the term 'consultancy', which the change prohibits. They noted that they are regularly asked questions on the harmonised standards, the essential requirements and toy safety in general and make suggestions of changes that would need to be made to toys to comply. The proposed modifications need to make clear that responding to such questions does not constitute consultancy, but forms part of the wider duty of Notified Bodies to educate on toy safety.

Conformity Assessment Procedures

Most Notified Bodies agreed that the modification provided useful clarification of the responsibility of the manufacturer in relation to conformity assessment, and would help to ensure the safety of product. One Notified Body and one industry respondent pointed out, however, that the meaning of 'individual identified products' was not clear and could be confusing.

Activities to be Performed as Part of EC-Type Examination

The aim of this proposed modification is to clarify what activities should be carried out as part of an EC-type examination. Most Notified Bodies welcomed the clarification, even though it primarily reflects current practice. Respondents expressed some concern, though, about the requirement that 'the certificate shall be reviewed at any time' (which was seen as not being in line with the General Product Safety Directive). It was not clear who was expected to undertake this review, or the circumstances under which it would be carried out. One Notified Body noted that requiring them to undertake the review would incur additional costs, as they would have to develop databases to store the information to be used in the review.

5.6 Wider Impacts of Proposed Modifications

5.6.1 Impacts on International Trade and Competitiveness

Industry stakeholders were asked to comment on the impacts of the proposed modifications for international trade and the competitiveness of the EU toy sector.

Many respondents indicated concern that the proposed modifications would increase operating costs for EU manufacturers, especially for SMEs manufacturing in the EU. Such companies may find it difficult to pass on the additional costs to retailers, thus reducing margins. Some respondents felt that this could result in reduced quality and safety of products, as price is the main factor in sales of toys. Others believed that, as compliance costs increased, it would no longer be economic to import low-cost, low-quality products into the EU, with some indicating that the clarification of the scope of the TSD would improve the competitiveness of high quality and high value toy manufacturers. These are likely to be SMEs in niche markets, perhaps reflected in the high percentage of medium-sized companies indicating that the proposed changes would have positive impacts.

5.6.2 Impacts on Toy Safety

Views on the impacts of the proposed modifications on toy safety were mixed. Around 40% of industry respondents, together with the majority of Competent and Market Surveillance Authorities, Notified Bodies and consumer organisations believed that the changes would have a positive effect on toy safety. A number of these respondents, though, suggested other ways in which the TSD could be improved to enhance toy safety further. These suggestions are summarised in Table 5.8.

Table 5.8: Suggestions for Further Improvement of the TSD

Stakeholder	Suggestion
Industry	The TSD needs to be updated to reflect modern toy trends and the speed of introducing modifications to Toy Safety Standards needs to be rapidly increased. Currently, the fad for a particular toy is well over before the standards are updated. A precise definition of testing requirements would be very useful, not only for toys but especially for 'non-toys' - items that come into contact with children and must therefore be safe (e.g. clothes racks, Christmas decorations, candle holders, pencil cases, mugs, etc.). Manufacturers of these items may have a poor understanding what 'safe' means.
Competent and Market Surveillance Authorities	The proposed TSD needs to significantly reduce the number of products falling outside its scope. The essential requirements of the TSD ought to be made clear and precise in order to provide better guidance to standards bodies and Notified Bodies. This is particularly important in the chemical field. The possibility of setting threshold limits within the essential requirements should also be explored leaving the standardisation bodies to elaborate on the test methods. The possibility of using the comitology procedure to ensure that the essential requirements of the TSD are in line with developments in the toy sector should also be explored.
Notified Bodies	Self-certification procedures are not clear and should be improved. The TSD also needs to focus on importers/distributors as they are currently responsible for most of the toys on the market (particularly the low cost and high diffusion toys). It should recognise that importers rely on the declarations and testing results of manufactures. If the manufacturer does not run the proper tests, importers will continue to put products which they believe to be safe (but which may not be) on the market. Notified Bodies need to improve their expertise and range of testing. The basic requirements for Notified Bodies (e.g. knowledge of EN 71, training of personnel and facilities) need to be checked periodically. Activities which could result in Notified Bodies developing uniformity in testing methods would also be useful.

Table 5.8: Suggestions for Further Improvement of the TSD	
Stakeholder	**Suggestion**
Consumer Organisations	More work should be undertaken on hazard identification and risk assessment. Test purchases should be based on statistical sampling to ensure objectivity and fairness and uniformity throughout the EEA. There should be a possibility to add, modify or specify in detail essential requirements in a flexible way after adoption of the Directive, by making use of the comitology procedure.

Around 60% of industry respondents, and a number of other respondents, believed that the proposed modifications would **not** result in improved toy safety. A number of reasons were given for this:

- the existing TSD is effective and functions smoothly; more efficient enforcement of the regulations is all that is needed to improve the safety of toys. Without efficient enforcement, the proposed modifications will increase costs to industry without safety benefits;

- the most effective use of resources to reduce accidents caused by toys is to concentrate on preventing product failure caused by inconsistency or human error in production. Where an accident is related to the design of the product, pre-launch risk analyses clearly have not detected the design shortcomings. In many cases, though, recurrence of the accident can be prevented or reduced by timely product modification. A requirement to retain and analyse accident data would be a more effective way of reducing the number of safety related incidents;

- there is a limit to how safe a product can be. The play value of toys has been reduced by legislation and toys need to remain fun and educational. There are already significant constraints on the toy industry, which are currently stifling development of new toys; and

- there needs to a greater recognition of where the consumers' responsibility for the proper use of products begins and where the role of industry ends. Industry believes that educating consumers and making parents aware of the risks they expose their children to when they buy certain toys would have a far greater impact in reducing toy-related accidents.

Industry's views on the importance of enforcement in improving toy safety were also shared by other respondents. Comments included:

- there is no point modifying the TSD if control of the toy market is not improved. There is also a need to ensure that controls on certain products are more co-ordinated (Competent and Surveillance Authorities);

- while the proposed TSD may not result in significant additional costs for authorities, actual market surveillance requires money, and resources allocated for surveillance activities are strictly limited (Competent and Surveillance Authorities);

- the possibility of the proposed TSD achieving its aims is heavily dependent on the effectiveness of market surveillance activities. The obligation of Member States to carry out market surveillance activities should be more clearly defined in the proposed TSD as they suffer from serious budget restrictions (Notified Body);

- unclear phrasing of the TSD results in uncertainty for manufacturers, authorities and consumers. While the proposed modifications clarify the scope of the existing TSD and address certain risks more clearly, most of the unsafe toys are produced by manufacturers who have a total disregard for the TSD. This can again only be addressed by a strong market surveillance system (Notified Body); and

- the effectiveness of the existing TSD (as well as proposed modifications) is related to surveillance work by enforcement officers and there is little indication that they have the resources needed to carry out this work (Consumer Organisation).

5.6.3 Views of Chinese Manufacturers

Questionnaires were sent to Chinese manufacturers to obtain their views on the proposed modifications to the TSD.

The views of the Chinese respondents are summarised as follows:

- where the modifications may result in costs to the Chinese manufacturer, some pointed out that they would simply adjust their operational strategy to develop new products and thus remain competitive. None of the companies expressed any major concerns over the impacts of the proposals on their industry. This may, however, reflect their position in the supply chain, as they would simply pass on any costs incurred to their customers. One respondent pointed out that manufacturers will have no choice but to comply with the proposed regulations when they are implemented, hence the impact on costs, production/sales and profits were not really relevant;

- some of the modifications were identified by respondents as having potential benefits/positive implications (particularly the definition of the responsibilities of economic operators), by improving the quality of exports and their international competitiveness, while other proposals were indicated as not being relevant or useful (for instance, the proposal requiring that choking risks are covered for toys intended for children up to 60 months and REACH); and

- one manufacturer noted that it currently adopts higher safety standards than those in the TSD. As such, the higher degree of responsibility placed on the economic operators under the proposed TSD will eliminate manufacturers that do not maintain similar high standards. Another manufacturer pointed out that it had noticed many forged CE marks on the market and thus stringent verification of such marks would be required.

6. COST-BENEFIT ANALYSIS

6.1 Introduction

6.1.1 Scope of the Analysis

The aim of this Section is to identify and then quantify the costs and benefits of the existing and proposed modifications to the TSD for economic operators, consumers and public authorities, together with its impact on the environment, as set out in the Technical Specification. In order to achieve this, we have set out the:

- characteristics of toy sector companies (Section 6.2);
- costs to industry of compliance with the existing TSD (Section 6.3);
- costs to industry of adopting the proposed modifications to the TSD relating to the safety of toys (Section 6.4);
- costs to industry of other proposals which may be included in the proposed TSD (Section 6.5);
- indirect costs of the proposed TSD (Section 6.6);
- costs to Competent and Market Surveillance Authorities of adopting the proposed TSD (Section 6.7); and
- benefits of the proposed modifications to the TSD(Section 6.8).

While undertaking the assessment of these costs and benefits, the following factors need to be borne in mind, as they essentially determine the approach taken:

- the complexity of the structure of the toy market (as described in Section 3) makes it impossible to develop meaningful aggregate estimates of the likely costs of the existing TSD, and proposed modifications to it, on the sector as a whole;
- companies were unable/unwilling to provide the data required to undertake a quantitative assessment of costs and benefits; instead, the conclusions must be more qualitative in many cases; and
- where companies did provide data, they were often inconsistent, as answers varied between their domestic, European and in some cases world-wide operations. The inconsistencies also reflected differences in respondents' understanding of the questions raised.

For the above reasons, we have approached the cost-benefit analysis in part through the use of case studies. As far as possible, these case studies have been developed to be representative of the different types of companies operating within the sector. The characteristics of the case study companies, and the assumptions used in the analysis, are set out in Section 6.2.

Table 6.1 below provides a summary of the key costs and benefits of the **existing TSD** and the **proposed TSD** to industry, consumers, Competent and Market Surveillance Authorities identified through consultation and data analysis.

Table 6.1: Summary of Impacts of the TSD on Stakeholders						
	Significant Cost			**Significant Benefit**		
	Industry	**Competent/ Surveillance Authorities**	**Consumers**	**Industry**	**Competent/ Surveillance Authorities**	**Consumers**
Existing TSD						
Conformity Assessment	Y			Y	Y	Y
Labelling/Packaging Requirements	Y			Y	Y	Y
Proposed Modifications to the Definition and Scope of the TSD						
Definition of Toys					Y/N	Y
Definition of Economic Operators				Y	Y/N	Y
Responsibilities of Economic Operators				Y	Y	Y
Scope of the Proposed TSD		Y/N			Y	Y
Proposed Modifications Addressing the Safety of Toys						
Reasonably Foreseeable Misuse	Y				N	Y
CE Marking – Reference to Other Directives	Y				Y	N
CE Marking on Toys and Packaging	Y				Y	Y/N
Toys at Fairs		Y/N	Y/N		Y/N	Y/N
Hazard Analysis	Y				Y	Y
Technical Files					Y	Y
Warnings on Toys					Y	Y
Asphyxiation					Y	Y
Choking	Y				Y	Y
Chemical Properties	Y					
Toys Intended for Children	Y					
Other Proposals which may be included in the Proposed TSD						
Third Party Verification	Y/N				Y	Y
Choking Age - 60 months	Y				Y	Y/N
Toys in Food				Y	Y	Y
Authorised Representative						
REACH	Y/N					
Speed of Electric Ride-0ns	Y			Y	Y	Y
Hearing	Y			Y	Y	Y
Burning	Y				Y	Y
Activity Toys	Y				Y	Y
Food Contact Materials	Y/N					Y/N
Proposed Modifications Concerning Regulatory Authorities and Notified Bodies						
Duties of Competent and Market Surveillance Authorities		Y			Y	
Notified Bodies						
Note: Y indicates that an increase in costs or benefits is predicted by stakeholder N indicates a decrease in costs or benefits is predicted by stakeholder Y/N indicates that general stakeholder opinion divided						

6.1.2 Overview of Potential Costs and Benefits

Sections 3 to 5 summarised our findings on the impacts of the existing TSD and the likely impacts of the proposed modifications to it on industry, public administrators and consumers. Taken together, the sum of these likely impacts provides an indication of the overall impact of the existing requirements and the proposed changes.

As Table 6.1 shows, industry respondents identified two main requirements of the **existing TSD** as entailing the most significant costs, these were:

- conformity assessment; and
- labelling and packaging requirements.[21]

Industry generally believes that significant market benefits have been generated by the implementation of the existing TSD, as standards have been successfully harmonised. Industry also indicated that, although costs have been incurred, the safety of toy products has improved, reducing the number of accidents. Many expressed the view that what is required is more effective enforcement of the existing TSD, rather than a modified Directive.

The existing TSD has also been broadly supported by Competent and Market Surveillance Authorities as having a positive impact on the quality of toys entering the EU. Although they still observe some problems with the TSD, they agree that significant benefits have been obtained for public bodies and consumers.

As described in Section 5, industry stakeholders have indicated that the **proposed modifications** relating to CE marking on toys and packaging (Section 5.3.4), changes in the labelling of toys (i.e. referencing other CE Directives (Section 5.3.3) and warnings on toys (Section 5.3.8)) are likely to have the most significant impact on their costs. The proposed modifications concerning reasonably foreseeable misuse (Section 5.3.1) and the age of children for which choking risks should be addressed (Section 5.3.10) could have impacts on the availability of toys as well as direct costs. The proposed modification regarding hazard analysis (Section 5.3.6) could lead to additional costs, but the implications of this proposed change are not clear.

In contrast, the proposed measures to clarify the definition and scope of the TSD (Section 5.2) should have a minor impact on industry costs. Moreover, industry notes that it could benefit from such clarifications, as they would reduce legal uncertainty and define responsibilities clearly, potentially helping to reduce costs in the future. Of the other proposals which may be included in the proposed TSD, the proposal regarding mandatory third party verification (Section 5.4.2) is likely to have the most significant impact on their costs.

[21] Other regulatory requirements (such as compliance with other Directives and meeting the safety requirements in Annex II of the TSD) were also identified as entailing costs to industry, however, there was a lack of consensus on these issues and the data required for a cost assessment was not available.

Some Competent and Market Surveillance Authorities anticipate cost increases under the proposed modifications to the TSD. These stem from the fact that greater numbers of products may need to be monitored, enforcement activities may need to be increased and this could require a higher level of product testing at a potentially significant cost. However, other authorities felt that the changes would be minimal and/or that they could improve efficiency.

Overall, consumer organisations and Competent/Surveillance Authorities agreed that most of the proposed modifications to the TSD will give rise to significant benefits through a reduction in the number of toy-related accidents involving children. Industry consultees did not necessarily agree with this conclusion, however.

In some cases, there was little consensus as to whether the proposed modifications would result in either costs or benefits to a particular stakeholder. For example, a number of industry respondents indicated that they already use outside testing laboratories, in response to customer requirements, suggesting that proposed requirements for third party verification would have little effect. Other industry respondents, though, believe that mandatory third party verification could add significantly to costs.

In trying to assess the net effects of the proposed changes to the TSD, it is important that such differences are taken into account. This is complicated, however, by variations in the circumstances of the individual companies' involved, related to size, range of activities and the number of toy product lines.

6.2 Characterisation of Toy Sector Companies

6.2.1 Structure of the Sector

Both the first and second questionnaires sent to toy manufacturers, suppliers and distributors included a series 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 TSD; 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 6.2 presents data on the percentage of companies involved in different activities.

Table 6.2: Percentage of Companies Involved in each Business Activity by Turnover			
	Large (>€50m)	**Medium (€10-€50m)**	**Small (€<10m)**
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 our 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 6.2, 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, one would expect that the more vertically integrated a company is, the more power it has to 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 TSD 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 6.2 also indicates that the re-export of toys imported into the EU can be important to the EU industry. Compliance with the revised TSD 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.

6.2.2 Case Study Companies

Based on responses to the questionnaires, case studies have been developed to illustrate the cost impacts of the existing TSD 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 6.1 to 6.4 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 TSD 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 TSD 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 principle 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 6.1 to 6.4. A summary of the structure of each case study company is presented in Table 6.3.

Table 6.3: Summary of Case Study Companies' Structure

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

Box 6.1: 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 €1,180m.

Key Assumptions – Costs of Existing TSD

- 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 6.9 (see below), the general view of 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 €2,500 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 €1,000 per toy product and upper boundary at €2,500 per toy product; and
- It is also assumed that the company will only need to modify 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 6.2: 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 reproduced 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 €2,500, 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 6.3: 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 doll 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)

Box 6.4: 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 €18 million.

Key Assumptions – Costs of Existing TSD

- 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).

6.3 The Costs of Compliance with the Existing TSD

6.3.1 Types of Cost

Labelling and Packaging Requirements

The initial survey asked manufacturers, suppliers and distributors to provide estimates of the increase in costs that they experienced in order to meet the labelling and packaging requirements of the existing TSD. Responses to this survey indicated that these costs comprised between 0.1 and 0.5% of annual turnover. Companies were asked to verify or comment on these estimates in the second survey (given that the number of responses received to the first survey was low). If they did not agree with these estimates, respondents were asked to indicate whether the costs would be higher or lower and to give their approximate estimate. Table 6.4 summarises the responses received.

Table 6.4: Percentage of Respondents Agreeing or Disagreeing with Labelling and Packaging Cost Estimates (0.1% – 0.5% Turnover)

	Large	SMEs		All
		Medium	Small	
Higher Packaging & Labelling costs (>0.5% annual turnover)	20%	16%	30%	23%
Agreed with estimate (0.1% to 0.5 %)	80%	67%	70%	73%
Lower Packaging & Labelling costs (<0.1% annual turnover)	0%	16%	0%	4%

The majority of respondents agreed that the labelling and packaging requirements under the existing TSD gave rise to costs of between 0.1 and 0.5% of turnover; although a significant percentage of small companies indicated that costs had increased by more than 0.5% of turnover. Some companies also gave approximate estimates of the actual increase in their costs due to the existing TSD requirements. For larger firms, these varied from around 0.5% to a high of 2% of annual turnover.

Conformity Assessment

The current TSD requires conformity assessment through self-certification when harmonised standards are used, with EC-type examination used when harmonised standards are not available or not followed in full. Industry respondents, had varying views on the cost difference that arises between the two approaches:

- all toys go through the same testing and risk assessment process during development, regardless of whether the toy is going to be EC-type examined or is self-certified to a harmonised standard; costs are therefore unlikely to vary significantly between the two approaches;

- EC-type examination is more expensive compared to self-certification and there are administrative costs incurred in preparing a submission for an EC-type examination; or

- self-assessment of products occurs throughout the life of a product and as such, costs are incurred continuously, unlike EC-type assessment which represents a one-off cost.

This question of cost differences in conformity assessment is examined further in Section 6.5.1, where two of the case studies are used to assess the costs of EC-type examinations as part of a proposal for mandatory third party verification.

In response to the first questionnaire, the costs of conformity assessment were indicated as being between €300 and €5,000 per individual toy product. In the second survey, companies were asked whether they agreed or disagreed with these figures and asked, if possible, to provide their own estimate. Table 6.5 shows the survey results, which indicate that the majority of respondents (80%) agree with these estimates, with the average cost per product tested being around €1,650.

Table 6.5: Percentage of Companies Agreeing With Estimated Range of Conformity Assessment Costs (€300 to €5,000 per product)

	Agree/Disagree	Average € per product
Disagree, higher cost range	12%	4,160*
Agree	80%	1,650
Disagree, lower cost range	8%	200
Total	**100%**	
* Reflects mean value of higher range provided		

6.3.2 Costs to Case Study Companies

Multinational Company

Based on the assumptions set out in Box 6.1, the total costs of the conformity assessment and labelling/packaging requirements of the current TSD for the multinational company are as presented in Table 6.6 below.

Table 6.6: Annual Costs of Existing TSD to a Multinational Company

	Cost Estimate Range (€000)		
	Low	**Medium**	**High**
Conformity assessment costs	840	2,800	4,760
Labelling/packaging costs	1,200	3,000	6,000
Total	**2,040**	**5,800**	**10,760**
% of total production costs (€1,180m)	0.17%	0.49%	0.91%

As Table 6.6 shows, the annual cost of the existing TSD for this company (based on the calculated costs of conformity assessment and labelling/packaging), based on the medium cost assumptions, is around €5.8 million. This is equivalent to around 0.5% of total production costs. The total figure is somewhat higher than the estimated costs of €3 - €4.4 million for implementing the existing TSD given by the real company on which

the case study is based, in response to the first consultation exercise (this is, however, above the lower range estimate provided above).

Costs to SME Case Study Company

From the assumptions in Box 6.2, the cost impacts of the conformity assessment and labelling/packaging requirements of the existing TSD to a SME company for low, medium and high scenarios are provided in Table 6.7.

Table 6.7: Costs of Existing TSD to a SME Company

	Cost Estimate Range (€)		
	Low	**Medium**	**High**
Conformity assessment costs	22,500	75,000	127,500
Labelling/packaging costs	20,000	40,000	60,000
Total	**42,500**	**115,000**	**187,500**
% of total production costs (€8m)	0.55%	1.5%	2.4%

As Table 6.7 shows, the costs of the existing TSD are more significant for the SME company than for the multinational company. In this case, the existing TSD may have added costs of around 1.5% of total production costs, compared to costs of around 0.49% for the larger company.

Costs to All Case Study Companies

Table 6.8 below summarises the total costs of complying with the existing TSD for all the case study companies.

Table 6.8: Total Costs of Existing TSD for Various Case Study Companies

Economic Operator	**Cost Estimate Range (€)**		
	Low	**Medium**	**High**
Large	2,090,000	5,800,000	10,760,000
SME	42,500	115,000	187,500
Importer	87,200	224,000	360,800
Medium Manufacturer	227,500	675,000	1,122,500

Table 6.8 clearly shows the variation in costs of complying with the existing TSD, depending on the structure of the company and its scale of activity. Costs also vary depending on whether the company is an importer or a manufacturer of toys. Similarly, the number of individual types or groups of products affects costs, as the more specialised the manufacturer the lower the level of testing required because of the smaller product range. For example, different versions of the same type of doll can be constructed from a single basic body, meaning that only a small number of conformity tests may be required across the range of different dolls. In contrast, the greater the variety of toys produced or the more rapidly innovations are made to the design of a product, the more likely a company will be to face higher testing costs.

6.4 The Costs of Adopting the Proposed Modifications to the TSD

6.4.1 Types of Cost

As discussed in previous sections, the focus of the second questionnaire was on gaining information on the impacts of the proposed modifications to the TSD. Companies were asked to provide data that would enable quantification of the cost impacts of a number of the proposed modifications, including those relating to:

- CE marking on toys and packaging;
- the reasonably foreseeable misuse of a toy;
- choking risks;
- undertaking a hazard/risk assessment; and
- age-related labelling.

The responses received to these questions are discussed below.

CE Marking on Toys and Packaging

Respondents 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 6.9. The Table indicates the percentage of respondents that agreed with different percentage changes in costs, by company size and annual turnover.

Table 6.9: Percentage of Respondents Agreeing with Different Cost Estimates for Changes in CE Marking Requirements

Change in Manufacturing Costs	Large Firms (>€50m/y)	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 partly be due to misunderstanding of the questionnaire, or 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 should need 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, if this is included at the same time as normal design modification or replacement of moulds. The exact costs, and variables that determine the degree to which this is possible, are discussed in more detail in the relevant case studies.

Reasonable and Foreseeable Misuse, Choking Risks and Hazard Analysis

The other proposed modifications to the existing TSD where costs can be quantified relate to:

- the requirement on manufacturers to account for reasonably foreseeable misuse;
- extending the requirements on choking risks; and
- undertaking hazard analysis.

During consultation, industry noted that all three of these proposed modifications could result in some additional costs.

For *reasonably foreseeable misuse*, there were differing views amongst industry respondents on the cost implications. Most respondents believed that the change would not affect procedures for assessing safety, as these are already extensive. In contrast, some industry respondents believed that the lack of coverage of misuse in harmonised standards would mean that every toy had to go through type approval. The requirement could also increase insurance costs (because of the likelihood of increased litigation), as well as result in the withdrawal of toys from the market.

For requirements regarding *choking risks*, industry considered that this would result in very significant impacts. The term 'enticing' was seen as problematic, as it is open to different interpretations by enforcement authorities. Industry indicates that this could be crucial for determining liability for toy-related accidents (with consequent cost impacts).

With regard to *hazard analysis*, the major concern related to what was meant by hazard analysis, as opposed to the risk assessment that is specified in harmonised standards. Industry believes that risk assessment is a more appropriate approach to adopt to ensure

product safety. Where the intention of the proposed modification is to refer to risk assessment, there are likely to be no or minimal costs as these are already being carried out. However, if the intention of the proposed modification is to require a different approach, the TSD should specify what hazard analysis entails and what additional information should be included in the technical files. In the absence of such clarification, the impacts of the proposed modification are difficult to determine.

Table 6.10 presents the responses to the questionnaire on this issue, which suggest that the cost of any additional testing (required for hazard analysis) is likely to be zero or minor for around 60% of companies[22]. Around 40% of companies, though, believe that the proposals will impose major additional testing costs, varying between €2,000 and €100,000.

Table 6.10: The Costs of Additional Hazard Analysis

Implication	Percentage of Responses		Estimated Cost per Product
	Large (>€50m/y)	SMEs (<€50m/y)	
Major testing required at high cost	40%	42%	€2,000 - €100,000
Minor testing required at low cost (as some information is already available)	30%	40%	€100 - €300
No further testing required (as hazard analysis is already carried out)	30%	18%	0

Warnings on Toys (Labelling)

The proposed modifications also include requirements for minimum and maximum ages or weights to be labelled on the toy (or its packaging), where relevant, in a visible and clear manner. Consultees 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 we were unable to evaluate this cost. The costs of modifying labelling and packaging in this manner are expected to be relatively low. 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 that costs may be increased by up to 100%.

[22] Costs may be zero due to the fact that hazards must be assessed first in order to determine risk (where Risk = hazard x exposure). These companies may thus consider that the hazards from their products are already known; however, others interpret the requirement as needing a wider review of potential hazards than is undertaken under the present approach to risk assessment.

6.4.2 Costs to Case Study Companies

Costs to Multinational Case Study Company

The costs of these proposed modifications to the TSD can also be estimated for the illustrative case study companies, based on the assumptions set out in Boxes 6.1 to 6.4. The costs arising from the proposed modifications are presented in Table 6.11.

Table 6.11: 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
Hazard Analysis	0	840	2,800
Labelling (warnings)	700	1,400	3,500
Total	**3,108**	**10,752**	**22,316**
% Increase in costs of production	**+0.26%**	**+0.91%**	**+1.89%**

A cost increase of 0.26% as indicated for the low set of assumptions is likely to have a negligible impact on the company. The cost estimates for the high assumptions suggest that, where multinationals have not already carried out hazard and risk analysis and where labelling costs are highest, a 1.89 % increase in total costs may be incurred, with potentially significant implications.

Costs to SME Case Study Company

Based on the assumptions set out in Box 6.2, the total additional costs arising from the proposed modifications for a SME manufacturer are presented in Table 6.12.

Table 6.12: 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
Hazard Analysis	30,000	75,000	150,000
Labelling (warnings)	18,750	37,500	93,750
Total	**120,000**	**350,625**	**686,250**
% Increase in costs of production	**+1.6%**	**+4.6%**	**+8.9%**

Again, as might be expected, the costs for the SME manufacturer are predicted to be higher and more significant than for the multinational company, due to reduced economies of scale and lower production volumes across which costs can be spread.

Costs to Medium-sized and Importer Companies

The medium-sized manufacturer of toys adopted in this case study was chosen as it produces wooden and plush toys which, by their nature, cannot be CE marked in the same way as in the multinational and SME company case studies, where the products are

plastic moulded. Assumptions remain the same though for testing and labelling on packaging as in the SME study. Therefore, the only difference is the cost of CE mark labelling on products. From consultation with industry representatives, the estimated cost per toy of attaching a tag label or sticker on a product would be around €0.05 per toy. However, as another consultee noted, labelling on plush toys could simply be altered to include the CE mark at minimum cost, while wooden toys could have a label attached (where this is acceptable under the proposed TSD) to denote the CE mark and any other information required under the TSD. Significantly, the costs of making the necessary modifications to labelling that would encompass the CE mark have already been quantified under our estimates for labelling costs. Therefore, a company producing wooden and or plush toys will not incur any additional costs from the CE marking proposals.

The importer case study can be compared against the costs of the medium case study, using the same assumptions as the medium company. The cost estimates are shown in Table 6.13.

Table 6.13: 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
Hazard Analysis	220,000	550,000	1,100,000
Labelling (warnings)	137,500	275,000	687,500
Total	**357,500**	**825,000**	**1,787,500**
Importer			
CE Marking	114,000	381,000	708,000
Hazard Analysis	49,600	124,000	248,000
Labelling (warnings)	31,000	62,000	155,000
Total	**194,600**	**567,000**	**1,111,000**

Although the total costs shown in Table 6.13 do not differ significantly (i.e. within the range of €150,000 - €600,000) for both case study companies, the importer only supplies 124 different product lines compared to the medium manufacturer's 550. In effect it appears that, where CE marking is required on plastic, ceramic or metal products, the total cost of the modified TSD are likely to more than double compared to those faced by a manufacturer of plush and/or wooden toys. On the other hand due to the higher number of products produced, the medium-sized firm faces much higher testing and labelling costs.

It should also be noted that the importer in the case study above may have to bear the full burden of any additional costs, if it cannot pass these on to its overseas manufacturer. It may also have to take responsibility for product safety if the company wishes to continue to trade in the EU, unless an authorised representative is appointed. It could also be difficult to pass costs on to retailers and consumers. The medium manufacturer, on the other hand, has the option of reducing the number of product lines, or passing the costs

through to distributors and retailers, assuming that its products are specialist and unique enough to enable prices to increase. In effect, the importer of toys is constrained by the manufacturer above and retailer below it in the supply chain. In contrast, the manufacturer should only be constrained by the actions of those below it in the supply chain.

In understanding the costs derived for the proposed modifications to the TSD in Tables 6.11 to 6.13, it should be noted that the following assumptions apply:

- for **CE marking on toys and packaging**, toys produced by the case study companies do not currently carry any CE mark (i.e. the CE mark is currently on the packaging);

- for **hazard analysis**, the calculations assume that all the companies concerned would have to undertake minor or major testing to comply with the Directive. As noted earlier, a significant number of respondents do not expect to undertake further testing. Also, where the intention of the proposed modification is to refer to risk assessment, there are likely to be no or minimal costs as this is already being carried out; and

- for costs of **labelling**, the calculations reflect the costs to a company where 50% of the toys produced need to carry warnings (relating to weight or age of the user). Potential costs associated with making reference to other Directives requiring the CE mark are not included.

6.5 Costs of Other Proposals

6.5.1 Types of Cost

A number of additional modifications to the TSD have been suggested. These are:

- mandatory third party verification;
- increasing the age limit of concern for risks of choking;
- restrictions on the noise levels produced by toys;
- modifications to burning risks;
- restrictions on the speed of ride-on toys and requirements concerning the safety of activity toys; and
- restrictions on the presence of toys in food products.

Third Party Verification

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 6.14.

Table 6.14: 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**	**>€2,500**	
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 burning and choking risk tests not currently undertaken. The cost increases are likely to be minimal for many SMEs, at €300 where third party verification already takes place increasing to €1,000 on average and €1,700 as a maximum for companies not currently using third parties. Medium volume manufacturers are predicted to face costs of between €300 and €1,700, with €1,000 as the average.

Risks of Choking

Another modification that has been suggested is for the age limit that is covered by an assessment of choking risks to be raised from the current 36 months to 60 months. In response to a question on the implications of such a revision, industry indicated overwhelmingly that it would increase risk and hazard assessment costs, but more significantly it would result in many small toys being removed from the market and

would make product development and research much more costly. This is because few toys are specifically targeted at children between 36 and 60 months.

The costs to manufacturers of increased hazard and risk assessment costs would mirror the cost of EC-type examination (as estimated earlier) for each time a product has to be sent to a testing or laboratory facility. Thus, they would be in the region of €500 to €2,000 per toy product for a 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.

Restrictions on Noise Levels

Restrictions on the volume of noise exerted by a toy to prevent injury to hearing, especially on younger children, have also been proposed. Industry supported this idea in general, but also pointed out that it could have significant cost implications because of the restrictions it might put on product design, development and testing costs. Unfortunately, no respondent was able to quantify this cost due to a lack of information on possible volume limits.

Modifications to reduce burning risks were also addressed in consultation, with industry indicating that significant costs could be incurred if design modifications and restraints on product development result. As with other proposals made in this Section, the costs are of a qualitative nature and, therefore, difficult to quantify at this stage.

Ride-on Toys and Activity Toys

Other costs would arise if modifications to restrict the speed of electric ride-ons and the safety risks of activity toys were to be included in the Directive. Assessment and testing costs would also increase, although the main increases in costs would result from the need to redesign such toys, with associated increases in development costs. The potential level of cost increase is unquantifiable at this point in time.

Toys in Food Products

The implications of proposals to place restrictions on the presence of toys in food are at present unquantifiable. However, the costs will depend on whether such legislation refers to toys embedded in food, toys outside the food but packaged with food or toys that make food; the toy industry is more involved in toys outside the food but packaged with food.

6.5.2 Costs to Case Study Companies

Estimates of the additional costs of the other proposals (which may be included in the proposed TSD) are presented in Table 6.15 for the multinational company and in Table 6.16 for the SME company.

Table 6.15: Estimated Costs of Other Proposals for a Multinational Company			
	Cost (€ 000)		
	Low	**Medium**	**High**
Third party verification*	2,800	4,200	5,600
Choking risks/hazard analysis	1,120	2,800	5,600
Other costs	+	+	+
Total	**3,920+**	**7,000+**	**11,200+**
% Increase in Production Costs	**+0.33%**	**+0.6%**	**+9.5%**
Note: Costs referred to as 'other costs' are difficult to quantify, therefore these figures should be interpreted as minimum estimates. **The costs for third party verification assume that all toys would have to undergo this assessment.*			

Table 6.16: Estimated Costs of Other Proposals for a SME Company			
	Costs (€ 000)		
	Low	**Medium**	**High**
Third party verification*	22.5	75	127.5
Choking risks/hazard analysis	30	75	150
Other costs	+	+	+
Total	**52,500+**	**150,000+**	**277,500+**
% Increase in Production Costs	**+0.68%**	**+1.95%**	**+3.6%**
**The costs for third party verification assume that all toys would have to undergo this assessment.*			

The Tables above present the sum of costs arising from the other proposals put forward in consultation. 'Other costs' refer to the costs of making significant design changes to future and present products. As many of the product development and innovation costs are unquantifiable at this stage, the estimates given should be treated as underestimates of the costs involved.

6.6 Indirect Costs of the Proposed TSD

The costs calculated above, as well as those that are not quantifiable, may give rise to a number of other significant impacts, such as a loss of competitiveness, the reduction of product ranges and impacts on employment. Many of these cannot be predicted at this point in time, although it is possible from the consultation responses to gain industry's perspective on the likely impacts of the proposed modifications to EU competitiveness and trade.

In order to investigate this issue still further, industry respondents were asked for their views on the possible implications of the proposed modifications to the TSD for international trade and competitiveness of the EU toy sector.

Industry respondents indicated that, at present, over 70% (and >95% in most Member States) of all toys in the EU are produced outside the EU, in particular in China. Any action in the EU (including new regulations) which increases the operational costs for industry would make the option of relocating to China even more attractive to those companies still producing in the EU.

More than half of all industry respondents identified the proposed modifications as having a potentially negative impact on international trade. They indicated that the higher compliance costs incurred in meeting the requirements of the proposed modifications would raise the operating costs of EU manufacturers, especially SMEs which undertake production in the EU. This could cause the EU to become uncompetitive compared to high-volume and low labour cost countries such as China. One SME manufacturer considered that the modified TSD would reduce its competitiveness compared with producers in the USA. SMEs may also find it more difficult to pass on the additional costs to retailers, reducing profit margins, which could result in companies reducing the quality and safety of their products. Others (within industry), however, had the view that, as compliance costs increased, low cost and low quality products would avoid the EU.

Some companies felt that the clarification of which toys needed to comply with the Directive by the proposed modifications to the TSD would improve the competitiveness of high quality and high value toy manufacturers.

6.7 Costs to Competent and Market Surveillance Authorities

Respondents from our consultation with Competent and Market Surveillance Authorities indicated that the costs of the majority of the proposed modifications to the TSD were likely to be minimal, given that many of the proposals are already covered by the General Product Safety Directive (GPSD) and other New Approach Directives.

The proposed modifications are also unlikely to have a significant impact on the costs incurred by Competent and Market Surveillance Authorities because many of the measures are aimed at clarifying responsibilities and definitions and making information more accessible. These should, in fact, make such authorities' duties easier. Indeed, many respondents indicated that costs are not be expected to increase, but instead decrease, as their duties should take less time and legal uncertainty over responsibility will be reduced.

However, some Competent and Market Surveillance Authorities did indicate that there were possible costs associated with some of the proposed modifications, specifically:

- requirements that regulatory authorities organise appropriate checks on an adequate scale to ensure that toys comply with TSD, as well as take samples of toys and subject them to safety checks;

- widening the scope of the TSD could mean more products would need to be controlled under the Directive (although industry disagreed with this view), which might lead to increased costs for market surveillance and enforcement;

- where product recalls and random testing is to take place, the increase in the number of toys covered by the modified TSD are likely to require increases in testing capacity and enforcement at significant costs; and

- the increased requirements may instigate the need for accident databases, such as the (now defunct) UK Department of Trade and Industry's HASS, to monitor accidents and the products causing them. This is not a requirement of the proposed TSD, but can be viewed as an indirect cost as its introduction could make surveillance and assessment of future modification to the TSD more efficient and effective.

6.8 The Benefits of the Proposed Modifications to the TSD

6.8.1 Introduction

The benefits of the existing TSD in terms of increased toy safety are discussed in Section 4 of this Report. The focus here is on the benefits that might arise from the proposed modifications to the TSD and from any additional proposals, such as that relating to mandatory third party verification.

These are summarised below, covering benefits to the toy industry, to Competent and Market Surveillance Authorities and in terms of consumer safety.

6.8.2 Benefits to the Toy Industry

The direct benefits to industry of the TSD indicated by our consultation 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.

Unfortunately, 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.

It is expected, however, that setting out in detail the power and obligations of Market Surveillance Authorities will have a significant impact in reducing the level of counterfeiting affecting the toy sector. 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.

These benefits will only be realised, however, if the modifications to the TSD result in more effective enforcement.

6.8.3 Competent and Market Surveillance Authorities

Table 6.1 summarised the expected impacts of the proposed modifications to the TSD for Competent and Market Surveillance Authorities. This Table 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;
- hazard and risk assessment of general safety and specific risks;
- packaging and labelling requirements;
- mandatory third party verification; and
- toys in food.

Unfortunately, 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.

6.8.4 Consumer Safety Benefits

The consumer safety benefits that may arise from the proposed modifications to the TSD are difficult to quantify. The data presented in Section 4 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 any 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 statistics presented in Section 4 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. When combined, the economic value of reducing the risk of fatalities, of major, minor and more minor still injuries related to toys is likely to be significant.

6.9 Conclusions

The cost-benefit analysis undertaken in this Section identified industry, Competent/Market Surveillance Authorities and consumers as the stakeholders most likely to incur the costs and benefits from the existing and proposed modifications to the Toy Safety Directive.

The analysis attempted to quantify the costs of the TSD for all stakeholders, based on consultation responses and publicly available information. 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 (shown in Table 6.13).

The cost implications of the proposed TSD are summarised in Table 6.17 as the percentage change in the production costs of each case study company.

Table 6.17: 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 Proposals which may be included in the Proposed TSD			
Multinational	+0.3%	+0.6%	+9.5%
SME	+0.7%	+1.9%	+3.6%

[23] Health benefits generally relate to the value that society attaches to the economic costs associated with reductions in injuries or deaths, including the cost of medical, legal, administrative and emergency services, as well as the costs of any lost economic output and individuals' willingness to pay to avoid the injury or death. In the case of children, immediate lost output is not a relevant factor, but the other elements of economic costs are.

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 may fall disproportionately on smaller companies. 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.

Significant benefits may arise to the EU toy industry, though, 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.

In contrast, the likely costs to the Competent and Market Surveillance Authorities are expected to be minimal, and significant benefits are expected to be realised as a result of the improved clarity of the responsibilities and roles of economic operators, including improved access to technical files.

The main benefits are likely to be experienced by consumers, if the proposed TSD achieves its goals of a reduction in the number of toy-related accidents. However, current data makes it difficult to determine the extent of reduction in accidents that could arise as a result of the proposed modifications.

7. CONCLUSIONS

7.1 Achievement of the Objectives of the Existing TSD

A number of positive aspects of the existing TSD have been identified, and these are:

- better manufacturer awareness of requirements for toy safety;
- reductions in the level of non-conformity amongst toys on the EU market;
- establishment of a harmonised framework (based on the New Approach) for ensuring that toys comply with the TSD's essential safety requirements and, consequently, ensuring the free movement of toys; and
- reductions in the number of toy-related accidents.

The following were identified as areas where the existing TSD may not have achieved its objectives:

- the definition of toys;
- linked to this, the labelling of toys;
- the adequacy of harmonised standards and gaps in essential requirements; and
- enforcement.

A number of actions that could be taken to address the areas for improvement of the Directive were also identified, and these cover:

- the definition of toys;
- the classification and labelling of toys;
- the scope of standards and requirements;
- assessment methods and information for consumers;
- updating the TSD in line with developments in the toy sector; and
- improvements in quality and extent of enforcement.

7.2 Proposed Modifications to the TSD

The proposed modifications to the TSD cover:

- clarifications in the **definitions and scope** of the TSD;
- clarifications and additions intended to address the **safety of toys**;
- **other proposals** relating to the safety of toys which may be included in the proposed TSD; and
- clarifications on the duties of regulatory authorities and Notified Bodies.

Consultees were asked to give their views on the impact of the proposed modifications for them, and on the overall impact on trade and the competitiveness of the EU toy industry and on toy safety.

Many of the proposed modifications were considered to provide useful clarification of the TSD, without introducing significant new requirements. However, a number of the proposed modifications were highlighted as potentially giving rise to more major impacts. These were:

- considering **reasonably foreseeable misuse** in assessing toy safety: manufacturers believed that this would not lead to changes in assessment procedures but that the scope for different interpretation of the phrase could leave them open to legal challenge and potentially result in unjustified withdrawal of toys from the market. However, consumer organisations believed that it could result in safety benefits;

- changes to **CE marking**, including reference to other Directives covered by the CE mark and inclusion of the mark on the toy as well as on the packaging. Industry was concerned about the practical difficulty of meeting these requirements and questioned their value for consumers. Adding a CE mark to a toy could be costly (for plastic toys where moulds would have to be modified) and cause practical difficulties (for example where SMEs purchased and imported part of a large manufacturing run, most of which was not destined for the EU);

- requirement to carry out **hazard analysis**: industry questioned the value of hazard analysis, as opposed to risk assessment. If the aim was that industry should carry out different procedures, these should be set out;

- **mandatory third party verification**: a proposed modification which has yet to be agreed or included, was viewed by industry as potentially increasing costs significantly whilst having limited safety benefits (although some manufacturers already undertake such verification for market reasons). Other consultees felt that the requirement could have significant safety benefits but would be impractical for all toys. Different suggestions were made as to which categories of toys should be covered;

- respondents were uncertain of the benefits of extending requirements for the assessment of **choking risks** to children **below 60 months** (from 36 months), as children above this age are less likely to put toys into their mouths. For industry, the suggestion (which has yet to be agreed or included) would be impractical. Few toys are specifically designed for children under 60 months and the suggestion would mean that toys such as small building bricks and dolls with changeable clothes, would no longer be available for this age group;

- while industry agrees that Annex II of the TSD addressing the **chemical properties of toys** must be upgraded to ensure that toys do not pose any risk of damaging children's health, there are concerns regarding how this is to be achieved particularly for substances which are Category 1, 2 and 3 CMRs, which may be prohibited or restricted under the new proposals. Industry also noted the importance of combining modifications to the Directive with specific testing requirements. Where this is not done, testing laboratories will be left to develop their own approaches, and there will be no means of ensuring that the Directive is being complied with; and

- **location of Notified Bodies**: Notified Bodies were concerned that allowing some operations of notified bodies to be carried outside the Member State where they were notified could lead to the transfer of jobs and toy safety expertise outside the EU.

Views on the impacts of the proposed modifications on international trade and competitiveness differed. Some industry respondents thought that they would increase costs, making the EU industry less competitive, leading to increased imports and loss of manufacturing jobs to the Far East. Others thought that the increased cost of meeting safety requirements would discourage imports of cheap toys into the EU. Views on the impacts on safety were also mixed. Around 40% of industry respondents, together with the majority of other stakeholders, believed that the proposed modifications would improve toy safety. The remaining 60% of industry respondents felt that toy safety would not be improved and that other measures, particularly better enforcement of the existing TSD, would be more effective.

7.3 Cost-Benefit Analysis

The cost-benefit analysis undertaken for this study identified industry, Competent/Market Surveillance Authorities and consumers as the stakeholders most likely to incur the costs and benefits from the proposed modifications to the TSD. A quantification of these costs has been undertaken using a number of case studies.

The cost implications of the proposed TSD for a multinational firm and an SME are summarised in Table 7.1 as the percentage change in the production costs of each case study company.

Table 7.1: Percentage Increase in Production Costs for a Multinational Firm and an SME

	Cost Scenario		
	Low	**Medium**	**High**
Proposed Modifications to the TSD Addressing the Safety of Toys			
Multinational	+0.3%	+0.9%	+1.9%
SME	+1.6%	+4.6%	+8.9%
Other Proposals which May be Included in the Proposed TSD			
Multinational	+0.3%	+0.6%	+9.5%
SME	+0.7%	+1.9%	+3.6%

In general, the larger the company in terms of turnover, the lower the impact of the proposed TSD costs, implying that the burden of costs associated with the proposed TSD may fall disproportionately on smaller companies. The cost scenarios included variations in each cost to account for the different levels of testing, assessment and labelling required by different companies depending on current methods of compliance with the proposed TSD.

However, a number of factors have been identified that can determine the extent of the costs faced, such as:

- **product type**: a large disparity was found in the costs of CE marking between companies producing plush or wooden toys and those producing 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 have to be carried out for each separate product.

It is expected, however, that setting out in detail the power and obligations of Market Surveillance Authorities under the proposed TSD could have a significant impact in reducing 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; reducing the level of such activity by only a small amount will yield significant benefits.

The likely costs to the Competent and Market Surveillance Authorities are expected to be minimal, and significant benefits are expected to be realised as a result of the improved clarity of the responsibilities and roles of economic operators, including improved access to technical files.

The main benefits are likely to be experienced by consumers, if the proposed TSD achieves its goals of a reduction in the number of toy-related accidents. However, current data make it difficult to determine the extent of reductions in accidents that could arise as a result of the proposed modifications.

8. REFERENCES

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