REVISION OF THE CHEMICAL REQUIREMENTS OF DIRECTIVE 88/378/EEC ON THE SAFETY OF TOYS

Final Report by Europe Economics

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EXECUTIVE SUMMARY

Background to the report

1 This report has been prepared for DG Enterprise to provide analysis of the overall likely (qualitative and quantitative) impacts of the three different proposed approaches for revising the chemical requirements in toys as stated in Directive 88/378/EEC (the Toy Safety Directive).

2 The Toy Safety Directive (TSD) is a New Approach Directive, meaning that it only sets the essential safety requirements and that technical details are fixed by standardisation organisations such as European Committee for Standardisation.

3 As noted by the EC, while the TSD has worked well over the last two decades, new technological developments in the toys market have raised new issues with respect to the safety of toys and increased consumer concerns. This has led to the conclusion that there is a need to update and complete the safety requirements, in particular in the areas of noise and chemicals.

4 This study is primarily concerned with examining the impact of revising the chemical requirements component of the TSD. On the basis of a 2005 study by RIVM/SIR and discussions in its Expert Group Committee, the EC has prepared three proposals for revision of Annex II of the TSD on chemical requirements. These are summarised below:

(a) **Risk-based proposal (approach 1):** This includes a new provision for allergenic substances and certain fragrances as defined in the Cosmetics Directive (ban/labelling requirement, which is based on a hazard approach) as well as the revision of the limit values for elements.[1]

(b) **Combined hazard/risk-based revision proposal (approach 2)**: Besides the provisions for allergenic substances, fragrances and the revision of limit values for elements, this proposal bans the use of CMR substances (categories 1 and 2) unless authorised by the procedure stated in REACH legislation.[2]

(c) **Hazard/risk-based proposal with authorisation by Comitology procedure (approach 3)**: The third proposal contains provisions for banning CMR substances (categories 1, 2 and 3) unless evaluated by a Scientific Committee and authorised by Comitology procedure. In addition, it bans allergenic substances from being used in toys and extends the provisions of nickel under the chemicals legislation to toys in general.

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[1] It should be noted that the listing of allergenic fragrances in the Cosmetics Directive involves their restriction at certain limits, which is not on the basis of a risk assessment, but it rather based on their intrinsic properties (hazards) alone. Thus, strictly speaking Approach 1 should not be denoted as the "fully risk-based approach"

[2] In practice, given that authorisation under REACH could take up to several years the number of substances that may profit from this exception is likely to be very low.

5 A secondary piece of analysis has examined the impacts of amending the requirements for toy companies to hold technical files relating to their toys. The EC is considering three proposals.

(d) **Proposal 1**: A detailed description of the design and manufacture, including the safety data sheets on chemicals used (to be obtained from chemical suppliers).

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

(f) **Proposal 3**: A detailed description of the design and manufacture, including substances contained in the toy as well as the amount of the individual substances and the relevant safety data sheets on chemicals to be obtained from chemical suppliers.

Impacts of each TSD approach

6 This report has analysed the impact of each proposed approach against the baseline counterfactual of "do-nothing" or no revision. Impacts are classified along the lines of economic, social (in particular, health) and environment effects. The main affected parties are the manufacturers and importers of toys, and the households which use (or play with) the toys.

7 Our analysis has involved the use of innovative techniques to quantify and qualify costs and benefits, which have built on a comprehensive review of the existing literature, a limited stakeholder consultation exercise, as well as accepted principles used in previous impact assessment studies. In particular, our benefits model has built on a scientific evidence base and exiting methodologies to provide quantitative estimates for the health benefit.

8 We discuss in the report the advantages of our approach and why it was chosen, as well as why alternative methodologies were rejected.

9 The table below summarises the overall costs and benefits associated with each approach relative to the counterfactual of do-nothing. The table presents the central estimates that were obtained from the calculations described later; they should not be taken as more precise than is explained in the main text.

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

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

** Given the caveats stated in the text, we do not include these costs in the total cost.*

10 As above table shows, we have not identified any environmental costs or benefits. This is primarily for two reasons. In the first instance, the disposal of toys is already governed by a number of existing Directives such as WEEE, ROHS, and Packaging and Packaging Waste. Further, the issue of general exposure of chemicals through the environment is usually much less than that of specific exposure gained through playing and everyday use of the toy.

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

12 We have also calculated the cost per DALY saved associated with each approach. We divided the number of DALYs saved by the total costs increase associated with the various approaches. The resulting figure using the central estimates is €27,000, €71,000 and €72,000 for approach 1, 2 and 3 respectively. Thus, using the example of approach

1, as long as the value of a DALY exceeds €27,000, on this measure, the approach should be chosen.

13 Below, we break down the overall result by company size. As one sees, the incremental costs to SMEs are larger than those of multinationals.[3]

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

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

14 The next table shows the possible price increases that might be associated with each approach, based on our modelled calculations (central estimates).

Table 3: The impact on prices of each approach

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

15 Details of ranges (and methodologies) for each set of calculations are contained it the main text. Details are also provided of assumptions used, so that further analysis can be carried out using the same methodology, if required.

Impact of each technical file proposal

16 The table below summarises the costs and benefits associated with each proposal relative to the counterfactual of do-nothing. The table presents the central estimates that

[3] Where multinationals refers to all firms except SMEs, as used in the RPA report.

were obtained from the calculations described later; and as with the previous calculations they should not be taken as more precise than is explained in the text.[4]

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

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

17 As the table shows the overall costs of each of the proposals is far lower than that of the chemical requirement revisions. As the table shows, proposals 1 and 2 have the same implications, with the proposal 3 generating an incremental cost of €33m over the period 2008 to 2051. All of these costs can be characterised as additions to the administrative burden.

18 It was not estimated that any of the proposals would cause a change in toy prices, because the overall magnitude of the change is very small.

Recommendation

19 On a plain reading of Table 1, it is clear that approach 1 is the preferred revision option, as it gives net NPV financial benefits of over €7bn for the period in question.

20 There are a number of observations to make about this recommendation. In the first instance, one should be aware of the degree of accuracy that attaches to them. As our report discusses in more depth, our main source of data for costs was our stakeholder questionnaire (cross-referenced by expert group discussions and our literature review) and thus the level of accuracy is function of their responses. Each stakeholder was

[4] The methodology has followed the Dutch Standard Cost Model of identifying new legislative demands and putting a price tag on these demands consisting of increased time and money spent to fulfil the requirements.

presented with the three approaches and their responses are based on their interpretation and how they would expect to react to them — and the outturn may differ from expectations, i.e. unintended consequences.

21 Secondly, there is the issue of weightings between the different stakeholders. Our preliminary analysis has indicated that the toys industry in Europe is competitive.[5] Economic theory predicts that under such conditions any changes in input costs (in this case from testing) will be passed through to the end user — in this case, the household. Thus, while the household might receive the benefits from reduced probability of contracting diseases from the chemicals, they are, in a very real sense, having to pay for this via higher toy costs. Thus, one cannot characterise the situation as one of simple equity between manufacturers/importers and households and weighting different parties is not straightforward.

[5] A full competition study in beyond the Terms of Reference.

1 INTRODUCTION

Scope

1.1 This is the final report for an assessment of impacts on the revision of the chemical requirements of Directive 88/378/EEC on the safety of toys. The scope of the analysis covers the overall likely (qualitative and where possible quantitative) impacts of the three different proposed approaches for revised chemical requirements in toys. The scope of the report covers the economic, social (in particular health) and environmental impacts of the proposed action, both in the short term and in the long term.

1.2 In addition, the report considers three proposals for revising the technical documentation held by manufacturers and importers of toys.

1.3 The approach taken is this report has followed EC guidelines on impact assessment.[6] Given the nature of the study and uncertainties in the evidence base, there are inevitably some areas of our analysis which contain caveats. However, through the use of scenario and sensitivity analysis we present a range of possible outcomes that might result from adopting one of the three proposed approaches.

Directive 88/378/EEC and its revision

1.4 The main piece of legislation covering toy safety is Directive 88/378/EEC: the Toy Safety Directive (TSD). This harmonises safety provisions on toys between Member States and is part of the so-called New Approach, meaning that the Directive only sets the essential safety requirements and that technical details are fixed by standardisation organisations.[7]

1.5 As noted by the EC, while Directive 88/378/EEC has worked well over the last two decades, new technological developments in the toys market have raised new issues with respect to the safety of toys and increased consumer concerns.[8] This has led to the conclusion that there is a need to update and complete the safety requirements, in particular in the areas of noise and chemicals. The Directive also needs to be modified to become consistent with new developments in market surveillance, and also be consistent with the Better Regulation initiative.

1.6 The stated objectives of the revision have been divided into three categories:

(a) modernising the safety requirements;

(b) clarifying of the scope and concepts; and

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6 Impact Assessment Guidelines (SEC(2005) 791), March 2006 update.

7 Namely the CEN standards of EN71 (1-8 which have been approved, and 9-11 which have not yet been) and a CENELEC standard applicable to electrical toys.

8 See Background Document to the Public Consultation – Revision of the Toys safety legislation

(c) improving the efficiency and coherence of enforcement.

1.7 The first objective aims to modernise the safety requirements by updating the essential safety requirements in the TSD. This entails the updating of some requirements on electrical properties and in physical and mechanical areas, e.g. suffocation and choking hazards. In addition, new safety requirements are required for newly identified hazards. This is particularly the case for noise, lasers, activity toys, speed limits, and chemicals.

1.8 The second objective seeks to clarify the scope of the Directive, in particular with regard to videogames and peripherals. There is also need to clarify the relationship of the TSD and the General Product Safety Directive.

1.9 The final objective aims to develop conditions for a better common approach by national market surveillance authorities in the implementation of the legislation in force.

Chemical requirements revision

1.10 This study is concerned with examining the impact of revising the chemical requirements component of the TSD. In 2005, a study by RIVM was conducted on certain chemicals used in toys. This study provided an update of the limits values for certain heavy metals already contained in Annex II of the Directive and examined the possibility of setting specific limit values for toys for children under 36 months and for (other) toys intended to be put in the mouth by using the food contact material legislation.

1.11 Three proposals have been prepared for the revision of Annex II of the TSD. In summary these are:

(a) **Risk-based approach:** includes a new provision for allergenic substances and certain fragrances as defined in the Cosmetics Directive (ban/labelling requirement) as well as the revision of the limit values for elements;

(b) **Combined hazard/risk-based approach**: besides the provisions for allergenic substances, fragrances and the revision of limit values for elements, this proposal bans the use of CMR substances (categories 1 and 2) unless authorised by the procedure stated in REACH legislation;

(c) **Hazard/risk-based approach with authorisation by Comitology procedure**: the third proposal contains provisions for banning CMR substances (categories 1, 2 and 3) unless evaluated by a Scientific Committee and authorised by Comitology procedure. In addition, it bans allergenic substances from being used in toys and extends the provisions of nickel under the chemicals legislation to toys in general.

Technical file revision

1.12 In addition to the three approaches under consideration in the revision of the TSD, there is also the possibility of updating the requirements for the technical documentation held by toy manufacturers and importers on their toys. The EC is considering three proposals.

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

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

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

1.13 In order to avoid confusion, when referring to revisions to the main TSD we use the term "approaches" and when referring to revisions of the Technical File we refer to "proposals".

Structure of the report

1.14 This report is structured along the following lines.

(a) Context of assessment: following the guidance of the EC on impact assessment, this section discusses the problem definition, policy objectives and the policy options to be considered.

(b) Research methodology: here we discuss our methodological approach used in this report. It contains a description of the techniques used, challenges faced and analytical steps leading to the drafting of this report.

(c) Analytical framework: the purpose of this section is to set out the conceptual framework for analysis. This is a combination of standard economic techniques and innovative new health impact assessment techniques to measure the costs and benefits of each approach.

(d) Evaluation results: the results of our analysis are contained in this chapter.

(e) Conclusions.

1.15 Further details of our approach to this study can be found in the appendices.

(a) Overview of the toys industry: in this section we provide an overview of the European toys industry, examining issues such as market characteristics and dynamics, as well as trends and forecasts for the future.

(b) Legislative framework: given that this report is examining the impact of revising the TSD, it is important to gain a complete mastery of the existing regulatory framework. This section provides such an understanding, noting how the toys industry is not just affected by the TSD, but also a number of other Directives, standards and guidelines, not all of which are mandatory.

(c) The chemicals in question: here we set out in more detail information about the chemicals named in the TSD and their known effects.

(d) Literature summary: of the main (non-scientific) documents used for this study.

(e) Stakeholder consultation: as part of this report, we conducted a stakeholder consultation programme. This was done through interviews and a questionnaire survey. This section presents the results.

(f) Summary of questionnaire responses: this section presents an overview of responses received to our online questionnaire.

(g) Case studies: a brief review of how the three options might affect representative toy companies.

1.16 The appendices also include a copy of our questionnaire and the bibliography.

About Europe Economics

1.17 Europe Economics is an economics consultancy based in central London and experienced in applying economics to public and business policy issues. Particular specialisms include impact assessment, competition policy and regulatory economics.

1.18 Clients include government departments, regulatory and competition authorities, the European Commission, private sector companies and trade associations, and law firms.

1.19 Europe Economics' Chairman is Dermot Glynn and Managing Director is Dr. Andrew Lilico. The firm's website is www.europe-economics.com and telephone number is (+44) (0) 207 831 4717.

2 CONTEXT OF ASSESSMENT

Introduction

2.1 As set out in the Impact Assessment Guidelines (SEC 2005/791) of the EC, an impact assessment is a "set of logical steps which structure the preparation of policy proposals." An impact assessment has six key analytical steps:

(a) identifying the problem;

(b) defining the objectives;

(c) developing the main options;

(d) analysing their impacts;

(e) comparing the options; and

(f) outline policy monitoring and evaluation mechanisms.

2.2 In this section we set out the analysis for the first three of these steps (in which we have been guided by statements by the EC). In latter sections we move to analyse in detail the impacts of each options and make an evaluative comparison.

Problem definition

2.3 As stated in the EC's Background Document to the wider Public Consultation on the revision of toy safety legislation, the high-level objective of revising the entire TSD is to further improve the safety of toys, in particular avoiding any possible harmful medium and long-term effects of toys on children. An improvement in the functioning of the internal market for toys is also stated to be an objective.

2.4 In light of the general objectives of Better Regulation, the overall goal is given to improve the quality and efficiency of the toys safety regulations and to simplify the current legislation.

2.5 The Background Document gives three specific objectives of the revision of the TSD:

(a) modernising the safety requirements;

(b) clarifying of the scope and concepts; and

(c) improving the efficiency and coherence of enforcement.

2.6 The revision of the chemical requirements predominantly falls under the first category. While the existing TSD does contain provisions on limits for some chemicals (in annex 2), a 2005 study carried out for the EC provided data to update the limits for certain heavy

metals and suggested the inclusion of additional limits for further chemicals which may be harmful to toy users: children.

2.7 It is our understanding that the proposed revisions have not been specifically directed at any particular environmental concerns, as these are covered by other directives and regulations.

Policy Objective

2.8 The specific objective therefore is to revise the TSD so that toys do not contain chemicals in amounts that may be harmful to users. This would reduce the exposure of children to such chemicals and have the effect of potentially reducing the incidence of diseases or medical conditions associated with these chemicals found in toys.

2.9 We take as given that this policy objective is consistent with the objectives of other EU policies and horizontal objectives, such as the Lisbon and Sustainable Development strategies or respect for fundamental rights

Three proposed revision approaches

2.10 Given the above issues, Directive 88/378/EEC of the European Council on the safety of toys in the European Union is now being revised.[9] This proposed revision of the Directive includes the revision of its chemical safety requirements.

2.11 Three different proposals have been prepared, and are labelled as follows.

(a) Risk-based approach (approach 1).

(b) Combined hazard/risk-based approach (approach 2).

(c) Hazard/risk-based approach with authorisation by comitology procedure (approach 3).

2.12 The parentheses are added for the reader's convenience and are used throughout this report.

2.13 Of course, there is a fourth approach – the do-nothing scenario. We quantify the other approaches relative to this counterfactual.

[9] Where toy is defined as "any product or material designed or clearly intended for use in play by children of less than 14 years of age".

Common features of all the approaches

2.14 Within the three revision approaches, there are some common features. These are summarised as follows:

> Manufacturers shall ensure that toys are so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed of or which they contain, when the toys are used as specified in Article 5 (2) of the Toy Safety Directive.
>
> Toys shall in all cases comply with relevant Community legislation relating to certain categories of products or to the prohibition of use of certain dangerous substances and preparations.[10] Toys that are themselves substances or preparations must comply also with Directives 67/548/EEC and 1999/45/EC relating to the classification, packaging and labelling of dangerous substances and dangerous preparations.
>
> Cosmetic toys, such as play cosmetics for dolls, shall also comply with directive 76/768/EEC.[11]
>
> For the protection of children's health, a number of new migration limits for chemicals are proposed, from toys or components of toys that are accessible to children during use, shall not be exceeded

2.15 The last paragraph refers to new chemical limits for a number of chemicals already mentioned in the existing TSD, e.g. antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium. Building on the existing limits, the revision adds aluminium, boron, chromium (VI), cobalt, copper, manganese, nickel, silver, strontium, tin, organic tin, and zinc [12]

2.16 We now move to discuss the detailed differences between the three approaches.

Risk-based approach (approach 1)

2.17 Approach 1 contains the following clause not contained in the other options:

> Toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children when toys are used as specified in Article 5 (1) shall not contain allergenic fragrances that appear on the list of substances in Annex II of Directive 76/768/EEC. In addition, toys that are themselves substances or preparations that are intended to be

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[10] This provision covers all chemicals legislation applicable to toys, including Directives 2002/95 (ROHS) and 2002/96 (WEEE) as well as REACH.

[11] Thus, there is an obligation to label certain fragrances (annex III) and a prohibition to use certain fragrance compounds (annex II) + IFRA code of practise.

[12] We note that in the following documents there is discussion of units and analytical correction factor for analysis in different laboratories for estimation of bioavailability: Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on Assessment of the Bioavailability of certain elements in toys. Adopted by the CSTEE June 22nd 2004: pg 4 section 1; also see their previous document of May 28th 2004

> released from toys or components of toys, and toys or components of toys that are accessible to children during use as specified in Article 5 (2) shall list if added, as such, at concentrations exceeding 0.01 per cent by weight, the allergenic fragrances that appear on the list of substances in Annex III, Part 1 of Directive 76/768/EEC.

Combined hazard/risk-based approach (approach 2)

2.18 Approach 2 contains the above additional clause for approach 1, but amends it to include the following change:

> Manufacturers shall ensure that toys are so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed of or which they contain, when the toys are used as specifed in Article 5(2) [of the main TSD].
>
> Toys shall not contain substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2 (CMR) according to Directive 67/548/EEC unless the incorporation of that substance has been authorised in accordance with the procedure foreseen in Article [57 to 61] of Regulation […..] (REACH). However, the presence of traces of those substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and it conforms to paragraph [above].

2.19 Thus, the main addition is the ban on the use of CMRs of category 1 and 2, save where trace elements are technically unavoidable in good manufacturing practice.

2.20 It should be noted that while Approach 2 does allow that certain CMR 1 and 2 substances may be authorised via REACH, this is a long process, and only a few substances are likely to be exempted.

2.21 Some examples of CMRs of category 1 and 2 in toys and their uses are given below:

Table 2.1: CMR category 1 and 2 definitions and examples in toys

Category	Definition	Examples	How used in toys?
1	Substances have proved to be carcinogenic, mutagenic, teratogenic, or to impair fertility in animals and humans.	Butadiene Acrylamide Trichloroethylene Acrylonitrile	Butadiene is used for various polymerizations for plastics manufacturing. Acrylamide is used to synthesise polyacrylamides which find many uses as water-soluble thickeners. Trichloroethylene is also widely used as a degreaser for metal parts. Acrylonitrile is used principally as a monomer in the manufacture of synthetic polymers, especially polyacrylonitrile which comprises acrylic fibers. It is also a component of synthetic rubber.
2	Substances are probably carcinogenic, mutagenic, teratogenic or probably impair fertility based on animal tests or by some other important information.		

Source: http://www.msa.org.mt/fccd/fcc_g_301.pdf, European Commission 2007, wikipedia

2.22 Later sections consider other CMRS used in toy manufacturing.

Hazard/risk-based approach with authorisation by Comitology procedure (approach 3)

2.23 Approach 3 contains the above additional clause for approach 1, but amends it to read as[13]:

> Manufacturers shall ensure that toys are so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed of or which they contain, when the toys are used as specifed in Article 5(2) [of the main TSD].
>
> The use in toys of the following substances shall be prohibited:
>
> > (a1) substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1, 2 and 3 (CMR) according to Directive 67/548/EEC,
> >
> > (b2) substances such as those having endocrine disrupting properties or and which are identified as causing serious and irreversible effects to humans which are equivalent to those of substances listed in point (a).
>
> However, the substances referred to in the first subparagraph can be used under the following conditions:
>
> > (a2) the substance is essential to the functioning of the toy;

[13] For ease of reading, we have added additional paragraph references.

(b2) there are no alternative substances available with intrinsic hazard properties of a lower order of toxicity than the referred to in the first subparagraph (a1);

(c2) the manufacturer has demonstrated that the substance is not released in amounts that are detectable by a validated method when the toy is used as specified in Article 5 (2); and

(d2) the substance has been evaluated by the Scientific Committee on Health and Environmental Risks found acceptable to be used in toys by a decision taken by the Commission in accordance with the procedure laid down in Article X [Comitology procedure].

The presence of traces of substances referred to in subparagraph 1 shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and it conforms to [the quoted first] paragraph.

2.24 Under approach 3, all levels of CMR are banned, with the same provisio that trace elements are allowed in cases of good practice.

2.25 Some examples of CMR3s used in toys are shown below:

Table 2.2: CMR category 3 definition and examples in toys

Category	Definition	Examples	How used in toys?
3	Substances have tested to be possibly carcinogenic, mutagenic, teratogenic or to impair fertility in animal tests or based on some other important information; and substances which are suspected to have the hazard but more research is needed.	Bisphenol A Toluene Formaldehyde Dichloromethane Aniline	Bisphenol A is used in the production of epoxy resins and polycarbonate plastics. Toluene is a common solvent, able to dissolve: paints, paint thinners, many chemical reactants, rubber, printing ink, adhesives (glues), lacquers, leather tanners, and disinfectants biochemistry experiments. Formaldehyde is used to produce glues used in the manufacture of particleboard, plywood, veneers, and other wood products as well as spray-on insulating foams Dichloromethane is widely used as a paint stripper and a degreaser.

Source: http://www.msa.org.mt/fccd/fcc_g_301.pdf, European Commission 2007, wikipedia

2.26 We note that approach 3 prohibits the use in toys of substances with endocrine disrupting properties *and/or* any other substances that have equivalent health effects as CMRs, even if they are not listed as such.

2.27 The EU Comitology procedure enables the Council and European Parliament to check the legislative measures of the European Commission. This approval involves implementation committees composed of policy experts from the Member States. Comitology committees are divided into three categories: advisory committees, management committees, and regulatory committees. Changes by Comitology procedure with regard to the Toy Safety Directive would be overseen by a regulatory committee, because the changes would be related to health and safety.[14]

Summary

2.28 Table 2.3**Error! Reference source not found.** illustrates the detailed different clauses contained in each approach, and compares them with the existing TSD. A detailed explanation of each point added by the three options follows.

[14] Euractiv (2007) "Comitology" http://www.euractiv.com/en//comitology/article-117454.

Table 2.3: Comparison between existing TSD and three proposed revision options

	Toy Safety Directive	Risk-based approach	Combined hazard/risk-based approach	Hazard/risk-based approach with authorisation by Comitology procedure
No risks of adverse effects on human health due to exposure permitted	√	√	√	√
Toys comply with relevant Community legislation	√	√	√	√
Dangerous substances not permissible by CEN		√	√	√
CMR 1,2 substances prohibited*			√	√
CMR 3 substances prohibited*				√
Substances having endocrine disrupting properties prohibited**				√
Cosmetic toys comply with 76/768/EEC		√	√	√
Toys not contain allergenic fragrances from Annex II of 76/768/EEC		√	√	√
Toys not contain respiratory or skin allergens from 76/768/EEC			√	√
Toys not contain respiratory or skin allergens from 67/548/EEC				√
Provisions for nickel apply				√
Enhanced migration limits apply		√	√	√

* Except under certain specified conditions.

** We note that this point is given in brackets in the Commission description of the three approaches, which may suggest that it has yet to be finalised.

Source: European Commission, 2007

Provisions contained in the option that are addressed already

2.29 It should be noted that a number of CMRs are already restricted in toys via existing legislation and standards. This is important for the purpose of developing a baseline counterfactual for assessment purposes, from which the benefits/costs of the three approaches can be compared to. The table below highlights these.

Table 2.4: CMRs already covered by other regulations/guidelines

Chemical	Class	Toy material	Regulation/standard	Mentioned in Directive 76/796?*
Acrylamide	Carc 2, Muta 2	Polyacrylamide	FCM SML / EN 71-9	√
Toluene	Repro 3	Solvent and polymers	FCM R(food) / EN 71-5; EN 71-9	√
n-Hexane	Repro 3	Solvent and polymers	EN 71-5; EN 71-9	
Dichloromethane	Carc 3	Solvent and polycarbonate	EN 71-9	
Formaldehyde	Carc 3	Preservative; resins; textiles; paper; and resin-bonded wood	FCM SML / cosmetics / EN 71-9	
N-Nitrosamines e.g. NDMA	Carc 2	Contaminant (rubber)	Cosmetics (Annex II)	
Lead compounds	Repro 1	Stabiliser for PVC	EN 71-3 (certain toys)	√
Aniline	Carc 3	Some dyestuffs	EN 71-9	√
Nitrobenzene	Carc 3 Repro 3	EVA & PU foams	EN 71-9	
Trichloroethylene	Carc 2 Muta 3	PVC; elastomers	EN 71-9	√
Certain glycol ethers & glycol ether esters	Repro 2	Solvents for lacquers and varnishes	FCM, Gp t-TDI / EN 71-9	
Toluene diisocyanate	Carc 3	Epoxy resins and polyurethanes	FCM QM	√
Isophorone	Carc 3	PVC inflatables	EN 71-9	
Bisphenol A	Repro 3	Polycarbonate	FCM TDI / EN 71-9	
Phenol	Muta 3	PVC	FCM TDI / EN 71-9	

Where:

Carc 3 = carcinogen, category 3

Muta 2 = mutagen, category 2

Repro 3 = toxic for reproduction, category 3

FCM = food-contact material assessed by the SCF

SCF = Scientific Committee for Food

SML = specific migration limit

TDI = tolerable daily intake

Gp t-TDI = group temporary tolerable daily intake

QM = maximum permitted quantity of the substance in the finished material or article

R(food) = restriction of amount in food

**For more details see appendices*

2.30 It is worth considering EN71-9 in some further detail. EN71-9 supports but does not reduce the responsibility of toy manufacturers, importers and suppliers for ensuring that

the use of other substances will not endanger the health whilst playing with toys as intended or in a reasonably foreseeable way. There should also be no exposure to children from toys in amounts which may harm their health of organic chemical substances which are classified by other relevant statutes such as CMRs and for which no requirements are specified. Organic chemicals are classified within the groups of solvents, preservatives, plasticizers, colouring agents, flame retardants, monomers, biocides, and processing aids.

2.31 In particular, EN71-9 specifies requirements for migration or contact of certain hazardous chemicals, compounds by the routes of mouthing, ingestion, skin contact, eye contact and inhalation.

Technical file

2.32 In addition to the revision of the TSD, he EC is considering three proposals to revise the technical file requirements.

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

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

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

2.33 These three proposals build on the existing requirement in Article 8(b) of the TSD which requires the manufacturer or his authorised representative to hold:

> - a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity of production with the standards referred to Article 5(1)…
>
> - the addresses of the places of manufacturer and storage,
>
> - detailed information concerning the design and manufacture.
>
> Where neither the manufacturer nor his authorised representative are established within the Community, the above obligation to keep a dossier available shall be the responsibility of the person who places the toy on the Community market.

2.34 Although these proposals can be associated with particular TSD chemical requirement revision approaches, they are not necessarily linked, and therefore should be analysed separately.

3 RESEARCH METHODOLOGY

Introduction

3.1 This section contains details of our methodology for assessing the impacts of each of the three proposed approaches. At the core of that methodology lie the European Commission's impact assessment guidelines.[15] The use of this approach also allows the results of this report to be easily comparable to other impact assessments carried out on revisions to the TSD.[16]

Methodological challenges

3.2 Given that the study has three overlapping themes of analysis (economic, health and environmental), this necessitates the use of a number of techniques, not all of which can be used for each theme.

3.3 While there are a number of standard economic techniques available to analyse the financial and wider economy effects of a change in the chemical requirements of the TSD, techniques to measure health and environmental benefits are not as well developed (although there is much literature discussing possible approaches). The assessment of health and environmental costs and benefits is further complicated by the fact there is a great deal of uncertainty in the scientific evidence base on the impacts of the chemicals listed in the TSD, or that the data themselves have not yet been collected. For a number of chemicals, sufficient research has yet to be carried out which can tell us if a particular chemical has any adverse effects for humans or the environment.

3.4 This therefore presents a challenge to the evaluator. Our response has been to use, where possible, already established techniques and data from reputable sources. We have built on a number of theoretical and empirical studies to develop an innovative, robust conceptual framework to analyse the health impacts of the three options (discussed in more detail in the analytical framework chapter), and then integrated this into more standard economic assessment models: making the outputs available in monetary terms.

3.5 Where there remain uncertainties and data gaps, we have constructed plausible scenarios to build a range of outcomes. We then come to a view as to which scenario is most plausible: our preferred scenario.

3.6 Our analysis of the environmental benefits and costs is largely qualitative.

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[15] http://ec.europa.eu/governance/impact/docs/SEC2005_791_IA%20guidelines_annexes.pdf

[16] E.g. Study on the impact of the revision of the Council Directive 88/378/EEC on the safety of Toys (2004) by RPA

Literature review and conceptual analysis

3.7 One of our first steps was to conduct a comprehensive literature review in order to develop a complete and up-to-date mastery of the European toys industry and the associated regulatory framework. We have reviewed literature on the chemicals contained in the TSD to analyse the evidence base concerning their effects on humans, and also existing methodologies in health impact assessments.

3.8 The literature review has considered a number of sources, listed in the bibliography. These include:

(a) peer reviewed academic journals;

(b) industry literature such as annual reports;

(c) research from public agencies;

(d) research from associations and other relevant bodies;

(e) legal journals and the relevant legislation; and

(f) documentation on industry standards and guidelines.

3.9 Specifically, the review has been undertaken to:

(a) understand the major types of impacts to be assessed and potentially their relative importance;

(b) understand the main mechanisms or channels through which such impacts would arise;

(c) gather high level statistics about the industry and the use of chemicals in question; and

(d) select issues of particular significance for detailed consideration at the later stages of this study.

3.10 The result of the literature review has been the development of an analytical framework for use in the reminder of the study.

Stakeholder consultation

3.11 As is best practice in impact assessments, we have undertaken a stakeholder consultation. The purpose of the consultation is manifold. In the first instance, it has been done to ensure that the analysis contained in this report reflects the technical and practical realities currently experienced in the toys industry, as well as the latest technical thinking in the area and expected market trends. It also provides a further opportunity to collect specific data elements that are not available in the public domain or other known

databases. Lastly, while not a substitute for a full-scale EC consultation, it does provide us with an opportunity to learn stakeholder views on the three proposed approaches to the revision of the chemicals requirements in the TSD.[17]

3.12 We have used a three stage stakeholder approach in this study:

(a) pilot interviews with the Expert Group of the Commission on chemicals in toys;

(b) a questionnaire survey of industry stakeholders;

(c) a limited follow-up stakeholder interview programme.

3.13 At the outset of this project, we contacted experts from a list provided to us by the EC. These experts were located across the European Union and could provide both a pan-European and a Member State perspective. The discussions with the Expert Group were generally high level in nature, in order to provide us with an up-to-date understanding of the industry and the context of the proposed amendment to the TSD. The experts were also able to direct us to further documents and data for our literature review.

3.14 The second stage of our stakeholder consultation consisted of an online questionnaire hosted on the EC's Interactive Policy Making Tool. This was developed in consultation with the EC and we also received suggestions on its structure and content from the toys industry. The purpose of the questionnaire was primarily to acquire data for our model on the economic impacts of the proposed approaches. However, there were also more general questions about the industry and the health and environmental impacts of the named chemicals.

3.15 The questionnaire was sent out to a number of bodies across the European Union in the following categories:

(a) Toy manufacturers.

(b) Toy importers and toy retailers.

(c) Consumer and health groups.

(d) Others including chemical testing laboratories and environmental groups.

3.16 In total, the questionnaire accessed over 500 stakeholders in the toys industry, and elicited 79 useful replies between 18 May and 8 June 2007. This response rate compares favourably to the number of responses received to the questionnaire sent to authorities and notified bodies in the 2004 RPA report.

[17] It was suggested by a number of stakeholders that a more comprehensive consultation is required before any final decision can be made to revising the TSD.

3.17 Questionnaires contained some common questions, but also a number of questions specific to particular groups of stakeholders, e.g. manufacturers were asked about the impacts in the manufacturing process, whereas health agencies were asked about the health impacts. A copy of the questionnaire is placed in the appendix to this report.

3.18 The final stage of the stakeholder consultation was limited interviews with selected stakeholders in order to clarify outstanding issues and seek further data/views. This stage also included discussions with the companies chosen for our case studies.

3.19 Where possible the interviews were face-to-face. If these were not possible, then interviews took place via telephone and email correspondence.

Modelling

3.20 Building on the conceptual framework and analyses gathered in the previous tasks, we constructed a model to quantify the costs and benefits of each of the proposed approaches relative to the "do-nothing" scenario.

3.21 We discuss the model in depth in a subsequent section, but note here note some general principles that were followed:

(a) Where possible, we have quantified the monetary aspects of each approach.

(b) Where possible, we have quantified the various impacts of the approaches in physical terms (e.g. time spent on compliance activities, reduction in statistical risk of death).

(c) Where possible, we have placed a value on these physical impacts, and where possible expressing it in terms of a monetary equivalent.

(d) We have distinguished between costs and benefits and transfers.

(e) We have distinguished between incremental and one-off sunk costs.

(f) We have considered different levels of compliance and associated enforcement procedures and costs for the approaches.

(g) We have identified how impacts fall on particularly interesting classes of stakeholder — e.g. young children; SMEs, EU manufacturers relative to non-EU manufacturers.

(h) Where costs and benefits arise over time, they have been appropriately discounted.

3.22 As noted above, it is inevitable that the level of future costs and benefits will not be known for certain. Thus, the impact assessments should take also account of the risks and uncertainties surrounding policy impacts rather than just focusing on central estimates. There are various ways in which the risks and uncertainties associated with policy impacts can be analysed such as scenario analysis, and where appropriate, these have been used in this study.

Evaluation

3.23 Inputting the data collected through our literature review and stakeholder consultation, we have run our model across a number of scenarios to evaluate the differing impacts of each of the proposed approaches.

3.24 Where data were not forthcoming or there was too much uncertainty in the evidence base to allow for robust quantitative analysis, we have reverted to qualitative analysis.

3.25 The results of the evaluation directly feed into our conclusion and recommendations.

4 ANALYTICAL FRAMEWORK

Introduction

4.1 This chapter contains our analytical framework to assess the three proposed approaches along economic, social (in particular, health) and environment dimensions. The section ends with the statement of our modelling assumptions.

4.2 The next section presents our evaluation results for both the three approaches for the TSD revision, and also for the three proposals for the technical file.

Identification of impacts

4.3 This sub-section serves to identify possible impacts of the revision of the TSD chemical requirements. While we discuss particular impacts at a high level, we reserve our full analysis for the evaluation section. The intention here is to merely identify the possible impacts, not quantify them.

4.4 The impacts discussed are based on those identified in EC's own Impact Assessment Guidance handbook. We have attempted to be as broad as possible in identifying the impacts (not all of which can be easily quantified), as well as considering possible unintended consequences in the short- and long-term. Discussion with stakeholders has also assisted us in building a picture of potential impacts.

4.5 Given the differences between the three proposed approaches is incremental in nature, we have not identified any benefits or costs that are unique to any particular option. The differences relate to the size and scope of the associated benefits and costs of each proposed approach.

Economic impacts

4.6 Our identified potential economic impacts under the three proposed approaches are summarised in the table below. This table (and subsequent ones) set out our initial analysis on which areas to focus on for the full impact assessment in the subsequent chapter, and as such do not necessarily represent our final view. The categories of impact are those suggested by the EC in its impact assessment guidance.

4.7 Below we briefly discuss the salient issues in turn, but the main analysis is contained in the Evaluation section that appears later in this report.

Table 4.1: Economic impacts of the proposed three approaches for revision

Impact on	Description	High level assessment of potential effect
Competition and the internal market	Do any of the approaches affect EU competition policy and the functioning of the internal market?	We do not believe any of the approaches will affect the functioning of the internal market. Further, given the highly heterogeneous nature (see appendix on toys market structure) of the market it is unlikely that consumer choice will be reduced. However, higher standards of compliance may imply higher barriers to entry.
Competitiveness	Do any of the approaches have an impact on the competitive position of EU firms in comparison with their non-EU rivals?	There should be no intra-EU effect on competition, as all manufacturers (EU and non-EU) will need to adhere to the same standards if they wish to sell their products in the EU. EU firms could suffer in foreign markets as it is unlikely that they will be able to develop two separate production chains.
Trade and investment flows	Do the approaches cause any cross-border investment flows such as relocation of economic activity?	There is unlikely to be relocation of economic activity outside of the EU as a result of these approaches as production is already largely carried out outside the EU currently. Conversely, it may be there case that there may be more investment in testing facilities in the EU.
Operating costs	Do the approaches cause additional adjustment/compliance/transaction costs to businesses?	It is quite possible that manufacturer costs will rise in response to changed chemical requirements — for instance, in finishing processes.
Administrative costs	Do the approaches impose additional administrative requirements or increase administrative complexity?	Each approach requires manufacturers and importers to provide more information than is currently required, and there will be costs associated with administrative related to testing. Regulators may also have greater costs of enforcement.
Property rights	Are property rights affected?	Increased disclosure requirements may lead to issues over property rights if suppliers are unwilling to make public their techniques and chemical make-up of their raw materials.

Impact on	Description	High level assessment of potential effect
Innovation and research	Do the approaches stimulate or hinder research and innovation?	While there may be some innovation to find substitutes for chemicals, this is a long term process, and in the short term, innovation and research in new toy products may decline as companies choose to rely on known products. Should the hazard approach be adopted the lengthy process for authorisation may discourage innovation.
Consumers and households	Do the approaches affect the price consumers pay and does it affect their ability to benefit from the internal market?	Increased manufacturer/importer costs may be passed on to end users via higher toy costs. Poorer households may be disproportionately affected. However, consumers may also benefit through greater information about toys.
Specific regions and sectors	Do the approaches have particular effects on certain sectors or business types?	Given that the toy industry is competitive, one would only expect the inefficient firms that cannot absorb the costs to go out of business. It may be the case that it is SMEs that are most likely to be affected. However, if there were to be elements of buyer power in the industry and the larger manufacturers can squeeze suppliers, then SMEs may suffer disproportionately. Other sectors are not likely to be affected by the approaches, with the exception of retailers solely selling toys.

4.8 The table above identified that, prima facie, the main costs and benefits of each approach will relate to changes in manufacturing and administrative costs for manufacturers, as well additional costs of monitoring and enforcement for regulatory agencies.

4.9 A high-level analysis suggests that none of the approaches should have a major impact on the functioning of competition and the internal market for toys. While the TSD may affect different toy manufacturers and importers in different ways (i.e. those that use more named chemicals will be likely to be more affected), the changed chemical requirements will apply equally to all market participants, thus no one manufacturer or importer will be uniquely advantaged or disadvantaged competitively as a result. Consumer choice seems also unlikely to be affected given that toys are sold in niche markets and generally have low shelf lives.

4.10 However, one should not discount the possibility that higher standards for chemicals may indirectly raise entry barriers to the industry as start-up costs may increase due to the necessity of having to ensure that the product complies with stricter regulations.

4.11 Similarly, overall market competitiveness should not be affected since all manufacturers and importers must comply to the same standards if they wish to sell their products within the EU. However, for those manufacturers producing toys in the EU and selling some overseas and some domestically, there may be some adverse impacts. This may be due having to comply with two different sets of safety standards across two different jurisdictions. Given that European standards are among the most stringent in the world, unless the manufacturer can have two separate production lines, if his production costs rise due to the TSD revision, his costs will rise for both his domestic toy and his export toy. Domestically, this may not matter (as all other competitors face similar cost pressures), but for the overseas market he may lose market share if the cost increase is passed on to consumers.

4.12 From our research and stakeholder discussions, it is clear that the level of toy manufacturing in Europe is low and is focused in niche markets (which are likely to be less price insensitive). Thus, none of the approaches would cause a shift in production away from Europe for the simple reason there is very little there currently. Conversely, there may be investment in Europe to upgrade and create new testing facilities to test for compliance to the new TSD requirements.

4.13 It is quite possible that both operating costs and the administrative burden might increase due to the three approaches. Manufacturers may have to change their production techniques if certain chemicals are prohibited or the limits revised — this will entail, at the very minimum, a one-off cost. The administrative burden (for both importers and manufacturers) associated with filling in new documentation, verifying compliance down the supply chain, recording of multiple testing, etc. might also increase. There are also costs associated with enforcement to be borne by the regulators and other agencies, as well as under approach 3 the costs of conducting a comitology procedure.

4.14 Under the proposals to revise the technical file it is possible that there may be some intellectual property right issues. These may arise from the fact that suppliers have to disclose formulas and chemical input amounts for certain (possibly patented) products and raw materials.

4.15 With regards to innovation, the three TSD approaches may stimulate new research into chemical substitutes, but there may be a short term trade-off in the form of reduced innovation in toy products as firms choose to rely on known products that already comply with the revisions.

4.16 It is quite conceivable that the three approaches will have impacts to households via higher prices. The extent to which these costs are past through will depend on how competitive the market is, the extent to which costs can be absorbed, and market elasticities. Further, one should not discount the possibility that some manufacturers and

importers may use the TSD revision as an excuse to raise their prices over and above the actual cost change.

4.17 The approaches are likely to impact differently across types of business, in particular according to their size. If elements of buyer power exist for the larger firms that mean they can squeeze their suppliers and keep costs constant, SMEs may face higher input costs as suppliers try to recover their costs elsewhere.

4.18 These economic impacts are quantified and qualified in the next section in greater depth.

Social impacts

4.19 Our identified potential social (in particular, health and employment) impacts under the three proposed approaches are summarised in the table below. The categories of impact are those suggested by the EC in is impact assessment guidance.

Table 4.2: Social impacts of the proposed three approaches for revision

Impact on	Description	High level assessment of potential effect
Public health and safety	Do the approaches affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity?	Potentially, there are significant impacts here with toys containing reduced amounts of certain chemicals. This may lead to a reduction in the incidence of certain health conditions associated with toys. A lower number of people suffering from health conditions will also be beneficial in that healthcare costs will fall.
Employment and labour markets	Do the approaches lead to the creation/ loss of jobs?	There may be a net change in employment (although this may be small).
Standards and rights related to job quality	Do the approaches have an impact on job quality?	No impact.
Social inclusion	Do the approaches affect access to the labour market or affect equality?	No impact.
Equality of treatment	Do the approaches affect equal treatment and equal opportunities?	No impact.
Private and family life	Do the approaches affect the privacy of individuals?	No impact.
Governance	Do the approaches affect the involvement of stakeholders in issues of governance?	No impact
Crime, terrorism and security	Do the approaches improve or hinder crime, terrorism and security?	No impact.
Access to and effects on social protection, health and educational systems	Do the approaches have an impact on services in terms of their quality and access to them?	No impact.

4.20 Assessing the health impact on children of specific chemicals from exposure to toys is problematic. The main issues include the fact that any health effects from chronic exposure at low levels may not be apparent for many years. There is now increasing emphasis on reproductive effects which again would not be manifest until puberty. Alongside the long latency of any adverse health effects is the impact played by the multiple chemical environments that children experience. Sensitisation by chemicals from dermal contact is also an issue. This is in part due to the number of available products

containing new chemicals that have not been fully tested, particularly the numerous organic chemical compounds.[18]

4.21 Nonetheless, potentially, the major social benefit of the three approaches is that of public health and safety. A reduced incidence of certain chemicals in toys may have significant downstream health benefits both currently and into the future. The impact on jobs is ambiguous. Some firms may require additional staff to carry out administrative or testing (i.e. more lab workers), while other firms may find the costs prohibitive and go out of business. Further, health workers who have previously been employed in treating diseases associated with these chemicals may now be redundant if the incidence has decreased sufficiently. However, it may be that these workers quickly find new jobs or react by diversifying their product base. It is impossible to say which effect (if indeed any) will dominate.

4.22 We have also identified there being a further possible employment effect due to the three approaches. If prices do not rise for toys and demand falls, then it is quite possible that production in Europe is reduced and jobs directly and indirectly associated with the toys industry be affected. This is investigated further in the next chapter.

4.23 On the other social impacts identified by the EC guidance, we have not identified any further impacts of the three approaches.

Environmental impacts

4.24 Our identified potential environmental impacts under the three proposed approaches are summarised in the table below. The categories of impact are those suggested by the EC in is impact assessment guidance.

4.25 As the table shows, we do not believe that any of the proposed approaches have significant environmental impacts for the entire lifecycle of a toy. The lifecycle of a toy begins with its manufacturing and sourcing of raw materials and ends with the toy's disposal.

4.26 When toys have been outgrown or are no longer wanted, there are a number of channels they can be disposed of which in, for instance charities, garage sales or other auctions. Toys that are no longer fit for purpose, however, must be disposed of. Typically, toys are not recyclable (although often their packaging is) and so are normally disposed of as municipal solid waste.[19] The disposal of toys is governed by a number of EC Directives such WEEE, ROHS, Packaging and Packaging Waste, and the Batteries Directive, and the proposed revision to the chemical requirements

[18] The concept of trace substances such as zinc, being an essential part of the healthy diet should also be considered. The delicate balance between a "trace" being essential and a larger amount being toxic, requires further study.

[19] We are aware of one company which does offer to recycle their own brand toys.

4.27 However, one might argue the options do refer to new limits for particular chemicals and the ban of CMRs under certain conditions, thus meaning the amount of chemicals which could potentially enter the environment is reduced, e.g. fewer chemicals could seep into soil or be released into the air. We do not find this argument convincing because currently chemicals do not escape from the toys and enter the environment in significant quantities due to existing regulations[20] — thus reducing limits will not impact the probability of, or amount, of chemicals escaping from the toys.

[20] Principally we note that issues of general exposure through the environment are usually much lass than those of specific exposure (i.e. through playing with toys)

Table 4.3: Environmental impacts of the proposed three approaches for revision

Impact on	Description	High level assessment of potential effect
Air quality	Do the approaches have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health?	No impact.
Water quality and resources	Do the approaches decrease or increase the quality or quantity of freshwater and groundwater?	No impact.
Soil quality	Do the approaches affect the acidification, contamination or salinity of soil and soil erosion rates?	No impact.
The climate	Do the approaches affect the emission of ozone-depleting substances and greenhouse gases?	No impact.
Renewable and non-renewable resources	Do the approaches affect the use of renewable and non-renewable resources?	No impact.
Biodiversity	Do the approaches reduce the number of species/varieties/races in any area or increase the range of species?	No impact.
Land use	Do the approaches have the effect of bring new areas of land into use for the first time?	No impact.
Waste production/ generation	Do the approaches affect waste production or how waste is treated, disposed or recycled?	No impact. Toys are already covered by existing legislation which accommodates changed chemical limits.
Likelihood and scale of environmental risks	Do the approaches affect the likelihood of fire, explosions, breakdowns, accidents and accentual emissions? Do they affect the risk of unauthorised dissemination of environmentally alien or genetically modified organisms?	No impact.
Use of energy	Do the approaches increase or decrease the use of energy?	No impact.
The environmental consequences of firms' activities	Do the approaches lead to changes in natural resource inputs required per output?	While the raw material inputs may change, these will not be related to natural resources.
Animal and plant health, food and feed safety	Do the approaches have an impact on health of animals and plants?	No impact.

Modelling framework and transmission mechanisms

4.28 Building on the above high level analysis of impacts, our calculations to estimate quantitatively the impacts of the three different options proposed have separated the impacts on costs from those on benefits.

Costs

4.29 The overwhelming majority of the costs deriving from the proposed changes will be borne by manufacturers and importers that will need to adapt their processes to the new requirements. In addition to these costs one should take into account the increased administrative burden and the time involved in implementing the changes.

4.30 However apart from the hazard based approach, where a Committee would have to be set up in order to examine the chemicals and authorise (or otherwise) their use in toys (the Comitology process), the administrative costs seem far smaller than the effects on manufacturing costs.

4.31 To estimate the effects on costs of the various options we mainly relied on our questionnaire survey (reported in the appendix) where we asked questions on the impacts on costs of the different options. We acknowledge that this could lead to an overestimate of costs as we are obtaining information from companies that have a vested interest in the proposed modifications rather than from an impartial third party. Conversely, it might be the case that the costs are underestimated as the respondents to the questionnaire are existing market players, and might favour regulations that push up (or erect new) entry barriers, however, from our discussions with stakeholders we think this is unlikely to be the case.

4.32 We have asked manufacturers to provide information on:

(a) costs on each part of the manufacturing process: we have broken this down into five parts;

(b) cost for each part of the manufacturing process for each option;

(c) current and new administration costs;

(d) current and new costs of testing for chemicals;

(e) costs of distribution, importing and retailing before and after options; and

(f) one-off costs of having to change by each option.

4.33 We also note that users from toys themselves might face costs arising from the three revision approaches. In particular, children may lose “utility” or well-being from playing with toys that are now banned (due to containing excessive amounts of chemicals or

banned chemicals) or are costed out of existence. Such costs can, without behavioural studies, be only discussed qualitatively.

Benefits

4.34 The conceptual framework used to estimate the health related benefits stemming from the different options can be described as follows.

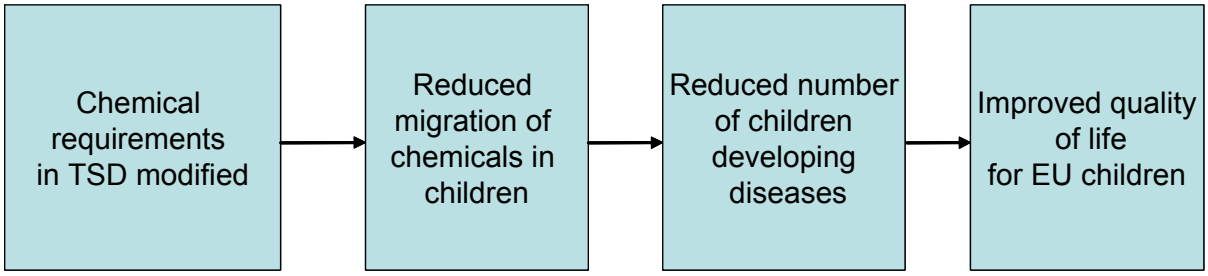
4.35 Children in contact with chemicals present in toys have a certain probability of developing a disease linked with this chemical. This implies that a certain share of the total number of children in the EU will develop the disease after exposure to the toy. Accounting for population growth and population dynamics and a horizon of 44 years[21] this implies that we can estimate the total number of children that will get the disease in the EU.

4.36 After each of the different approaches are implemented toys will contain a smaller amount of chemicals (the extent of this reduction is different under the different approaches). This therefore implies that a lower share of the total number children in the EU will develop the disease.

4.37 In order to calculate the benefits of the different options we need to value the number of years lived with a disability (i.e. the disease) saved by each option, comparing this result with what would happen should the "do nothing" option be implemented.

4.38 Figure 4.1 illustrates the mechanisms that drive our analysis.

Figure 4.1 : Mechanism of social impacts



Source: Europe Economics

4.39 The reduction in the incidence and prevalence of the diseases is a benefit to society, per se. However we have to bear in mind that society will also benefit from the fact it will not be necessary to pay for the cures necessary to the children. We do not provide precise estimates of these benefits but they are taken into account qualitatively.

[21] Eurostat data on population projections are available up to the year 2051.

Major Assumptions

4.40 In evaluating the impacts of the three different proposed approaches it is important to establish what the benchmark against which these impacts are judged is. In our case we will assess the three options against the "do nothing" option of not revising the TSD and allowing the industry to continue as is. Importantly, this includes adherence to all parts of the similar (but not equivalent) EN71 guidance.

4.41 Our stakeholder consultations suggested that the impact of REACH on the toys industry will be limited. One should interpret this comment with care. Toys are not exempt from the provisions of REACH as far as they are substances, preparations or articles under the definition in Article 3. Under REACH, chemicals will need to be registered (but not classified). Indeed, toys that are produced within the EU will be subject to the REACH authorisation procedure which provides that substance of high concern (such as CMRs of category 1 and 2) will be eventually placed in Annex XIV of the REACH regulations. However, this provision will not apply for toys that are manufactured outside of the EU — which is the majority of toys, and presumably this is what stakeholders meant by the comment that they would not be affected.

4.42 The impact of REACH will therefore be different according to whether a company manufactured toys in the EU or not. Evaluating the economic impact of REACH is outside the scope of this study, but we note that further work is required to assess the impact of these obligations on EU-based producers of toys.

4.43 In addition, it should be noted that while the first obligations of REACH will apply from 2008, it will not be until 2018 that all provisions have been implemented, and that even then it will take further years to classify all the chemicals that falls within its scope.

4.44 Although it is likely that there will be trends influencing the toys industry over the medium to long term, we do not aim to include them in our modelling efforts. There are two main reasons why we opted for this simplifying assumption: first of all the most important trends will have an impact on both costs and benefits and therefore the preferred approach would not be influenced by them; secondly our discussions with the interested stakeholders highlighted the fact that they do not expect any major change in the toys market in the future.

4.45 Over the last few years, the market of toys has shifted from traditional toys to videogames. The main concerns regarding chemicals are for those toys that children put in their mouth and therefore traditional toys. If the trend towards videogames continues then overall costs will be reduced since manufacturing companies will not be producing as many toys as they are now. On the other hand, children would not be playing with traditional toys as much as they are now. If, for some reason, the trend starts to reverse in favour of traditional toys then both costs and benefits would tend to increase.

4.46 For modelling purposes, we have assumed that the changes to the toy safety directive will be implemented instantaneously at the end of 2007. Therefore all costs and benefits have been calculated starting from 2008 but in 2007 prices.[22]

4.47 We have also assumed 100 per cent compliance.

4.48 Our period of analysis is between 2008 and 2051, which is the last year for which Eurostat population projections are available.

[22] We further note that the existing approach options do not mention any transitional mechanisms, and so we have assumed a "big bang" approach to implementation and that all toys produced after this date are affected by the TSD revision.

5 EVALUATION

Introduction

5.1 Having set out the analytical framework in the previous section, we now present out modelling results for the three TSD revision approaches and the three proposals for revising the Technical File requirements.

Three approaches for TSD revision evaluation

5.2 As discussed in the previous section we evaluate the following economic and social impacts.

Table 5.1: Identified impacts for evaluation

Impact	How evaluated
Economic	
Operating costs	Quantitative costs for manufacturers and importers modelled.
Administrative costs	Quantitative administrative costs for manufacturers and importers modelled. Comitology and other enforcement costs discussed qualitatively.
Consumers and households	Impact on prices modelled.
Specific regions or sectors	Impacts differentiated by business type and size.
Social	
Public health	Health benefits quantitatively modelled.
Employment changes	Net direct employment change estimated.

Motivation for methodological approach

5.3 We believe that our chosen methodology is a solid, innovative and scientifically-based way of quantifying economic and social costs and benefits associated with hazardous substances. Our methodological choice has been informed by existing methodologies and similar studies, as well as the time constraints imposed on the project.

5.4 Although alternative approaches do exist (for example a detailed bottom-up cost model for economic costs), these are not viable for industry wide assessments. Alternative social models, mainly based on qualitative analysis and expert opinion do exist, but we believe that results using such approaches would not be as strong as those we obtain here. Our health benefits model draws both on the scientific evidence base, expert opinion, and modelling techniques for risk assessment.

5.5 Notwithstanding any uncertainties and caveats which we will describe when discussing each methodological step, we are confident that the theoretical underpinnings of our

methodology represent the best available choice based on peer reviewed scientific evidence and best practice in impact assessments.

Quantitative impact assessment — Costs

5.6 The purpose of this section is to quantify the likely impact of each policy option on manufacturers' costs. Given the nature of the proposed changes it is reasonable to assume that the overwhelming majority of the costs will be captured by the increase in costs borne by manufacturing and importing companies. Testing for the presence of various chemicals and developing new products that use alternative materials (or less of a substance) will increase manufacturing costs more than anything else. However, the administrative costs associated with approach 3 may be non trivial, and there are also costs involved in setting up the Comitology procedure.

5.7 In order to calculate the costs stemming from the options we have relied on the results of the stakeholder questionnaire.

5.8 We have asked manufacturers and importers to provide information about the likely changes in costs deriving from the different options in terms of their current operating costs, i.e. how they would react to and interpret each approach. They were also asked to provide an estimate of the one-off increase in those costs related to the transition between the current and the potential new rules (see the appendix for detailed information on the questionnaire).

5.9 In order to check whether the options were impacting disproportionately on one particular process we asked respondents to disaggregate the impact according to the different processes involved in toy manufacturing. In addition we have also asked respondents to provide their answers in terms of manufacturing, administrative and distributional costs.

Administrative burden

5.10 One important component of the cost calculation is that of the changed administrative burden. The EC IA guidance defines administrative costs as "the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide the information on their action or production, either to public authorities or to private parties".

5.11 In the case of the proposed approaches the administrative burden would relate to the costs of having to find out more information about one's products, fill in forms related to testing and other regulations and so forth.

5.12 In order to calculate the administrative burden associated with each approach, we have followed the standard cost model proposed by the EC. This assesses administrative costs on the basis of the average cost of the required action multiplied by the total number of actions performed during a given year. The formula is as follows:

$$\text{Administrative burden} = \sum \text{Price} \times \text{Quantity}$$

5.13 Where the price is calculated as the average labour cost per hour (in the EU) multiplied by the time associated with each approach. Quantity in this case refers to the number of individuals involved in administrative activities.

5.14 From TIE literature, we know that the total European toys industry employs approximately 98,000 people, of which 45,000 are not involved in manufacturing. For the purposes of this analysis, and based on our understanding of the industry, we assume that 5,000 of these are directly involved in administrative activities pertaining to chemical requirements.

5.15 From our questionnaire survey we are able to derive how the time allocated for administrative duties will change across each approach, and thus the equation becomes as shown below. The average labour cost per hour comes from Eurostat and is given as €21.22.

5.16 The administrative burden is then calculated over the entire period in question (2008-2051) using the standard discount rate of 4 per cent. The breakdown is as follows:

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

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

Source: Europe Economics calculations.

Manufacturing and distribution costs

5.17 To calculate the manufacturing and distributive costs, we have calculated an average percentage cost increase for each of these cost categories for each of the different options. Then we have calculated an average ratio between turnover and operating costs in the toys industry from the annual reports of companies operating in the European market.

5.18 The last step needed to estimate costs is a measure of overall turnover to which the calculated ratio has to be applied. According to the Toy Industries of Europe[23] the overall turnover of the toy industry in Europe 2005 (the last year for which data are available) was roughly €13 billion.

5.19 With these data we calculated a stream of costs from 2008 to 2051 assuming no adjustment will take place in the toy industry i.e. that the increase in ongoing costs is permanent.

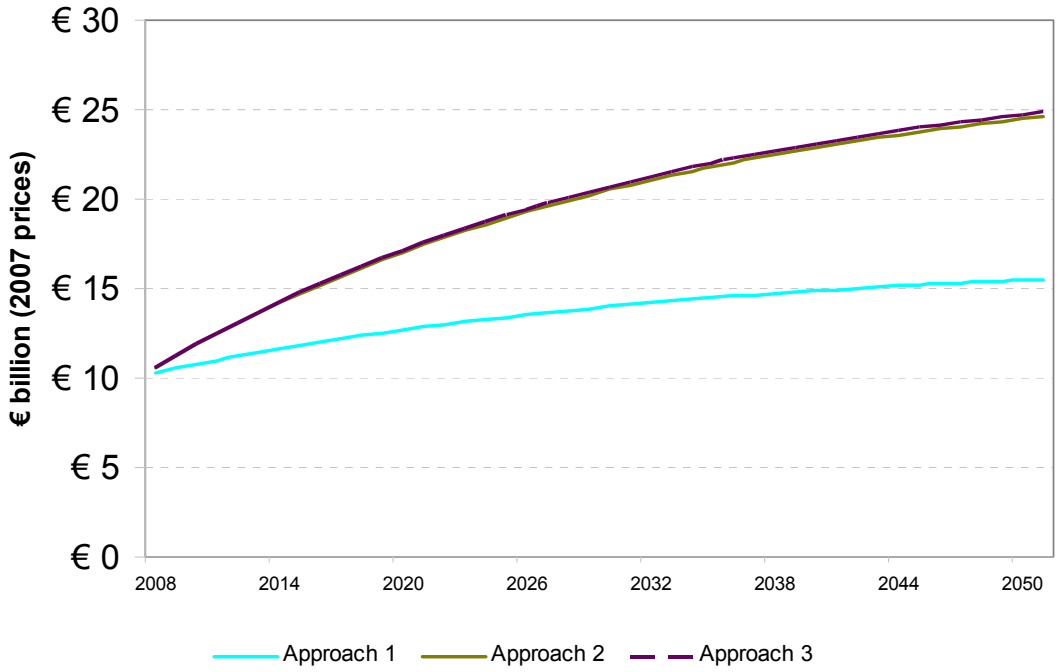
[23] Toy Industries of Europe, *TIE Facts and Figures*, 2006

5.20 Then we have discounted these amounts using a 4 per cent annual discount rate as suggested in the EC guidelines on impact assessment.

5.21 According to the methodology described we estimate that the implementation of approach 1 would cause a one-off increase of €240 million on operating costs, while approaches 2 or 3 would cause a €520 million rise.

5.22 Figure 5.1 reports the pattern followed by operating costs starting in 2008 according to the different approaches. We can see that all approaches imply an increase in the cost paid by manufacturers but that there would be no significant difference between approach 2 and approach 3.

Figure 5.1: Costs differentials by approach*



Source: Europe Economics

** Includes administrative burden.*

Comitology costs and other enforcement and monitoring costs

5.23 Approach 3 includes a provision for certain chemicals to be continue to be used, provided that they have been approved by the Commission via the Comitology procedure.

5.24 We have been informed by the Commission that the Comitology procedure can take between 6 to 18 months (although staff may be involved in related activities for longer periods — see below). If there were a large number of chemicals submitted to the

Scientific Committee on Health and Environmental Risks, then the time taken may be even longer (for example around 200 substances are classified as CMR3).

5.25 Using the average monthly wage of a Grade 8 EC staff member (EC Staff Regulations[24]) of €5,519, we have been guided to assume that half of his/her time would be spent on Comitology related activities over a period of five years. Thus, summing across the five years gives a figure of €165,570. This is then the per unit incremental cost per chemical to be considered.

5.26 From our stakeholder questionnaire, we have identified at least seventeen different CMRs that are used in toys. Using the figure of €165,570 per substance, then the total Comitology cost (in terms of staff costs) calculated is €2.8m.[25] This would be a one-off cost as once a chemical is approved it does not need to be submitted in later years.

5.27 However, this figure should be read with a number of caveats. In the first instance, it only relates to EC staff — it does not include any estimate for external scientific expertise being used (estimated to be three man-weeks per substance) or the costs of reimbursing Member State experts. Nor does it include any non-staff costs, such as venue hire for committee meetings or new testing equipment. Further, the figure is calculated on the basis of assumptions made on labour costs, staff time and staff numbers. If any of these were to change, then the overall figure would change. We also make the assumption that staff members only work on Comitology and cannot be reallocated from other tasks at no cost. It is also quite conceivable that over time more chemicals are submitted, thereby increasing the total cost. We have not discounted this figure.

5.28 A similar exercise could also be conducted for additional enforcement and monitoring costs — and this would be both at the Member State and EC level.

Total costs for manufacturers and importers

5.29 Table 5.3 reports the sum over the entire horizon of the increase in costs. As well as the cost differential between the different options. We can see that the risk-based approach would increase the costs of the toy industry in Europe by a total of €5 billion over the next 44 years.

[24] http://ec.europa.eu/civil_service/docs/toc100_en.pdf
[25] Calculated by multiplying the incremental cost per substance by the number of substances.

Table 5.3: Cost associated with the options (€ billion)

	Approach		
	Risk-based approach (approach 1)	**Combined hazard/risk-based approach (approach 2)**	**Hazard/risk-based approach with authorisation by Comitology procedure (approach 3)**
Total added cost	5.0	13.5	13.7
Incremental cost	5.0	8.5	0.2

Source: Europe Economics calculations.

5.30 The combined hazard/risk-based approach is significantly more expensive than approach 1, adding an additional €8.5 billion to total operating costs, whereas approach 3 is only €0.2 billion more costly than approach 2.

5.31 It is interesting to note that the incremental cost between approaches 2 and 3 is relatively small. Given that our cost model uses data derived from our stakeholder survey, this would suggest that manufacturers and importers regard the costs associated with approaches 2 and 3 to be largely similar. Intuitively, one might think this would not be the case, as in practice, additional testing for CMR3s under approach 3 may add significant expense.

5.32 Given this caveat, our estimates suggest that approach 2 and 3 are essentially equivalent from a cost perspective, but they are both roughly 2.7 times more expensive than approach 1. Therefore, the additional benefit of shifting from approach 1 to either 2 or 3 would need to be high in order to compensate the significant additional increase related to those options.

5.33 This is even more the case for approach 3 since, as we have already stated, it is also the only one for which a significant cost for setting up and running the Committee would be expected.

5.34 We regard the average cost estimates illustrated above as a likely upper bound estimate of the average costs. This is for a number of reasons.

5.35 First of all, since manufacturing companies knew that the data were being collected in order to conduct an impact assessment of the various approaches they may well have overestimated costs. In addition by assuming that the increase in ongoing costs is permanent we are implicitly assuming that there would be no adjustment at all from the manufacturers: this is very unlikely to be the case.

5.36 The management of the manufacturing companies would implement measures that would increase efficiency should they be hit by a shock such as a change in regulation. it is also likely that, at least in the case of approach 1 and 2 innovative chemicals would be

developed to face the more restrictive regulation and therefore that the increase in ongoing costs would not last indefinitely but only for a limited number of years.

5.37 However, should approach 3 be adopted it is likely to assume that the length and difficulty of the Comitology procedure necessary to use newly developed chemicals might reduce innovative efforts on the part of manufacturers.

Ranges

5.38 In addition to the average values reported we have also estimated likely maximum and minimum values based on the questionnaire responses. These values are reported in Table 5.4.

Table 5.4: NPV for ranges of total costs associated with the approaches (€ billion)

	Approach 1	Approach 2	Approach 3
Minimum	3.5	3.9	3.9
Maximum	13.0	25.6	32.0

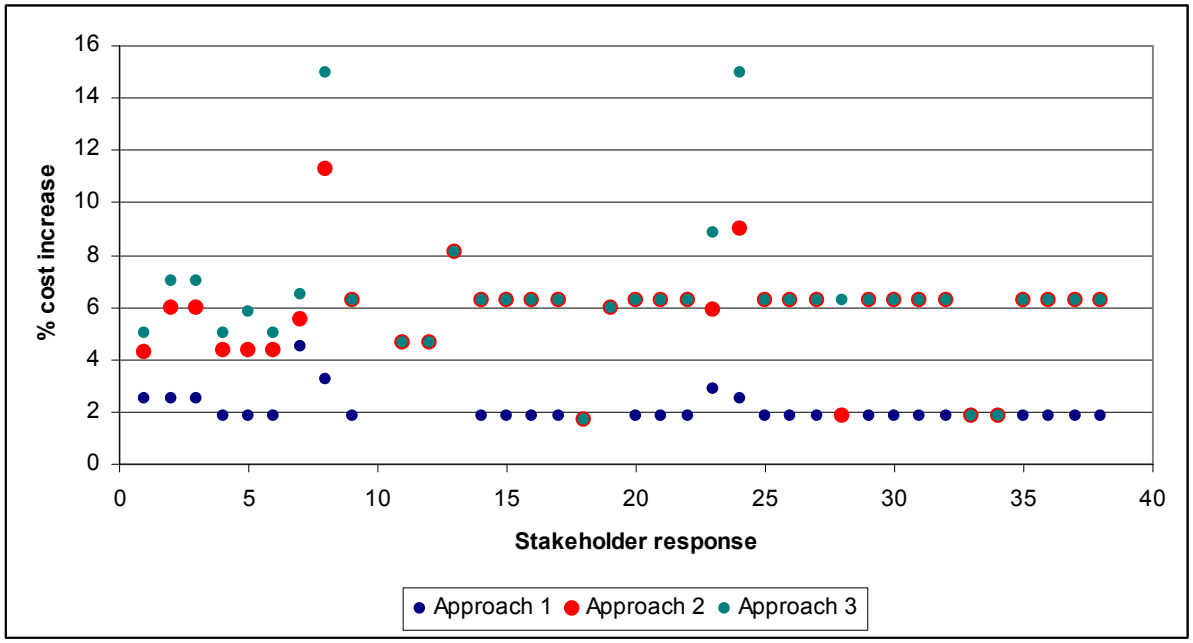
Source: Europe Economics calculations

5.39 For approach 2 and 3 the range is very wide as responses from manufacturers are extremely variable in this respect. In addition the maximum values are much larger than the average because a small number of respondents to our questionnaire indicated very high incremental costs. We do not believe that the maximum estimates are realistic.

Distribution of responses

5.40 The scatter-plot below shows the range of answers to our cost questions in our stakeholder questionnaire, upon which the above modelling is based.

Table 5.5: Distribution of cost responses



Note: the cost increase figures are average points in a given range.

5.41 As one notes, manufacturers and importers consistently replied that approaches 2 and 3 would increase their costs more than approach 1, and that approaches 2 and 3 have similar cost implications. In addition, the results are relatively uniform across much of the sample.

Impact by size

5.42 The table below shows the impact of each approach divided into manufacturing, distributional and administrative costs for the entire toys industry.

Table 5.6: Cost change by component (€m)*

	Approach 1	Approach 2	Approach 3
Administrative	488	1,306	1,331
Distributional	2,227	5,966	6,078
Manufacturing	2,321	6,217	6,334
Total	**5,036**	**13,490**	**13,743**

Source: Europe Economics calculations.

**Breakdown of cost components based on published Annual Reports*

5.43 As the above table shows, the most important component of the cost increase associated with the three approaches are manufacturing costs, followed by distributional and administrative costs. Testing costs are contained within the manufacturing category.

5.44 One should be careful to note the meanings of each category. As discussed above, our calculations are based on responses by industry. It is also important to distinguish between cost changes felt by manufacturers in the EU and those outside the EU and how these are passed on.

5.45 Thus, in Table 5.6 the term "distributional" is used by both manufacturers and importers, but they mean subtly different things. For manufacturers, distribution costs refer to those associated with moving their toys along the supply chain to retail. However, when importers refer to distribution costs, they refer to the cost of importing the toy into the EU from non-EU manufacturers. Given than manufacturing costs are modelled to be rising in the EU for toys to be sold in the EU, it is not surprising that imported toy costs to be sold in the EU will also rise — hence the large increase in distribution as well as manufacturing.

Impact by company size

5.46 The table below shows how the impact of each approach varies according to the size of company involved in the toys industry using the terminology adopted in the RPA study.

Table 5.7: Ongoing cost change associated with the proposals (as % of total annual operating costs)

	Approach 1	Approach 2	Approach 3
Multinational	2.2%	4.9%	5.8%
SME	2.9%	5.8%	6.4%
Average	2.8%	5.7%	6.3%

Source: Europe Economics calculations.

5.47 As the above table shows, the cost increase associated with all three approaches will be larger for SMEs than for larger multinationals. As with the actual cost calculations, the incremental cost is greater between approaches 1 and 2.

5.48 The table below shows the impact broken down by company type (manufacturer and importer/retailer).

Table 5.8: Ongoing cost change associated with the proposals by company type (as % of total annual operating costs)

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

Source: Europe Economics calculations.

5.49 Note the numbers do not average across the tables due do to the European market being dominated by SMEs.

5.50 Given that manufacturers are most directly affected by the new approaches, it is not surprising that they experience higher increases than importers. However, this is not the case in approach 1. This may be due to a large number of manufacturers already being able to meet the requirements of approach 1 (i.e. they do not use the prescribed chemicals or are already below the limits). Importers may find it more costly to acquire this information in the first instance.

Quantitative impact assessment — Benefits

5.51 Having quantified the costs associated to the different approaches we now turn to the evaluation of the benefits.

Methodological framework

5.52 In this section we describe in detail the methodology that we adopted to estimate the potential benefits in terms of health stemming from the three approaches. We quantified this impacts in terms of Disability Adjusted Life Years (DALYs) saved by each policy option.

5.53 Our approach is similar to that used in Life Cycle Impact Assessment (LCIA), which according to the Commission guidelines on Impact assessment, can be defined as:

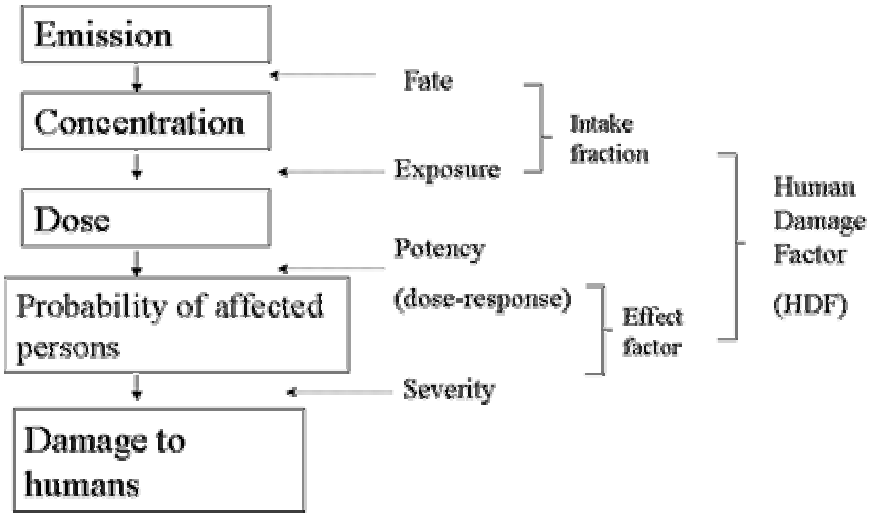
> The process of evaluating the effects that a product has on the environment over the entire period of its life.

5.54 More precisely LCIA entails the comparison of products according to their total estimated environmental impact, summed over all chemical emissions and activities associated with a product at all stages in its life cycle (from raw material acquisition to final disposal).

5.55 We are interested in one particular aspect of LCIA, i.e. the health impacts associated to chemicals.

5.56 Figure 5.2 describes the procedure and terminology used for the characterisation of human health effects.

Figure 5.2: The LCIA Framework



Source: Crettaz et al (2002)

5.57 According to the above framework the assessment can be divided into two parts: the intake fraction and the effect factor.

5.58 The intake fraction can be defined as the fraction of material released into the environment that eventually passes into a member of the population through inhalation, ingestion or dermal exposure.

5.59 Having calculated the intake factor (in a way that will be described below) we need to multiply it by two measures of effect (the effect factor), i.e. the potency and severity. The toxicological potency is a quantitative measure of the likelihood or risk of an effect on the population. The toxicological severity is a measure of the effects, consequences, or damage incurred as a result of exposure.

5.60 Crettaz *et al* (2002) and Pennington *et al* (2002) developed a detailed methodology to estimate the potency and severity factor and, consequently, the effect factor for both cancer and non cancer effects. Bachmann (2005) extended their methodology and provided guidance on its implementation.

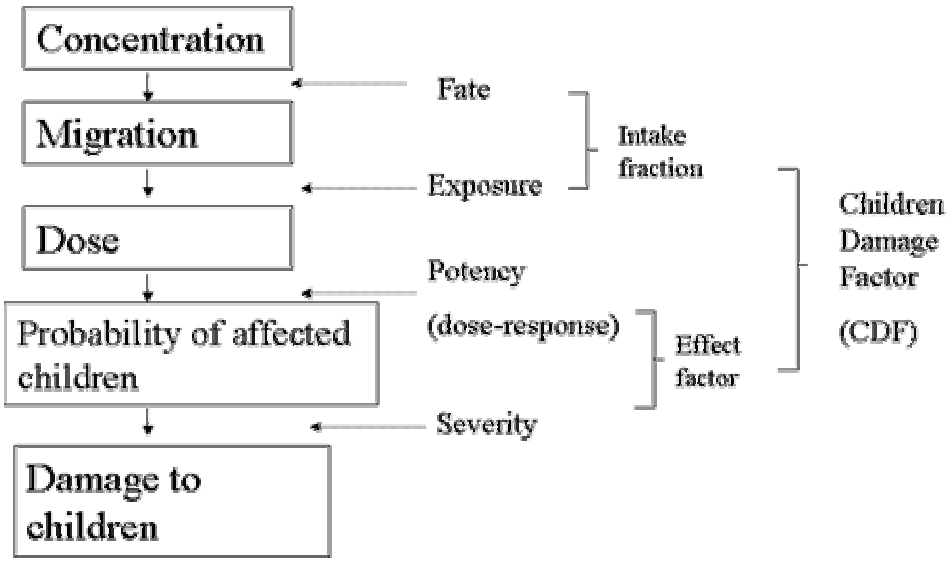
5.61 In calculating the effect factors related to the substances mentioned in the proposed changes as well as the CMRs that are more frequently used in the production we have followed the Bachmann (2005) methodology. We will describe this methodology in detail later.

5.62 LCIA is very often used to assess the impact on human health of factories or plants, and this is the main reason why Crettaz et al (2002) mention emission and concentration in their characterisation of the intake fraction. In our case we do not deal with emissions of polluting chemicals in the environment but with the chemical content of toys that are not meant to be released.

5.63 Thus we have to modify the LCIA approach to obtain an intake fraction that can be applicable to children playing with toys. Figure 5.3 describes this modified approach. As we can see there are no modifications in the calculation of the effect factor[26] while the intake fraction has taken into account the fact that it is the migration level of the chemicals from the toy to the child that determines the dose that triggers the effect.

5.64 We will now describe how we have calculated the intake fraction and the effect factor. To assist the reader and follow a clear logical process we will start from the former and then move to the latter, however we want to stress that the two steps have been done separately as the results of one do not depend on the results of the other.

Figure 5.3: The modified framework



Source: Europe Economics elaborations on Crettaz et al (2002)

The intake fraction

5.65 As noted above, the intake fraction represents the amount of chemicals contained in toys that end up in the body of children.

[26] Apart from the consideration that we are dealing with children and therefore that we are focusing on a particular subset of the population.

5.66 To calculate the intake fraction of each of the chemicals in question we have performed the following steps:

(a) Establish what is the relevant population;

(b) Calculate the variation in the quantities of the chemicals ingested or inhaled by children according to the various proposed option;

(c) Use the results of steps (a) and (b) to estimate a total intake fraction for the EU27.

5.67 The establishment of the relevant population is a straightforward exercise as we know that we are interested in all toy users in the EU27 and it is possible to extrapolate a definition of toy user from the current TSD. We have already mentioned that a toy can be defined as "any product or material designed or clearly intended for use in play by children of less than 14 years of age", therefore it is reasonable to assume that toy users are all those individual in the EU27 that are less than 14 years old.

5.68 From the Eurostat website we have downloaded the population projections by age for the EU25[27] from 2008 to 2041. Then we have aggregated all the individuals with less than 14 year for any available year. Finally, we have scaled up this figure to take into account Romania and Bulgaria basing our calculation on the share of the population of the EU27 that lived in these two countries in 2005.

5.69 Calculating the reduction of the various chemicals that is implied by each of the proposed options is slightly more complicated and requires more assumptions. The RIVM/SIR Advisory Report provides some guidance on this point.

5.70 The Advisory Report recommends[28] a number of values to for the amount of toy ingested according to the characteristic of both the child and the toy.

5.71 For children older than three it recommends 8 mg/day for all toys based on a worst case scenario of one hour of mouth contract per day.

5.72 For toys intended to be put in the mouth and children younger than three the following values are recommended, based on a three hour per day mouth contact:

(a) 400 mg/day for toys consisting of liquid and sticky material;

(b) 100 mg/day for toys consisting of dry, brittle, powder-like or pliable material;

(c) 8 mg/day of toy material scraped off.

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[27] There are currently no yearly projections available for Romania and Bulgaria.

[28] See pg. 116 of RIVM/SIR, 2006.

5.73 For all children a 100 per cent absorption rate is recommended, this implies that the entire amount ingested or inhaled ends up in the body of the child.

5.74 We have used a number of the suggested values in our scenario analysis in order to take into account possible uncertainties.

5.75 In order to establish the variation in ingestion we need a final step i.e. the changes implied by each different policy option. To do this we have distinguished between four categories, namely:

(a) (eight) substances that are already present in the TSD;

(b) (twelve) substances introduced by (all three) proposed approaches;

(c) CMRs 1 and 2, which are included in approach 2 and 3 and;

(d) CMRs 3 which are only taken into account in approach 3.

5.76 For the substances that were already present in the TSD it was straightforward to calculate the reduced amount as we can use the variation between the quantity reported in the current TSD and the limits in the various approaches.[29]

5.77 For the twelve new substances we have assumed a reduction equal to the average reduction of the eight substances for which we have two data points. However if by applying this limit we obtain an initial limit that is higher than 100 per cent we cap the initial value at 100 per cent.

5.78 The reduction for CMRs 1, 2 and 3 have been calculated using the limits currently set out in the EN 71 standards as a starting point and assuming that the lower acceptable limit for all CMRs would be 0.1 per cent. . Where this limit is higher than the current limit we have assumed no reduction in the intake. Finally, when the current limits were not available in the standards we have assumed a starting point of 5 mg/kg.

5.79 There is a difference in the way we treated the substances and the CMR 1, 2 and 3. For the substances we have assumed that the entire ingested quantity (8 mg per day in the majority of scenarios) was made up of the various substances, while for CMRs we have calculated the reduction using the quantity of toys ingested as a starting point.

5.80 E.g. for dichloromethane that has a current limit of 5 mg/kg assuming that 8 mg of toys are ingested in one day we calculated that the reduction in the daily ingested amount of dichloromethane was 0.032 mg ((5 mg/kg -1 mg/kg) * 8 mg).

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[29] We acknowledge that while the TSD reports limits in terms of allowed migration the three approaches deal with quantity of chemical per toy. The RIVM/SIR Advisory Report, however, provides guidance on how to convert migration limits to quantitative limits (see pg. 64 of the Report)

5.81 We have included in the analysis those CMRs that the stakeholders indicated as those most frequently used in the production of toys.

5.82 The final step (c) to calculate the intake fraction is using the previous results to estimate the total ingested amount in the EU27. In order to do this we have just assumed that all children ingest the same quantity of toy per day and then multiplied this amount for the total number of children in the EU27 using the population projections of Eurostat.

5.83 Thus, the final output of this task is the reduction in the amount of chemicals ingested by children in the EU27 according to the three different approaches. In the next sub section we describe how we have calculated the effects associated to each of the chemicals.

The effect factor

5.84 To calculate the effect factors associated to the substances as well as to CMRs we have followed the methodology developed by Crettaz *et al.* (2002) Pennington *et al* (2002) and Bachmann (2005). The interested reader can refer to these publications for a detailed description of the methodology. Here we only report the most important points.

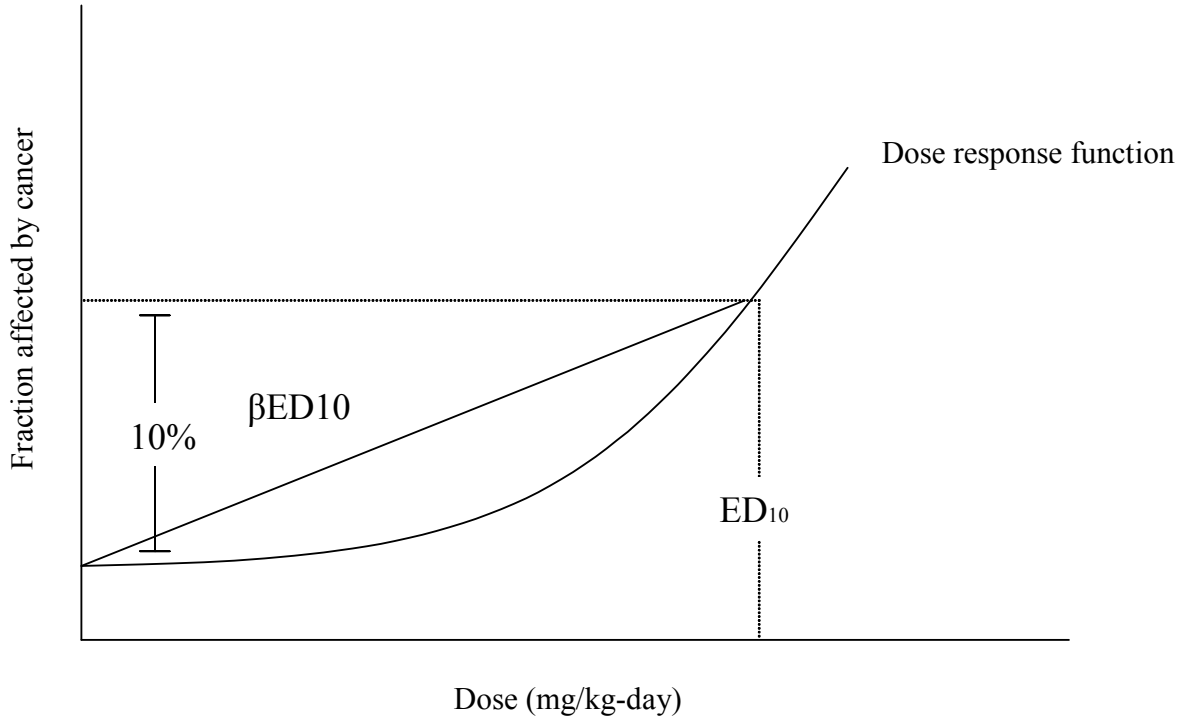
5.85 The methodology entails calculating linear *slope factors* (called βED_{10}) for both cancer and non cancer effects. Slope factors represent individual lifetime risks per mg/kg of bodyweight per day. They are a measure for the population averaged excess individual risk of an effect per unit daily dose for a lifetime exposure.

5.86 The effective dose (ED_{10}) is the maximum likelihood estimate of the dose corresponding to 10 per cent response of humans over background. The effective dose is taken as a point of departure to extrapolate the effects of a substance to lower doses, assuming that the dose response curve is linear.

5.87 Figure 5.4 illustrates the point using an example for cancer effects. On the x-axis we measure the dose ingested per day and on the y-axis the share of the relevant population that develops the disease (e.g. cancer). A share of the populations would develop the disease even if it is not exposed to the chemical (the "background level"), therefore the response function does not pass through the origin. At increasing doses of the chemical an increasing share of the population of develops the disease. The ED_{10} is (the maximum likelihood estimation of) that dose that corresponds to a 10 per cent increase in the population that develops the disease.

5.88 Having obtained a value for the ED_{10} it is straightforward to estimate the slope factor, i.e. the slope of the straight in the figure below. We know that the dose response function passes through the points ("0"; "background level"): and ("ED_{10}"; "background level + 10 per cent") and thus: $\beta ED_{10} = \frac{0.1}{ED_{10}}$. Therefore the only datum required to estimate individual slope factors is the ED_{10} dose.

Figure 5.4: An illustration of ED_{10} and βED_{10}



Source: Europe Economics

5.89 We have relied on multiple sources to estimate the ED_{10} for the various substances.

5.90 For some of the chemicals in question the ED_{10} is readily available from the US Environmental Protection Agency IRIS dataset or from the Superfund Chemical Data Matrix (3 substances). For some of the other substances we have the BMD_{10} (benchmark dose) available. It is defined as the 95 per cent lower confidence limit on the dose that produces a 10 per cent response over background. As suggested by Bachmann (2005) we have used the formula $ED_{10} = BMD_{10} / 0.54$ to estimate the ED_{10} starting from the BMD. Finally for those substances that did not have either the ED_{10} or BMD_{10} readily available we have estimated the ED_{10} on the basis of the Reference Dose (RfD).

5.91 Crettaz et al (2002) and Pennington et al (2002) suggest the use of the NOAEL or LOAEL to estimate the ED_{10}. However the RfD is available for a higher number of chemicals and is often based on NOAEL and LOAEL anyway. Therefore we have estimated a regression of the log of the ED_{10} on the log of the RfD for the 32 chemicals for which these doses are both available. In this way we have estimated the statistically significant relationship $ED_{10} = 2.7 \cdot RfD^{0.524}$. Thus we use this estimated relationship for those chemicals for which the ED_{10} is not yet available or cannot be estimated on the basis of the BMD.

5.92 Having calculated the slope factors, the estimation of the effect factor (EF) for each substance is straightforward using the formula from Crettaz et al (2002): $EF = \frac{\beta ED_{10}}{BW \cdot LT \cdot 365} DALY_p$ where BW represents the bodyweight of the individual, LT the lifetime of the individual and DALY the number of DALY lived per affected person. The effect factor is measured in number of years lost per mg of intake.

5.93 We have used 7.5 Kg for children younger than 3 and 15 kg for children older than 3 as bodyweight as suggested in the RIVM/SIR Advisory Report. LT has been estimated at 78.4 years for the EU27 (from the World Development Indicators).

5.94 For the number of DALY per incidence we have used 12.8 years for irreversible and life-shortening effects (CMR 1 in our model), 1.28 for probably irreversible and life-shortening effects (CMR 2 and 3 in our model) and 0.128 for reversible and non life-shortening effects (non CMR in our model) as suggested by Bachmann (2005) or 6.7 years for irreversible and life-shortening effects, 0.67 for probably irreversible and life-shortening effects and 0.067 for reversible and non life-shortening effects as suggested by Crettaz *et al* (2002). Finally, it is necessary to convert daily intakes into annual effects and this is the reason why the EF is divided by 365.

5.95 Therefore at the end of this task we have obtained an estimate of the negative effects associated with the various chemical.

5.96 From the intake fraction we know the overall reduction in the chemicals under the different approaches. Therefore to obtain the number of DALY saved under each approach we have to multiply the quantity of each chemical obtained by calculating the "intake fraction" by the effect factor associated to that chemical.

The value of a DALY

5.97 The final building block to calculate a monetary value for the benefits associated with each proposed option is the value that society assigns to a saved DALY. We discuss in the annex the relationship between DALY and QALY. Here we assume that the value of a QALY is equivalent to a value of a saved DALY.

5.98 Unfortunately, at the time of writing there is no agreement on the value of a QALY, especially at the EU27 level. EU funded research is currently been carried out at the University of Newcastle but the project has only recently begun (March 2007) and the final results are not expected earlier than 2010.

5.99 In a recently completed study Mason et al (2006) have estimated various ranges for the societal value of a QALY for the UK. [30] The value of a QALY is estimated to lie in the region of £45,000 to £63,000 (€67,500 to €94,500 respectively).

5.100 In a review article, Eichler et al (2004) report a number of "threshold values" used in various countries. These are values to be used as rules of thumb by various international institutions and countries. The values are extremely variable, with a lower bound of 10900 USD (in 2002 prices), based on New Zealand reimbursement decisions up to 108600 USD (in 2002 prices) for the USA. Therefore although there is still considerable uncertainty on the societal value of a QALY (or DALY) the order of magnitude seems fairly consistent.

5.101 We use the results of the Mason et al (2006) as it is the most recent and based on an EU Member State. However, we acknowledge that their results are not yet definitive and may be subject to change; however the range of values proposed is reasonably large to be taken into account in our sensitivity assessment, where we use a lower bound for the value of a QALY of €45,000 based on the UK value for a QALY of £30,000 used by the National Institution of Clinical Excellence. Later estimates are also quoted in terms of cost per DALY

Results

5.102 As in the case of costs we calculate the benefits in 2007 prices assuming that the different options would be instantaneously implemented at the end of 2007. We discount the benefits at 4 per cent per year to be consistent with the discounting of costs.

5.103 Table 5.9 reports the results of some of the scenarios that we have run.

5.104 There are a few interesting results that emerge from the scenarios. First of all the variation of the benefits is between scenarios is large: in the lowest case scenario with a low monetary value of a DALY, low ingestion and low damages associated to the various chemicals the overall benefits of approach 1 would be €1.2 billion. In the highest case scenario of high ingestion, high damages associated with the chemicals and high value of a DALY this figure would increase to €50.9 billion.

5.105 In the scenario labelled as "middle", where all these values have been calculated as the average between the highest and the lowest scenario the benefits of the approach 1 are €12.4 billion.

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30 Helen Mason, Andrew Marshall, Michael Jones-Lee and Cam Donaldson, Estimating a monetary value of a QALY from existing UK values of prevented fatalities and serious injuries, Department of Public Health and Epidemiology, University of Birmingham, 2006

5.106 The variation is evident even for the two remaining approaches: the incremental benefits associated with the combined hazard/risk based approach vary from a minimum of €32 million to a maximum of €1.4 billion (with €340 million as the middle estimate), while for approach 3 the incremental benefits vary from €6 million to €278 million (with €68 million as the middle estimate).

5.107 The incremental benefits associated with approach 2 and 3 with respect to the benefits of approach 1 alone are always very small.

Complete ban scenario

5.108 If, in the "middle" scenario, we keep al the other values constant and assume that, rather than a lower bound of 0.1 per cent, in Approach 2 and 3 CMRs are completely banned, we would see the incremental benefits associated with these options increasing to €427 million and €95 million respectively. This represents a material increase in the benefits associated with these approaches but falls well within the range of uncertainty of our estimates and would not change the overall picture or our view as to the appropriate central estimate to adopt. However, since it is impossible in practice to eliminate traces of substances this result is purely theoretical.

Cost per DALY

5.109 We have also calculated the cost per DALY saved associated with each approach. We divided the number of DALYs saved by the total costs increase associated with the various approaches. The resulting figure is €27,000, €71,000 and €72,000 for approach 1, 2 and 3 respectively. Thus, in the case of approach 1 as long as the value of a DALY exceeds €27,000, on this metric, this revision should be chosen (as in the case if a DALY is worth €45,000 or €67,500).

5.110 Indeed, if we were to follow the recommendations of the UK National Institute of Clinical Excellence then we would conclude in favour of Approach 1.[31]

5.111 Before we turn to discussing our recommendations based on the results of our model we wish to stress that the benefits that we estimated are likely to represent an underestimate of the true benefits.

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[31] *The National Institute of Clinical Excellence currently advocates that below a most plausible incremental cost effectiveness threshold of £20,000 per QALY, judgments about the acceptability of a clinical strategy as an effective use of NHS resources are based primarily on the cost effectiveness estimate. Above this, value judgements are more likely to make more explicit reference so such factors as the degree of uncertainty surrounding the calculations, the innovative nature of the intervention, the particular features of the condition and the population receiving it, and the judgements made in previous appraisals on related technologies. Finally, above an ICER of £30,000 per QALY, the case for supporting the intervention on these factors has to be increasingly strong.* (HM Treasury 2005 p. 50)

5.112 This is the case for mainly two reasons:

(a) we are not taking into account the reduction of the burden on the health systems of the various Member States; and

(b) we are not taking into account the productivity loss due to children falling ill. This loss may regard either the children themselves if they fall ill when they are adults or their parents if they fall ill when they are still children.

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

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

Source: Europe Economics calculations

Impact on Prices

5.113 During our stakeholder consultation we asked both manufacturers and importers on their expectation of how prices might change under each approach. The table below summarises the responses:

Table 5.10: The impact on prices of each approach (stakeholder responses)

Type of company	Expected price change		
	Approach 1	Approach 2	Approach 3
Importers	8.3%	8.4%	24.1%
Manufacturers	7.5%	8.3%	20%
Average	7.9%	8.4%	22.1%

5.114 As the above table shows, the larger incremental increase in toy price comes between approaches 2 and 3.

5.115 Of course, these figures should be read with care as one would not necessarily expect to see prices increasing across all types of toys. As previously noted, the toys market is extremely diverse and not all toys will be equally affected by the three proposed approaches. One would not, all other things being equal, expect to see price rises for toys that do not use the chemicals mentioned in the revised TSD.

5.116 However, one should treat the above numbers with care, as they come directly from affected stakeholders. It is quite possible that the stated price changes are biased upwards. One must also further expect for prices to rise over and above the change in costs arising from the approach if companies simultaneously use this as an excuse to raise prices for other reasons (but use the revised TSD as an excuse).

5.117 In order to provide some sort of benchmark, the table below shows the impact on prices that occurs if the estimated costs from our analysis of the three approaches is completely passed through into prices for all companies.[32]

[32] Of course, the increase in modelled costs will not be reflected in an exact same increase in prices, because a price consists of a profit margin as well as costs of production. We have assumed the same ratios for expenditure and revenue in prices as in our main model, thereby keeping the rate of profit constant.

Table 5.11: The impact on prices of each approach if only costs were passed through (based on modelled incremental costs)

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

** Calculated by taking modelled change in cost per approach and multiplying it by ratio for expenditure in price (77 per cent).*

5.118 Again, the same proviso applies to the averages.

5.119 As the above table shows, if only costs were passed through the price changes are lower than those stated by the manufacturers and importers themselves. The figures give an indicative minimum price change that one might expect from each approach, given the assumption of perfect markets.

5.120 The range for all companies for approach 1 is between 1.7 and 8.2 per cent; for approach 2 it is between 1.9 and 11.3 per cent; and between 1.9 and 13.8 per cent for approach 3.

Impact on employment

5.121 On the basis of the impact on prices estimated the impact of the three proposed approaches on employment. Our estimate is based on a number of simplifying assumptions.

5.122 The increase in prices would ultimately lead to a decrease in demand, the decrease in demand would force toy companies to reduce production and therefore to reduce employment. However we want to stress that this is an estimate of the one-off gross effect as it is likely to assume that at least some of the workers made redundant would find a job in a different sector.

5.123 We have assumed an elasticity of demand with respect to price of 0.5[33], and used the price variations reported in Table 5.11 to determine the expected reduction in demand. From this reduction in demand, assuming that the technology exhibits constant returns to scale we can establish the percentage reduction in employment.

5.124 As a final step for our estimation we apply these percentage reductions to the 98000 people that are employed by the toys industry in Europe.[34] The results of this exercise are reported in Table 5.12.

[33] The elasticity of demand with respect to price measures the percentage variation in quantity demanded following a 1 per cent variation in price

[34] See the Appendix for a description of the toys industry in Europe.

Table 5.12: Expected employment reduction in the EU27 for each approach (number of jobs lost)

	Expected employment reduction		
	Approach 1	**Approach 2**	**Approach 3**
Total	**1,200**	**3,000**	**3,300**
Production	650	1,600	1,800
Distribution, Retail, etc.	550	1,400	1,500

Source: Europe Economics calculations.[35]

5.125 It can be seen that the overall employment impact of the three approaches would be small for the EU27 as a whole. These impacts could be even smaller if we assume that only people directly employed in production would be affected by the reduction in demand.

Further Qualitative impact assessment

Costs

5.126 In addition to the calculated financial we note there are further costs associated with each approach, which although not quantified are not trivial.

5.127 In the first instance, each approach will necessitate additional resources to be allocated to monitoring and enforcement. At present, stakeholders have reported that enforcement of the existing TSD is weak and consumer response mechanisms are underdeveloped. While one would generally expect compliance with toy safety legislation to be high (given existing trends), the approaches will entail testing for a number of new chemicals (potentially hundreds for approaches 2 and 3) which will inevitably require more funding for compliance and enforcement agencies.

5.128 A further cost is that of delays. One line of argument is that if certain chemicals (CMRs) are banned, then research must be undertaken to find substitutes (or at least to find out that no substitutes are available). This will take time and be longer than the typical toy development cycle. Thus, during this period of substitute development, a number of scenarios may occur such as:

(a) no new toys being developed;

(b) the only toys produced are those that do not definitively contain the chemicals in amounts beyond the limits and contain no CMRs; or

[35] For instance, having estimated the increase in price for approach 1 to be 2.5 per cent and elasticity of 0.5 we estimate a 1.25 per cent decrease in demand (2.5 x 0.5). Given the 98,000 employees of the toys industry in Europe this represent a loss of 1200 jobs.

(c) production of toys is halted until research is complete.

5.129 Further, there is a risk that CMRs are substituted by substances or compounds who effects are not well researched and may be even more dangerous.

5.130 Of course, the TSD revision approaches do allow for CMRs to be used under certain circumstances. Approach 2 allows for them if they are trace amounts or if they have been authorised in accordance with REACH. Approach 3 also allows them under certain circumstances.[36] It also seeks to deploy the Comitology procedure to decide if the chemicals are safe enough to be used in toys. Each of these exceptions may lead to significant time delays for manufacturers and importers as they wait for the chemicals they use to be approved.

5.131 As noted earlier, we are not aware of any transitional arrangements to bring in the three approaches. Depending on how they are implemented, there may or may not be significant transitional costs beyond those faced by manufacturers and importers.

5.132 Through our stakeholder discussions we have been informed that SMEs may be disproportionately (negatively) affected by the new approaches as they are unable to absorb or pass on the costs of compliance. This may be the case if the costs are large in relative terms for SMEs compared to larger toy companies. For example, SMEs may not be able to test in-house, and so will need to pay a third party extra to test for additional chemicals. Further, SMEs who import will need to acquire more information about the raw materials used in their products – adding to their administrative burden (although this is faced by all).

Benefits

5.133 As noted above, the calculated benefits may be an understatement for two reasons.

(a) We are not taking into account the reduction of the burden on the health systems of the various Member States

(b) We are not taking into account the productivity loss due to children falling ill. This loss may regard either the children themselves if they fall ill when they are adults or their parents if they fall ill when they are still children.

5.134 Further, it should be noted that our quantitative analysis was done on the basis of available data. For some chemicals, e.g. aluminium, no data were available for modelling purposes. While some of these chemicals are not used in the manufacture of toys, others are, and so this may be another source of under-estimation.

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[36] Where they are essential for the functioning of the toy; there are no alternative substances available; the substance is not released in amounts that are detectable by a validated method.

Technical file evaluation

5.135 In addition to the three approaches under consideration in the revision of the TSD, there is also the possibility of updating the requirements for the technical documentation held by toy manufacturers and importers on their toys. The EC is considering three proposals.

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

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

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

5.136 These three proposals build on the existing requirement in Article 8(b) of the TSD which requires the manufacturer or his authorised representative to hold:

> - a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity of production with the standards referred to Article 5(1)…
>
> - the addresses of the places of manufacturer and storage,
>
> - detailed information concerning the design and manufacture.
>
> Where neither the manufacturer nor his authorised representative are established within the Community, the above obligation to keep a dossier available shall be the responsibility of the person who places the toy on the Community market.

5.137 Although these proposals can be associated with particular TSD chemical requirement revision approaches, they are not necessarily linked, and therefore should be analysed separately.

Costs

5.138 The main cost of the technical falls on manufacturers and importers. Depending on the proposal chosen, they will be required to keep detailed information as to the chemicals used by their raw material suppliers (and potentially their amounts), associated safety data sheets, and the components used to manufacturer the toy. This will necessitate discussions with its raw material suppliers as well as the manufacturing factories.

5.139 The addition of more technical documentation will not lead to any change in manufacturing or distribution processes, as all that is being asked is for information about

processes. Thus, this it is a change to administrative requirements for manufacturers and importers.

5.140 Our stakeholder consultation contained questions relating specifically to the costs currently associated with providing information for technical documentation. Typically, our consultation showed that for large companies the cost of such documentation did not exceed 1 per cent of total annual operating costs. However, the figure was slightly larger for SMEs, with the cost potentially be as much as 2.5 per cent of total annual operating costs.

5.141 Our methodology for calculating costs related to each proposal for the technical file is identical to that of calculating costs associated with revising the TSD's chemical requirements and is consistent with the Dutch Standard Cost Model. Manufacturers and importers were asked to provide information about the likely changes in costs deriving from the different proposals in terms of their current operating costs. They were also asked to provide an estimate of the one-off increase in those costs related to the transition.

5.142 On the basis of al the responses received we have calculated an average percentage cost increase for each of the different options.

5.143 Then we have calculated an average ratio between turnover and operating costs in the toys industry from the annual reports of companies operating in the European market.

5.144 The last step needed to estimate costs is a measure of overall turnover to which the calculated ratio has to be applied. According to the Toy Industries of Europe[37] the overall turnover of the toy industry in Europe 2005 (the last year for which data are available) was roughly €13 billion.

5.145 From our stakeholder consultation we estimated that across the industry, currently, costs associated with technical documentation are approximately €144m annually.

5.146 With these data we calculated a stream of costs from 2008 to 2051 assuming no adjustment will take place in the toy industry i.e. that the increase in ongoing costs is permanent.

5.147 Then we have discounted these amounts using a 4 per cent annual discount rate as suggested in the EC guidelines on impact assessment.

[37] Toy Industries of Europe, *TIE Facts and Figures*, 2006

5.148 According to the methodology described we estimate that the implementation of proposals 1 and 2 would cause a one-off increase of €5.9m on operating costs, while proposal 3 would cause a €7.5 million rise.[38]

5.149 The table below sets out the sum of costs over the entire horizon, as well as the cost differential between each proposal.

Table 5.13: Cost associated with the options (€ m)

	Proposal		
	(1) Detailed description of design and manufacture	**(2) Detailed description of design and manufacture plus list of components and materials used**	**(3) Detailed description of design and manufacture plus list of components and materials used plus amounts of individual substances**
Total added cost	126	126	159
Incremental cost	126	0	33

Source: Europe Economics calculations.

5.150 As the table shows, proposals 1 and 2 have the same implications, with the proposal 3 generating and incremental cost of €33m over the period 2008 to 2051. All of these costs can be characterised as additions to the administrative burden.

5.151 Additionally, we have conducted some scenario analysis based on the ranges provided by stakeholders for their expenditure current on technical file documentation. These are shown below.

[38] For instance, in the case of approach 1 we know, on the basis of stakeholder responses, that the costs related to the technical file will increase by 4 per cent. Thus, multiplying this against current industry expenditure (€144m) gives an incremental cost increase of €5.9m. The NPV is then taken of this for the period up to 2051. This is consistent to the Standard Cost Model Approach.

Table 5.14: Cost associated with the options (€m)

	Proposal					
	(1) Detailed description of design and manufacture		(2) Detailed description of design and manufacture plus list of components and materials used		(3) Detailed description of design and manufacture plus list of components and materials used plus amounts of individual substances	
	Min	Max	Min	Max	Min	Max
Total added cost	44	219	44	219	55	277
Incremental cost	44	219	0	0	11	58

Source: Europe Economics calculations.

5.152 It was not estimated that any of the proposals would cause a change in toy prices, because the overall magnitude of the change is very small.

5.153 In terms of the incidence of the cost on different types of companies, our analysis and stakeholder consultation suggests that SMEs may expect to face higher costs (as a proportion) than larger companies. This is because typically, suppliers of raw materials and toys for import, often resist providing information about their manufacture. The reasons cited often include intellectual property tights. For example, we were informed that in some extreme cases, suppliers have refused to release formulas to the toy importer. In order that safety requirements are met, a third party laboratory holds the information and must sign a non-disclosure agreement.[39]

5.154 In contrast, larger companies have more influence with suppliers of raw materials and reported that they would not have any difficulties in seeking additional information — indeed, many of them already have such information documented.

5.155 The table below shows how the different proposals might impact on different sized companies using the terminology adopted in the RPA study.

[39] For this analysis we have assumed that there would be no difficulties arising from each proposal with regard to intellectual property rights.

Table 5.15: Ongoing cost change associated with the proposals (as % of current costs for technical documentation)

	Proposal		
	(1) Detailed description of design and manufacture	**(2) Detailed description of design and manufacture plus list of components and materials used**	**(3) Detailed description of design and manufacture plus list of components and materials used plus amounts of individual substances**
Multinational	0-5%	0-5%	0-5%
SME	6-10%	6-10%	6-20%

Source: Europe Economics calculations.

5.156 It should be noted that this ongoing costs only relate to costs incurred during the creation of the technical file — they do not include other costs, such as manufacturing and marketing.

Benefits

5.157 Given that none of the proposals is expected to lead to a change in the ways are manufactured, the main benefit from each proposal will be an increase in information available to consumers and regulatory authorities.

5.158 It is important to clarify what this information would provide. If one assumes that all toys are already compliant with TSD chemical requirements, then all that the new technical file would show is how a particular toy is compliant. We would not expect to see manufacturers change their processes and reduce chemical content, and thus there would be no associated health benefit.

5.159 Thus, while we have not quantified the benefit of reduced information asymmetries (which also benefit those importers who currently find it difficult to ascertain information), we believe that such benefits will be small in nature.

Summary of evaluation

5.160 The table below compares the costs and benefits of each TSD revision approach relative to the do nothing counterfactual. Given the uncertainties, we have chosen to use our "middle" scenario as our preferred scenario. The table below integrates our qualitative and quantitative analyses to paint a global picture of likely impacts.

Table 5.16: Costs and benefits of the three proposed revision approaches to the TSD (€m) 2008 - 2051

	Approach 1	Approach 2	Approach 3
Costs			
NPV financial costs	5,036	13,490	13,744
Of which			
Administrative	488	1,306	1,331
Distributional	2,227	5,966	6,078
Manufacturing	2,321	6,217	6,334
Comitology*			3
Other economic	Enforcement and compliance costs	Enforcement and compliance costs	Enforcement and compliance costs
	Costs of delay to innovation and in authorisation	Costs of delay to innovation and in authorisation	Costs of delay to innovation and in authorisation
	Administrative burden	Administrative burden	Administrative burden
Other social	Risk from substitutes	Risk from substitutes	Risk from substitutes
	1,200 jobs lost	3,000 jobs lost	3,300 jobs lost
Other environmental	None	None	None
Benefits			
NPV financial benefits	12,447	12,787	12,855
Other economic			
Other social	Reduction in burden on health systems	Reduction in burden on health systems	Reduction in burden on health systems
	Reduction in productivity losses	Reduction in productivity losses	Reduction in productivity losses
Other environmental	None	None	None
Prices			
Expected price change	+2.2%	+4.4%	+4.9%

** Given the caveats in the text, this is not included in the overall figure.*

5.161 The table below summarises the costs and benefits associated with each proposal to amend the technical file requirement.

Table 5.17: Costs and benefits of the three proposals to update the technical file requirements (€ millions) 2008 – 2051

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

6 EVALUATION AND CONCLUSIONS

6.1 This report has assessed the impact of the three proposed approaches to revising the chemicals requirements of the Toy Safety Directive. Our methodology has encompassed a widespread literature review, a stakeholder consultation, and an innovative approach to modelling health and economic benefits.

6.2 Our headline conclusions for each approach are show reproduced below:

Table 6.1: Costs and benefits of the three proposed revision approaches to the TSD (millions €) 2008 – 2051

	Approach 1	Approach 2	Approach 3
Costs			
NPV financial costs	5,036	13,490	13,744
Of which			
Administrative	488	1,306	1,331
Distributional	2,227	5,966	6,078
Manufacturing	2,321	6,217	6,334
Comitology*			3
Other economic	Enforcement and compliance costs	Enforcement and compliance costs	Enforcement and compliance costs
	Costs of delay to innovation and in authorisation	Costs of delay to innovation and in authorisation	Costs of delay to innovation and in authorisation
	Administrative burden	Administrative burden	Administrative burden
Other social	Risk from substitutes	Risk from substitutes	Risk from substitutes
	1,200 jobs lost	3,000 jobs lost	3,300 jobs lost
Other environmental	None	None	None
Benefits			
NPV financial benefits	12,447	12,787	12,855
Other economic			
Other social	Reduction in burden on health systems	Reduction in burden on health systems	Reduction in burden on health systems
	Reduction in productivity losses	Reduction in productivity losses	Reduction in productivity losses
Other environmental	None	None	None
Prices			
Expected price change	+2.2%	+4.4%	+4.9%

** Given the caveats in the text, this is not included in the overall figure.*

6.3 As one notes we have not identified any additional incremental environmental impacts from the three approaches.

6.4 Taking into account the qualitative discussion and the available evidence base, only approach 1 yields an overall net benefit (€7.4bn), and is clearly ahead of approaches 2 and 3.

6.5 There are a number of observations to make about this conclusion. First, we believe that the costs and benefits will largely fall on the same stakeholders, so that the issue of weightings is largely by-passed. Recall that it appears (subject to a more comprehensive competition assessment than falls within the scope of this project) that the toys industry in Europe is competitive. Economic theory predicts that under such conditions any changes in input costs (in this case from testing) will be passed through to the end user — in this case, the household. Thus, while the household might receive the benefits from reduced probability of contracting diseases from the chemicals, they are, in a very real sense, having to pay for this via higher toy costs. Thus, one cannot characterise the situation as one of simple equity between manufacturers/importers and households and weighting effects on different stakeholders differently seems unlikely to affect the overall result.

6.6 Next, it is interesting to consider what are the main drivers in cost as one moves between approach 1 and approach 2. As the table shows, there is incremental cost of €8,454m between the two approaches. The difference between approach 2 and 3 costs is relatively trivial (and greater than the incremental benefit of moving from approach 2 to 3). If the choice were between do nothing and approaches 2 and 3, then it is clear than one would choose do nothing.

6.7 However, it should be stated the decision to choose *any* approach is largely contingent on the finalised testing regime and associated testing methodology. As our model shows, the main drive of incremental costs are costs related to testing. Indeed, the main driver of the large incremental costs between approaches 1 and 2 (and for that matter 3 as well) related to the increased costs of testing for CMRs known to be used in toy manufacturing. If the testing and methodological regime were to change, for example, if testing was for only those CMRs historically used by that particular company (as opposed to all CMRs used by the industry), that it is conceivable that the costs might fall. Under different testing regimes, different approaches may yield different cost benefit answers.

6.8 Thus, in summary, our evaluation of the three approaches suggests the following:

(a) The NPV of financial costs significantly rises between approach 1 and 2 (from around €5bn to around €13.5bn).

(b) The large incremental costs are mainly due to increased testing requirements.

(c) The NPV benefits do not differ widely between the three approaches.

(d) On a straightforward reading, approach 1 is the preferred approach for revision.

(e) However, if one were to modify the testing requirements, it is possible that the incremental costs would fall for manufacturers and importers, and lead to a different approach being preferred.

6.9 The table below summarises the costs and benefits associated with each proposal to amend the technical file requirement.

Table 6.2: Costs and benefits of the three proposals to update the technical file requirements (€m) 2008 – 2051

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

6.10 While the costs of all three proposals is relatively small over the time period in question, unless the qualitative benefits are seen to be greater than the modelled quantitative costs and qualitative costs, we would not recommend pursuing any of the approaches.

APPENDIX 1: OVERVIEW OF THE EUROPEAN TOYS INDUSTRY

Defining characteristics

A1.1 The toy industry is one of the world's oldest creative industries. A defining feature is innovation: spanning from the development of new products to the cyclical renewal and modernisation of classic favourites.

A1.2 The toy industry has some further defining characteristics which differentiate it from other industries as well as shape its economic behaviour.

(a) Volatility: variable and unpredictable demand, often literally driven by the unpredictable whims of children means that suppliers face specific selling-windows and short product lifetimes. Compounding this further is the seasonal nature of an industry which depends on cyclical booms in consumption around major holidays; most heavily Christmas. As such, the producers have incurred relatively high costs on products becoming obsolete, lost sales and mark-downs as compared to other industries. Risk-bearing is often a crucial issue in the toy supply chain.[40]

(b) Licensing: given the creative nature of the industry at heart, licensing is required to structure intellectual property rights and ensure sufficient levels of profit, and is therefore especially frequent.[41] Licensing may occur at any level of the supply chain, from design to manufacturing to distribution and retail.

Number of players and nature of rivalry

A1.3 Of the 2,000 or so toy companies in Europe, the majority can be classed as small and medium-sized enterprises (SMEs).[42] TIE (2005) reports that only 4 per cent of European toy companies have a turnover in excess of €40m and 85 per cent of toy companies have fewer than 50 employees.

A1.4 SMEs in the toys industry do not only manufacture toys. They play a number of roles in the supply chain, including importing toys from overseas, either as their own brand or to be marketed and/or distributed within the EU.[43] Compared to other industries, SMEs in the toys industry are much more integrated into the global market compared to other SMEs.

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[40] Wong, Chee Yew, Arlbjørn, Jan Stentoft, and Johanson, John (2005) "Supply chain management practices in toy supply chains" Supply Chain Management, Vol 10, No 5, pp. 367-378.

[41] 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).

[42] According to the Commission Recommendation of 6 May 2003, an SME is defined as an enterprise which employs "fewer than 250 persons and which [has] an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million."

[43] As RPA point out, some retailers are also known to carry out their own supply-chain management without the need for a third party importer.

A1.5 The leading EU locations where toys are manufactured are Bavaria (Germany), Alicante (Spain), Rhône-Alps (France), and near Milan (Italy).

A1.6 Although toys produced in the EU are remarkably differentiated horizontally, with diverse and innovative product ranges, domestic manufacturers face intense competition from abroad and must constantly work to ensure that their products are fresh, competitive, or possess a "wow factor". As a result, these firms tend to specialise, usually focussing on a group of products or specific geographic markets. Industrial measures work to encourage such innovation, for example through the provision by the British Toy and Hobby Association (BTHA) and similar organisations of an 'inventor's pack' for approximately €30.[44] The goal of the inventor's pack is to cheaply and accessibly facilitate the transformation of ideas into actual goods.

A1.7 Nevertheless, despite high levels of product differentiation, successful entry to the toy industry is not easy. Apart from entrepreneurial parents and the established SMEs, potential entrants have a much more formidable force to contend with: the global conglomerates. These large international toy manufacturing companies have headquarters in the USA, Japan, and the EU. The world's largest toy manufacturers are Mattel, Inc. (whose products include, among others, Barbie dolls, Hot Wheels, Cabbage Patch Kids, etc.), Hasbro, Inc. (who products include, among others, GI Joe, Monopoly, Transformers, etc.), Lego Co., Playmobil, and Ravensburger. In many cases the SMEs collaborate with the bigger players in design, manufacture, or distribution.[45]

A1.8 The manufacturing of toys, toy components and related products consumed in the EU and globally is primarily located in the Far East, with upwards of 8,000 suppliers in China. However, some skilled labour, such as research and development, marketing and administrative business is conducted within the EU. The cheap labour costs and economies of scale of the Far East are strategically important to the toy industry, because they are increasingly being used as a wedge between retailers and manufacturers, as detailed below.

A1.9 Competition in the toys industry has been impacted by the advent of toys sold by internet retailers, or "e-tailers". When eToys, a toy e-tailer, emerged online and began to offer low prices, easy comparison of products, and low search costs, it captured $107 million during the 1999 Christmas season alone. After leading US retailer Toys "R" Us unsuccessfully attempted to buy eToys, it settled on establishing an alliance with Amazon.com. By adopting a "click and mortar" approach in addition to offering additional services at their brick and mortar stores (such as allowing returns and exchanges), Toys "R" Us has gone on to become a leader in the reshaping of the toy retailing business. As a result, eToys had to close their business in spring 2001, in line with a broader trend for pure toy e-tailers to shut down operations. As a result of this short struggle, the toy industry has been

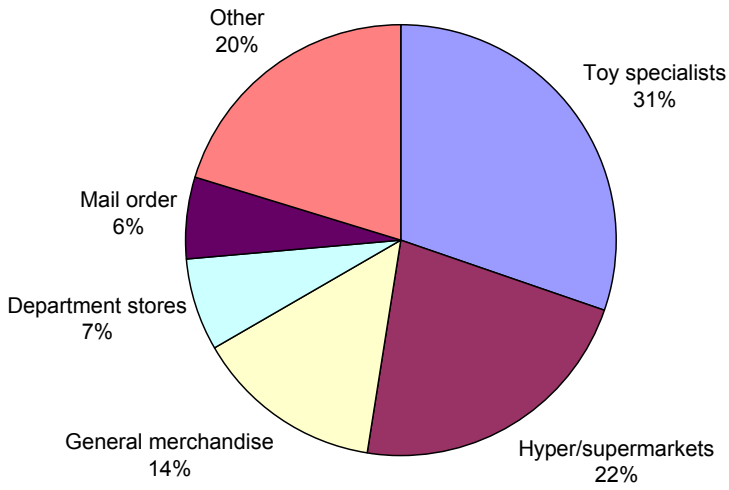
[44] CORDIS (2006) "Articles on innovation: new toys for Europe" http://cordis.europa.eu/aoi/print_version.cfm?article=1739&lang=EN.
[45] CORDIS (2006) "Articles on innovation: new toys for Europe" http://cordis.europa.eu/aoi/print_version.cfm?article=1739&lang=EN.

reshaped, seen a marked increase in downward price pressure, and been increasingly held to offering customers maximum value for their purchases.

Consumption

A1.1 As global prosperity increases, so does the demand for toys. Geographically, toys are mainly consumed in North America and Europe. Toy customers are children, parents, grandparents, and other gift-givers.[46] While consumers used to purchase most of their toys from the traditional channels such as department stores and independent toy specialists, the emerging sales channels of hypermarkets, discounters and toy superstores are dominating toy sales today (see Chart A1.1).

Chart A1.1: Various distribution channels of toys in the EU in 2003



Source: Toy Industries of Europe, 2003

A1.2 General merchandise stores are non-toy specialists including supermarkets and bookshops. The other sources category includes catalogue showrooms and other non-"bricks and mortar" non-toy specialists.

A1.3 Since the above data were published, one would expect the internet to have increased its share — but it should be noted manufacturers rarely sell direct online, so toys sold online will be primarily through retailer websites.

[46] Wong, Chee Yew, Arlbjørn, Jan Stentoft, and Johanson, John (2005) "Supply chain management practices in toy supply chains" Supply Chain Management, Vol 10, No 5, pp. 367-378.

A1.4 Changing consumer preferences, high impulse purchasing, concentrated seasonality and intensifying price-competition all contribute to high demand uncertainty. Although parents and grandparents typically make the purchases, children are the ultimate decision-makers. This separation between the preference-holder and consumer adds an element of disconnect — as well as reduced transparency — to the relationship between producers and consumers, enhancing the difficulty experienced by suppliers in understanding, and thereby keeping up with consumer demand.

A1.5 The unpredictable nature of children's preferences only adds to this difficulty. As does the seasonal drive of the toy industry, which means that sales are cyclical, with 60-70 per cent sold during the last quarter of the year. In quantity, the seasonality factor ranges from five to ten, meaning that manufacturers need between five and ten times their normal capacity during this period in order to keep up with spiked demand. Finally, the observed phenomena of "kids getting older younger"[47] and increasingly structured leisure time[48] implies a decreasing spread of consumers. Such demand unpredictability necessarily gives rise to an element of low supply reliability in the toy industry.

A1.6 Table A1.1 shows the breakdown of market shares of traditional toys in the EU in 2005. Infant and pre-schooler's toys are the leading products in the sector, followed by games and puzzles.

[47] Garner, C. (1996) "The loss of our innocence" *The Independent*, 15 August, p. 3.
[48] Retter, Hein (1999) "Postmodernity—what about toys?" International Toy Research Conference Symposium paper, Halmstad University.

Table A1.1: Breakdown of EU market shares of traditional toys (2005)

Toy category	Market share (%)
Infant/preschool	19.6
Games/puzzles	14.5
Dolls	12.5
Outdoor & sport toys	10.6
Vehicles	9.4
Building sets	7.2
Arts & crafts	5.8
Plush	5.7
Action figures & accessories	4.7
Learning & exploration	1.7
All other	8.3

Source: Toy Industries of Europe, 2006

Turnover and employment

A1.7 In 2005, toys and games from Europe generated sales of €13 billion. This accounts for approximately a quarter of the industry worldwide. The main producers of toys in the EU are Germany, Spain, Italy and France; with Germany accounting for over 20 per cent of production. Lego, the world's third largest toy company, is based in Denmark, though its production is not. Due to the toy industry being labour intensive, unskilled production in Western countries is increasingly outsourced to developing countries overseas, mainly China.

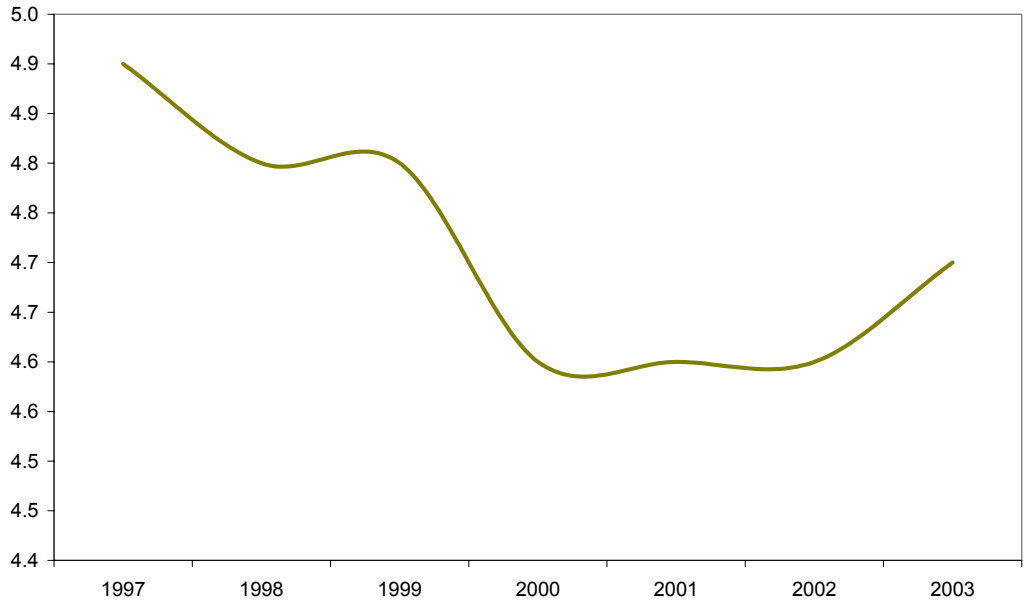
A1.8 Over the last decade, the EU toy industry saw a temporary drop in output (see Chart A1.2). According to a 2004 report by RPA, there could be two reasons for this drop.[49] First, the lower wages and economies of scale in Asia have made overseas manufacturing cheaper. Not only has this resulted in a slight decrease in domestic production and employment, but it has also somewhat reshaped the current structure of the toy and game industry: SMEs in the EU have shifted to occupy more specialised and niche-oriented positions that enable them to add more value to the product.

A1.9 The second cause for the decline in EU production relates to the recent rise in global demand of electronic games and toys, which are (imperfect) substitutes for the traditional toys that are typically manufactured in the EU. In 1999 the Lego management explained its 10 per cent reduction in staff —1,000 jobs — by explaining that due to the "unpleasant situation" brought on by increasing appeal of video and computer games. (1998 had marked the first year of losses in Lego company history.) Likewise, Toys "R" Us Germany cited its stagnant sales from 1995-1999 as a result of having "trusted in the traditional toy

[49] RPA (2004) "Study on the impact of the revision of Council Directive 88/378/EEC on the Safety of Toys"

business for too long."[50] Sales picked up again in 2006, rising to €5bn. Interestingly, the TIE attributes this to the growing demand for media-linked merchandise, such as toys modelled after film characters or cartoon personalities.

Chart A1.2: EU toy production (€ billion)



Source: Toy Industries of Europe, 1997-2003

A1.10 Because of the short product life cycle of toys, turnover in the industry is high. New, toys introduced in the current year contribute to the majority of annual toy sales. This trend may reflect the impact of the KGOY phenomenon on consumer preferences. However, it is also related to the rise of movie or cartoon-related products, the preferred characters of which are constantly being reshuffled in dominance in the child's mind's eye.[51]

A1.11 The EU toy industry employs almost 100,000 people, 53,000 of whom work directly in production and 45,000 in research and development, retail, distribution, and other services. Of the 2,000 companies in the EU, 85 per cent have fewer than 50 employees. Germany leads in direct employment while the UK had the highest level of indirect (R&D, retail and marketing) employment. While direct employment has decreased in the EU, indirect employment remains stable.

[50] Retter, Hein (1999) "Postmodernity — what about toys?" International Toy Research Conference Symposium paper, Halmstad University.

[51] Wong, Chee Yew, Arlbjørn, Jan Stentoft, and Johanson, John (2005) "Supply chain management practices in toy supply chains" Supply Chain Management, Vol 10, No 5, pp. 367-378.

A1.12 Reasons for the decrease in direct employment in the EU include the increased automation of certain manufacturing processes such as packaging; and strong movements in relocation of manufacturing to Asia. However, the rapid ascension of video games and electronic toy manufacturers has had negative repercussions on the "traditional" toys industry as well. In 2003 video games made up 27.5 per cent of the EU toy market.

Market shares and concentration

A1.13 Toy sales are dominated more and more by mass discounters and toy superstores. According to an NPD survey, between 1992 and 2001, the percentage of market share enjoyed by the top five toy retailers in America increased from 46 to 52 per cent; and Europe is said to be experiencing the same trend. In 1999, the five largest toy companies, Mattel, Hasbro, Lego, Playmobil and Ravensburger held over 75 per cent of the total market share. Due to the large number of SMEs that must compete with the "giants," many of them have devised strategies to collaborate with them in design, manufacturing, and distribution (see above). [52]

A1.14 Video games are becoming increasingly popular. According to the RPA report on the EU toy sector, the video games sector is growing more rapidly than the traditional toy sector — and expanding its market share of total industry sales.

Price and quality competition

A1.15 Competition in the toys industry operates along two main dimensions: price and quality. Due to its inherent seasonality and trend-dependent nature, the toy industry is fraught with frequent-discounting strategies. Although the consumer price index for the industry has been more or less stagnant, mark-up between the whole sale and retail price for toys is lower than average for consumer durables.[53]

A1.16 This downward pressure on the price of retail toys in recent years is made possible both by the consolidation of large manufacturers and retailers and the advent of internet sales. The Internet benefits the consumer on the supply side by generating greater efficiency levels through lower transaction costs and new organisational forms to reduce firms' cost functions.

A1.17 A repercussion of the consolidation of toy retailers is the development of competition between retailers and their suppliers. Large discounters and hypermarkets are discovering that if they manufacture their own toys, they can cut costs significantly. Furthermore, outsourcing manufacturing to the Far East is more often more economical than buying whole sale from the usual suppliers. As retailers increase their size and gain brand name recognition, they are better able to cultivate consumer trust. Such

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52 CORDIS (2006) "Articles on innovation: new toys for Europe" http://cordis.europa.eu/aoi/print_version.cfm?article=1739&lang=EN.

53 Toy Industry Association, Inc. (2004) *2001-2002 Toy Industry Fact Book*, New York: Toy Industry Association, Inc.

backwards integration breeds an asymmetrical power dynamic, which often results in manufacturers competing for distribution. Many suppliers will pay contribution-to-trade fees to retailers, which go towards in-store promotional devices, transportation, or warehousing allowances. Alternatively the contribution-to-trade may take the form of a general agreement on annual volume discounts.

A1.18 Quality competition is equally intense in the toy industry; to the degree that quality in the toy industry is shaped by innovation. Because most new toys on the market fail, innovation is critical.[54] However, because of the aforementioned price competitiveness, innovative efforts are arguably threatened. One solution to this conflict has been the return to the classic toy, which is inherently less risky.[55] Furthermore, built-in brand awareness means less required marketing investment than new and unfamiliar products.

Trade and international penetration

A1.19 In contrast with SMEs in most other industries, toy-manufacturing SMEs are often involved in additional aspects of the supply chain, such as directly importing products from overseas or purchasing from larger manufacturers within the EU. Of the toys sold within the EU an estimated range of €6-9bn are imported from outside the EU. Between 2004 and 2005 EU imports increased by 21.8 per cent. The strengthening of the euro against the dollar has contributed to this increase.[56]

A1.20 The most commonly imported toys include dolls and doll accessories, soft toys, electronic toys and games, video games, and boys' action toys. Video games are the most popular toy in the EU and hold about one fourth of the total market share. Toys are mostly imported from the Asia, with upwards of 75 per cent of total imports coming from China.

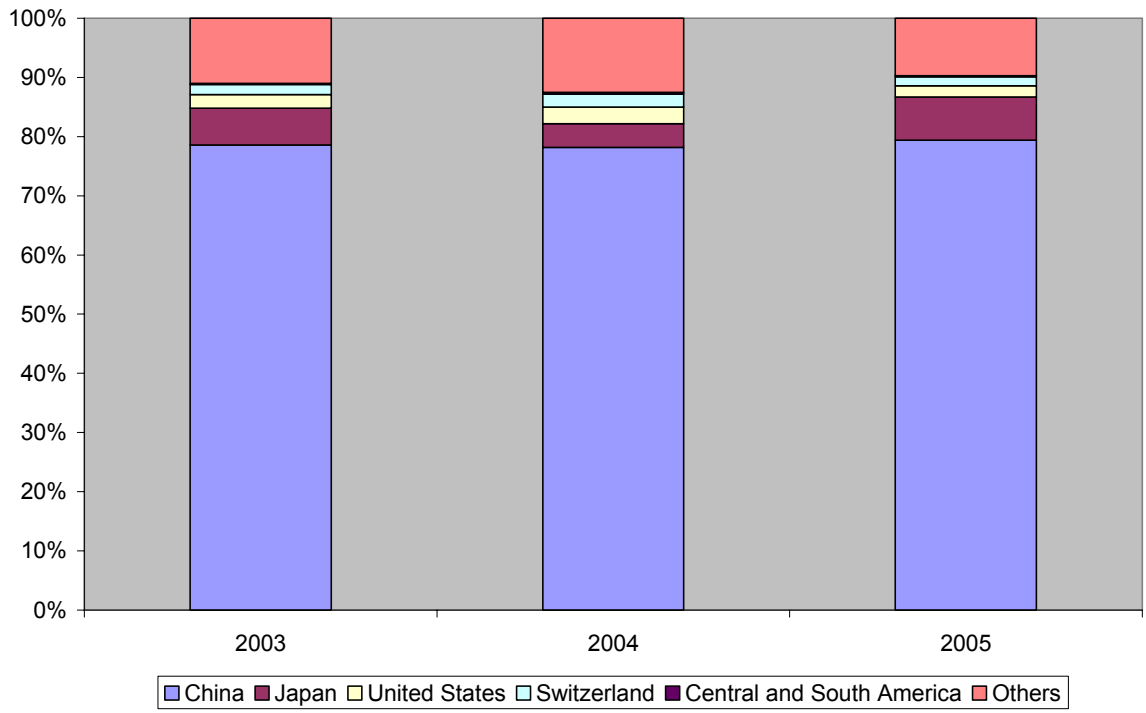
[54] Del Vecchio, G. (2003) *The Blockbuster Toy: How to Invent the Next Big Thing*, Los Angeles: Pelican Publishing Company.
[55] Chandiriamani, R. (2003), "Are retro toys stifling innovation?" *Marketing*, 31 July, p. 13.
[56] Toy Industries of Europe (2006) "Toy Industries of Europe: facts and figures," Brussels: Toy Industries of Europe.

Table A1.2: Toy imports into the EU (%)

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

Source: Toy Industries of Europe, 2006

Chart A1.3: Imports from non-EU countries



Source: Toy Industries of Europe, 2006

A1.21 Exports from the EU have been more or less stagnant, after a period of steady increase (1998-2003). The USA is the EU's primary trading partner. Annual exports range from €1-1.5bn. Primary toys exported are construction toys, board games, soft toys, baby toys, dolls and doll accessories.

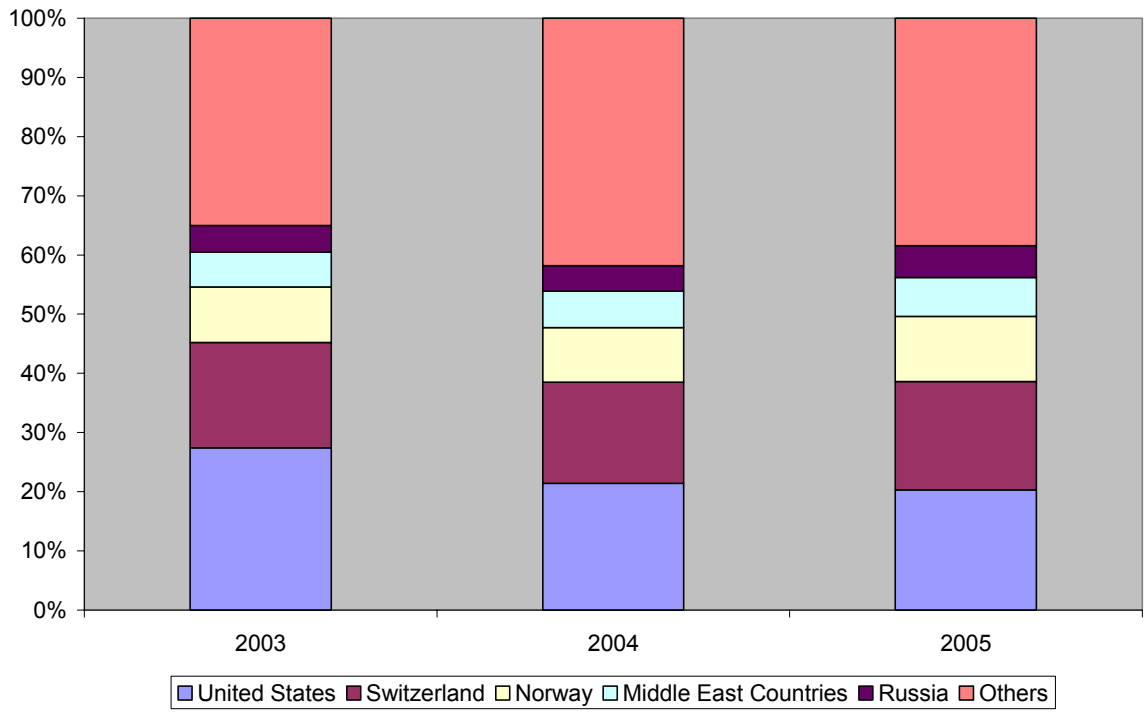
Table A1.3: Toys exports from the EU (%)

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

Source: Toy Industries of Europe, 2006

A1.22 Europe exports most of its toys to other EU countries; of these, most are sold to Switzerland. North America is the second largest global region to which the EU exports and nearly all are to the United States. Whereas Asian countries are among the largest exporters to the EU, they import relatively very little — Japan being the largest Asian importer of EU toys. See chart 6.4 below.

Chart A1.4: Exports to non-EU countries



Source: Toy Industries of Europe, 2006

Future trends

Market structure

A1.23 As reported in the RPA report, there is an increasing trend to link toy products to film, sports and music. The increased use of character licensing and branding tied to film "events" is expected to contribute to secure and stable employment in the retail, marketing and distribution sectors of the industry until at least 2010. Coupled with the revival of "classic" toy brands and other retro characters and films, demand is expected to stay stable.

A1.24 Within the industry, it is expected that the larger firms will continue to focus on internationally recognisable brands, whereas SMEs will increasingly focus on local tastes and niche markets, specialising in toys for particular age groups or a specific product line.

Industry structure

A1.25 Having already adapted to globalisation and taken advantage of outsourcing, the RPA report that within the EU, the underlying industry structure is expected to remain static in the near future. Despite the internet offering manufacturing the potential to directly retail their toys to consumers; our discussions have revealed reluctance by large manufacturers to enter the retailing side of the market. The focus of individual firms is likely to remain unchanged from their manufacturing, supply, distribution, and retail roles.

A1.26 While some Chinese firms involved in outsourcing have begun to register patents over parts of the manufacturing and design process, our discussions have revealed that, at least in the short term, Chinese firms are not expected to begin designing and manufacturing toys (and electronic games) in their own right.

A1.27 Direct employment in the sector is likely to continue to be shifted away from the EU to Asia. Indirect employment, such as retail, may begin to become increasingly affected by the internet, although experience in other sectors is inconclusive.

Manufacturing processes

A1.28 While each toy will have its own manufacturing process, it is possible to draw out some generic steps in the design and production of a toy. These processes are common to nearly all toys and include:

(c) design of the toy itself, which typically done at the company headquarters;

(d) sourcing of raw materials;

(e) putting the materials together through some or all the following techniques: moulding, stapling, sewing, gluing and other "normal" industrial processes;

(f) product finishing; and

(g) product testing.

A1.29 The testing is often done in house for the larger toy companies. The testing is to ensure compliance with the Toy Safety Directive (discussed in more detail later).

Importers

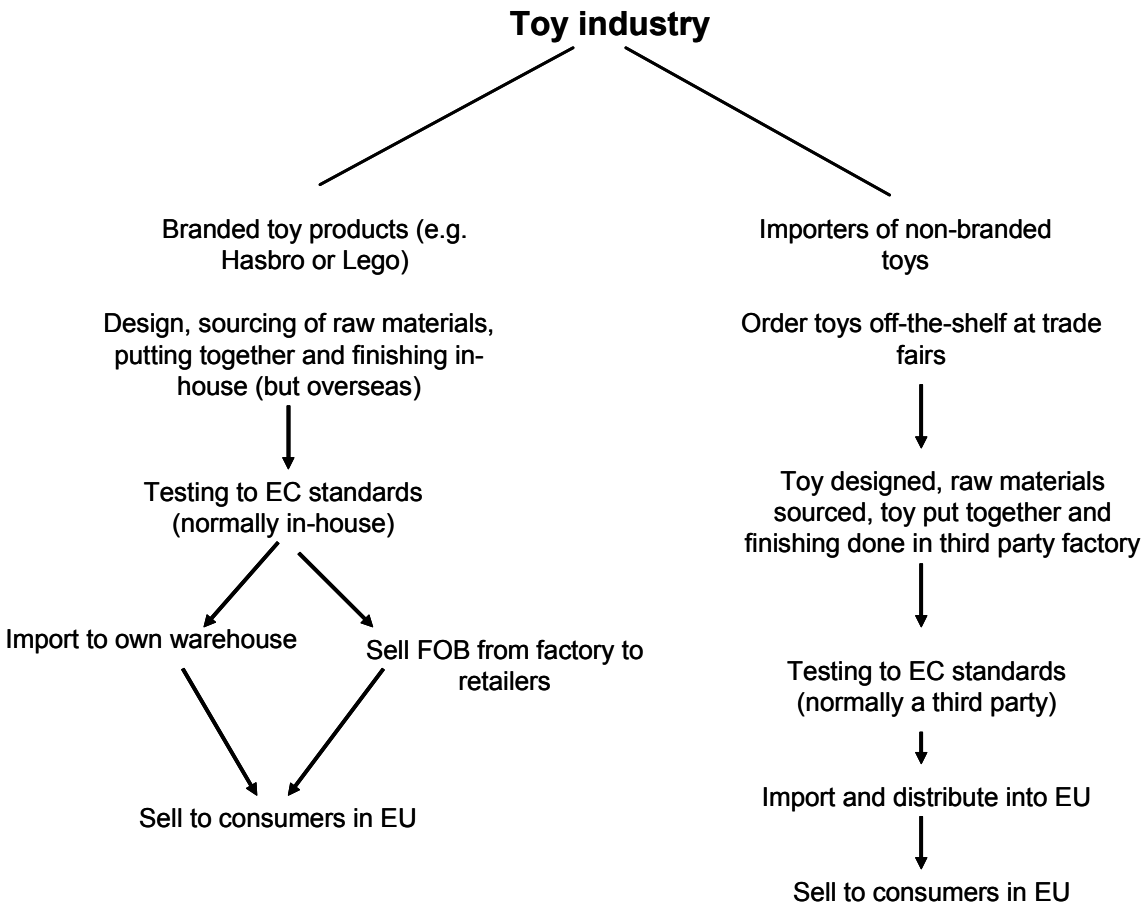
A1.30 Toy companies can be divided into two groups: those who make or sell branded products and those that do not. The branded product manufacturers (e.g. Hasbro) typically have complete control over their manufacturing process. They own their factories (and often have a representative present there) and know what exactly is going on. They typically import the toys into their own warehouses in Europe, or sell products FOB out of China to retailer warehouses.

A1.31 Those importers that do not sell branded toys buy products "off the shelf" in China, Taiwan, Hong Kong and so forth. Within this group there are some importers who have good knowledge of their supply chains and can easily find out what is contained in the toys they import. However, there are also those importers who are not able to easily find out what is contained in their toys (they often only deal with factories' agents).

A1.32 It should be recalled that under the TSD, companies that bring a product onto the EU market under their own name and/or trademark are directly responsible for the safety of the toy.

A1.33 The diagram below summarises the typology of toy companies.

Chart A1.5: Toy company typology



A1.34 Like all the New Approach Directive, the Toy Safety Directive is based on the responsibility of the manufacturer of the toy (whether it is in the EU or outside it). Importers (who are not manufacturers at the same time) have responsibility to keep a technical file available for inspection.[57]

Safety issues with chemicals in toys

A1.35 The European Commission hosts the RAPEX website. RAPEX is a rapid alert system for dangerous non-food products, including toys. Once a safety issue with a particular non-food product is raised in one Member State, it is able to inform all others via the RAPEX system.

A1.36 In practice, the system works as follows.

[57] For more details see http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

(h) When a product (e.g. a toy) is found to be dangerous, the competent national authority takes appropriate action to eliminate the risk. It can withdraw the product from the market; recall it from consumers or issue warnings. The National Contact Point then informs the European Commission (Directorate-General for Health and Consumer Protection) about the product, the risks it poses for consumers and the measures taken by the authority to prevent risks and accidents.

(i) The European Commission disseminates the information that it receives to the National Contact Points of all other EU countries. It publishes weekly overviews of dangerous products and the measures taken to eliminate the risks on the internet.

(j) The National Contact Points in each EU country ensure that the authorities responsible check whether the newly notified dangerous product is present on the market. If so, the authorities take measures to eliminate the risk, either by requiring the product to be withdrawn from the market, by recalling it from consumers or by issuing warnings.

A1.37 Under certain conditions, the Commission has the power to adopt a formal Decision requiring the Member States to ban the marketing of an unsafe product, recall it from consumers or withdraw it altogether from the market. Such Decisions at Community level can be taken:

(k) where the Member States have different approaches to dealing with the risks posed by such dangerous products;

(l) where urgency is needed due to the risk of the product, and where no other Community laws deal with that risk, and

(m) where such Decisions are the most effective way of eliminating the risk.

A1.38 A Decision of this kind is only valid for a maximum of one year. To date, two Decisions of this kind have been taken at Community level; one of which is in an area particularly relevant to toys: phthalates. In 1999, concern was raised in a number of member states about the potential adverse effects that phthalates might have on children's health. Phthalates are typically used as softeners for plastics, which in turn are used to make toys. The Commission Decision led to the banning of six phthalates from toys and other childcare products. The Decision was renewed on a number of occasions and eventually led to a Directive on Phthalates (discussed in a subsequent section).

A1.39 According to the RAPEX website, a number of toys have been identified as being a safety risk to toys. It is not uncommon for a toy to be found in breach of a Directive or a Standard. In fact, a toy was the first product to be reported under RAPEX.

A1.40 The majority of these safety issues relate issues of choking and suffocation, but there are a number of safety issues related to chemicals. Below are some examples:

Table A1.4: Selected examples of chemical safety issues in toys as reported by RAPEX

Notifying country	Product	Danger	Measures adopted
Finland	Product: Plastic toy Brand: Jokes for fun spider Country of origin: China	The product poses a chemical risk because the quantity of di-isonyl phthalate (DINP) and di(2-ethylhexyl) phthalate (DEHP) exceeds the limit (0.1%). The plastic material contains 3.4% (DEHP) and 31% (DINP) by weight.	Import rejected by the customs authorities
Germany	Product: Wooden jigsaw puzzle – Farm theme with clock Brand: Pfennigpfeiffer Country of origin: China	This product poses a risk of choking because it contains loose small parts which children may put into their mouth and they may choke. In addition, this toy poses a chemical risk because it contains formaldehyde and lead in green and red paints which exceeds the permissible limit values. This product does not comply with the Toys Directive and the relevant European standard EN 71-1.	Voluntary withdrawal from the market and destruction
Norway	Product: Sticky Ear and Brain Brand: Scooby-doo Type/number of model: Unknown Description: Two sticky toys formed as a brain and an ear, pale yellow/skin colour, dimensions 3.5 x 6 cm, packed in a plastic bag. Distributed as a gift with a children's magazine. Country of origin: Unknown	The toy contains 50-80% of hydrocarbons, with a small aromatic content. This toy may pose irritation and allergic reaction on skin if placed in mouth. This product does not comply with the Toys Directive and the relevant European standard EN 71-1.	Withdrawal from the market ordered by the authorities
Slovakia	Product: Bath toy - squeeze hippopotamus Brand: PROFIBABY Country of origin: Czech Republic	This toy poses a serious chemical risk because it contains an excessive value of 0.14% by weight of DEHP. With respect to the character of the toy, a prolonged contact of the mouth of a child with plastic parts is highly probable and poses a serious risk for the health of children. This toy does not comply with Chemicals Restrictions Directive 76/769/EEC.	Voluntary withdrawal from the market, recall from consumers and information to consumers by the distributor

Notifying country	Product	Danger	Measures adopted
Slovakia	Product: Booklet Brand: Play&Learn, Baby touch Country of origin: China	This product (in its plastic parts) contains phthalate esters DEHP in amount of 21.6% by weight which highly exceeds the limit.	Voluntary stop of sales, withdrawal from the market and information to consumers by the distributor
Germany	Product: Puzzle with farm images Brand: Unknown Country of origin: China	This product poses a serious chemical risk because it releases 206 mg/kg of formaldehyde in 24 hours, which exceeds the maximum limit of 110 mg/kg in 24 hours. This toy does not comply with the Toys Directive and the relevant European standard EN 71-1.	Voluntary withdrawal from the market by the distributor
Finland	Product: Doll set 'Little Ones' Brand: Kid Kore Type/number of model: No 1663 Country of origin: Hong Kong	The product poses a chemical risk because the shoes of the doll contain phenol at level of 980 mg/kg whereas the limit is 150 mg/kg. Phenol can cause various poisoning symptoms. The product does not comply with the Toys Directive and the relevant European standard EN 71-3.	Voluntary withdrawal from the market
Germany	Product: Wooden toy Brand: Tic Tac Toe Type/number of model: Felix motif, order No: 8759, EAN: 4 029753 087591 Country of origin: China	This product poses a serious risk to children because of very high amount of lead - 482 mg/kg. Limit set by the standard is 90 mg/kg. This product does not comply with the Toys Directive and the relevant European standard EN 71-3.	Voluntary recall of the product from the market

DEHP is classified as category 2 toxic for reproduction material. Phthalates have a negative effect on the development of male/female reproductive organs. Especially children are vulnerable as their body is developing and can be negatively affected by these toxic substances.

A1.41 One notes from this brief selection that safety issues with regard to chemicals have arisen across the EU. Most of the issues have related to phthalates. In almost all cases the product is removed from the marketplace.

Monitoring and enforcement

A1.42 Under current legislation, Member States are responsible for the toys produced within their economies and placed on their markets. This means ensuring sample checks are carried out, taking appropriate enforcement measures — including market surveillance,

and making products conform if they are found to be in violation of standards (or alternatively, prohibiting their sale if they continue to be non-conforming).

A1.43 Under the existing TSD, there are two measures for conformity certification: EC-type examination, or, under certain pre-approved conditions, self-certification. Competent and Market Surveillance Authorities in individual Member States are empowered with power to enforce conformity standards.

A1.44 Given the vital need to maintain safe toys for children, regulation and enforcement of industrial standards is an extremely important issue. The current harmonised framework is seen as enabling Member States to test products on a "comparable and consistent basis", but without incurring excessive costs as a result of asymmetric information and fear of under-regulation. [58] Because of its clear delineated structure for regulation, the proposed Toy Safety Directive is thought to enhance internal mobility in the market, as well as rendering exports more marketable globally.

A1.45 Nevertheless, regulation remains a tricky issue, as there are some issues which are difficult to control for, even through the use of legislative measures. According to RPA, there have been increasing numbers of occurrences of counterfeit toys and games on the market. In not adhering to health and safety regulations, these toys can often pose great risk, including the concern that counterfeit toys may be of dubious chemical safety. Although the industry recognises the need to eliminate counterfeit toys, there are a few matters which make it difficult to do so.

A1.46 First, the often short market life of a product can make it very difficult to impose counterfeit measures which are specifically designed for any one toy. Secondly, and related to the previous point, the cost of regulating counterfeit toys is likely to be high, perhaps apparently prohibitively so. The third reason why it is difficult to regulate counterfeited toys also relates to point one, as the rapidly shifting nature of the toy industry makes it extremely difficult to license effective patents.

[58] RPA (2004) "Study on the impact of the revision of Council Directive 88/378/EEC on the Safety of Toys"

APPENDIX 2: LEGISLATIVE FRAMEWORK

Introduction

A2.1 The proliferation of different laws, regulations and administrative provisions relating to the safety characteristics of toys in force in the various Member States of the EU resulted in differing scope and content of such laws in different Member States. The consequence of such disparities was viewed as being the likelihood of the creation of barriers to trade and unequal conditions of competition within the internal market. It was also recognised that different approaches did not necessarily afford consumers in the EU, especially children, effective protection against hazards arising from toys.

A2.2 It was therefore decided that a Directive was necessary to deal with the obstacles to trade and accordingly the Toy Safety Directive 88/378/EC (TSD) was carried into law in 1988. The Directive removes these obstacles by ensuring that the marketing and free movement of toys are subject to uniform rules based on objectives regarding protection of consumer health and safety. It is thus an early example of a New Approach directive.

A2.3 The TSD was amended in 1993 by the CE Marking Directive 93/68/EC which imposed uniform standards on all New Approach directives implemented prior to 1993 and laid down a procedure to be followed in the event that more than one new approach directive applied to the same product. There have been a number of subsequent directives and regulations mostly with respect to the metal and chemical content of products (including toys).

A2.4 This section looks at the present legislation and in particular the REACH Regulations and their likely effect on the proposed revisions to the TSD and discusses the three approaches under consideration as the approach to risk and hazard in the new proposed TSD.

The New Approach Directives[59]

A2.5 'New Approach' directives set out 'essential requirements' (for safety, for example), written in general terms, which must be met before products may be sold in the EU. European standards contain the detail and are the principal way that business meets the 'essential requirements'. Thus, the European Community rules (as set out in the New Approach directives) provide that EU countries and indeed EEA countries are required not to interfere with the supply of toys that carry CE marking and satisfy required safety and other provisions. It follows that toys bearing the CE marking are to be presumed to satisfy the provisions of the TSD and other New Approach directives as applicable unless there are grounds for suspecting otherwise.

A2.6 Underpinning new approach Directives are a series of CEN[60] and CENLEC harmonised European standards each specifically produced for use with a particular New Approach Directive and each of which sets out the detail of the essential requirements. For CE Marking to apply in any particular Member State the standards must be transposed into a national standard without change except for translation.

A2.7 By placing a CE mark on a toy the manufacturer confirms that the product meets the provisions of the relevant directives. Typically the mark is attached by either the manufacturer or his authorised representative in the EU in order to show that the product meet the essential requirements. It is the responsibility of the first supplier into the EU to maintain a Technical File which is a description of how the means of production conform to the agreed standards.

A2.8 It follows that if a product carries a CE Mark it is a manufacturer's declaration that the product complies with the essential requirements of the relevant European legislation. However it is not a quality mark as such but an assertion to government officials that the product may be legally placed on the market in their country. So if customs officers or other enforcement officers in a member state discover non-conforming product carrying a CE Mark they have powers of seizure and withdrawal from market of that product. However the CE marking system does enables buyers throughout the EEA to ensure that they are purchasing products which meet accepted safety and performance standards. As in many other industries, this system makes it easier for foreign competitors to sell their products, but it also opens up export markets. It makes European markets more attractive to potential competitors outside Europe, because producing merchandise to

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[59] A 'New Approach directive' is one produced under the provisions of Council Resolution of 7 May 1985 on a New Approach to Technical Harmonisation and Standards (85/C/136/01), published in the *Official Journal of the European Communities* (C276) on 4 June 1985.

[60] CEN is The European Committee for Standardisation responsible for preparing harmonized standards other than those dealing with electrical properties. Membership consists of the 18 European Economic Area countries and Switzerland CENELEC is the European Committee for Electrotechnical Standardisation responsible for preparing harmonised standards for electrical products - including the electrical safety of toys. Details of membership are as for CEN.

meet a single set of standards opens access to the entire EU market. Accordingly the mark can be thought of as a "passport for product

A2.9 Furthermore, in essence the CE mark is not primarily a safety mark, but a device to aid enforcement agencies to trace suppliers if they believe there is non-compliance. Tracing is easy as the address of each supplier is part of the CE mark.

A2.10 The CE mark appears on a number of products, not just toys. For example, some radio and telecommunications equipment carry the mark, as do personal protective equipment such as helmets and knee and elbow pads.

A2.11 Products must be independently certified, by a Notified Body. This is an organisation that has been nominated by a Member State and has been notified by the European Commission. Notified bodies serve as independent testing laboratories and perform the tests required by the TSD.

A2.12 The TSD applies to toys, which are defined as "any product or material designed or clearly intended for use in play by children of less than 14 years of age". The Directive sets out the conditions under which toys can be sold or distributed in the EU. These conditions can be summarised as:

(n) the toy does not jeopardise the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children (general safety requirement); and

(o) the toy conforms with the health and safety requirements laid down in the TSD.[61]

A2.13 Within the TSD there are 21 exceptions for goods which might be otherwise classified as toys, but have not been expressly not designed for children, e.g. Christmas decorations or detailed scale models for adult collectors, or goods that pose a particular risk not covered by the TSD, e.g. sports equipment.

A2.14 Under Annex II (titled Essential Safety Requirements), the TSD contains safety criteria for toys under the categories of "general principles" and "particular risks". The general principles include risks connected with design, construction or composition of the toy. The degree of risk present in the use of any given toy should take into account the ability of the user (and where appropriate supervisors). To observe this principle, the toy should contain labelling that specifies a minimum age for use.

A2.15 Particular risks include:

(p) physical and mechanical properties;

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[61] These are the New Approach provisions.

(q) flammability;

(r) chemical properties;

(s) electrical properties;

(t) hygiene; and

(u) radioactivity.

A2.16 For many of these particular risks there are further guidelines and standards, and these are discussed in relation to chemicals in more detail below. These guidelines and standards are Europe wide and as noted have been drafted by the European standardisation bodies of CEN, CENELEC and ETSI. The Directive makes direct reference to these bodies, for example:

> …to facilitate proof of conformity with the essential requirements, it is necessary to have harmonised standards at European level which concern, in particular, the design and composition of toys so that products complying with them may be assumed to conform to the essential requirements; whereas these standards harmonized at European level are drawn up by private bodies and must remain non-mandatory texts; whereas for that purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation … for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonized document) adopted by one or both of these bodies upon a remit from the Commission…

A2.17 CEN provides voluntary technical standards which help create consumer confidence, worker safety, and environmental compatibility in cross-border goods within the EU market and with worldwide trading partners.[62] The procedure by which it may issue mandates is rendered in Directive 83/189/EEC which was aimed at preventing the appearance of barriers to the operation of the Internal Market. It is worth repeating that that CEN mandates are voluntary. Those that relate to toys are EN 71-1: and there are 11 current documents ranging from Mechanical and Physical Properties to Organic chemical compounds – methods of analysis.

A2.18 Toy manufacturers or toy importers in the EU can conform to the essential requirements in two ways:

(v) Self-verification: whereby the manufacturer applies the standards. This involves drawing up a dossier and describing the way in which its production processes

[62] European Committee for Standardization (2007) "CEN: About us" http://www.cen.eu/cenorm/conformityassessment/index.asp.

conform to the standards. The manufacturer can then affix the CE mark, his name and address on the toy (or on its packaging) before placing the toy on the market.

(w) Third party verification or certification: in this case the manufacturer or importer submits its toy (as well as a design dossier if available) to a notified body.[63] The notified body then issues an EC type examination certificate. The manufacturer or importer has the means to ensure the conformity of his production with the approved model. Then a CE mark may be attached to each toy when it conforms with the approved model.

REACH

A2.19 Regulation EC/1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishes a European Chemicals Agency, amends Directive 1999/45/EC and repeals Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC REACH will have far reaching effect on a number of other directives and this includes the TSD and any revision to it.

A2.20 By creating an EU-wide system for the management of chemicals REACH will bring together the EU chemicals legislation. REACH will no longer differentiate between so-called "existing" and "new" chemicals. Previously all chemicals put on the market before 1981 were called "existing" chemicals while chemicals introduced after 1981 were termed "new" chemicals. New chemicals had to be tested quite rigorously under the legislative provisions which are repealed by REACH. There were no such provisions for "existing" substances. As a result knowledge on properties and uses of “existing” substances is rather limited. Under REACH, the burden of proof for demonstrating the safe use of chemicals will be transferred from Member States to industry.[64]

A2.21 REACH is based on the precautionary principle. It applies only to substances not to preparations or articles. The Commission has estimated that about 30,000 substances (excluding intermediates) will be registered; this estimate has been supported by industry organisations. However as many of these substances are manufactured and/or imported by more than one company, there is the potential for many more registrations to be received. Annex IV of REACH contains a list of substances exempt from the obligation to register under the present Existing Substances Regulation (EC/793/93) and Annex V provides a more general list of criteria for exemptions from the obligation to register. Annexes IV and V are to be reviewed by 1 June 2008.

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[63] A notified body is an organisation designated by Member States on the basis of common evaluation criteria, and then notified to the Commission and other Member States.

[64] www.europa.eu.int - REACH pages

A2.22 The REACH Regulation gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on substances. Companies that manufacture or import one tonne or more of a chemical substance annually will be required to register it in a central database at the European Chemicals Agency Manufacturers and importers are required to gather information on the properties of their substances, so they can be managed safely. There is an existing requirement upon a manufacturer to prepare a Safety Data Sheet (SDS) if requested to do so, or if there material is hazardous (Directive 2001/58/EC). A Safety Data Sheet could be prepared from generic data. This obligation ceased when REACH replaced the existing SDS Directive from 1 June 2007

A2.23 The registration procedure involves submitting a technical dossier containing information on the substance and guidance how to handle it safely. For quantities of 10 tonnes and more companies also need to submit a Chemical Safety Report (CSR) to document a safety assessment of the substance demonstrating safe handling for all identified uses and manufacturing. The CSR does not have to be undertaken for substances present in a preparation below the concentration limits in Directive 1999/45/EC and an exposure assessment of the substance is not required if it is not classified or PBT/vPvB.

A2.24 The CSR must also cover uses identified by downstream users to their manufacturers or importers, including the use of a substance in production of articles (e.g., toys). For the identified uses the CSR has also to cover waste management measures that the manufacturer or importer of a substance recommends to be implemented by downstream users. The CSR should also generically cover consumer use of substances as such, in preparations and in articles (e.g. toys) and subsequent waste handling. There is as yet no technical guidance to help with carrying out a CSR.

A2.25 Article 3 contains the following relevant definitions.

(x) “Substance” means a chemical substance and its compounds

(y) “Preparation” means a mixture or solution composed of two or more substances

(z) “Article” means an object which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition

(aa) “Downstream Users” means formulators and industrial users of chemicals

(bb) “Exposure Scenario” means a set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment

A2.26 Annex XVII contains restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles. Benzene is not permitted in

toys or parts of toys as placed on the market where the concentration of benzene in the free state is in excess of 5 mg/kg of the weight of the toy or part of the toy.

A2.27 Evaluation allows regulatory authorities to determine if further testing is needed and to assess whether information provided by industry complies with the requirements (dossier evaluation). Substances suspected to pose a risk to health or the environment will be selected for substance evaluation. This may lead to the actions under the restrictions or authorisation procedures. Substances of very high concern are subject to an authorisation procedure. Companies which apply for authorisation need to show that the risks posed by those substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks. The aim is to give industry the incentive to progressively substitute these substances with safer alternatives when technically and economically feasible.

A2.28 Substances of very high concern are:

(cc) carcinogens, mutagens or toxic to the reproductive system, categories 1 and 2;

(dd) substances which are persistent, bio-accumulative and toxic;

(ee) very persistent and very bio-accumulative; and

(ff) of equivalent concern.

A2.29 Member States and the European Chemicals Agency, on a request from the Commission, can place substances on a candidate list of substances of very high concern. The first list will be available on the Agency's website from late 2008. Some 1500 substances may fall to be considered. Restrictions are the safety net of the system. Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if its use poses unacceptable risks to health or the environment. Restrictions can be imposed on the use of a substance in certain circumstances and products, the use by consumers or even on all uses (complete ban of a substance). Restrictions and authorisations can also apply to substances produced or imported in volumes below 1 tonne per year.

A2.30 So it is plain that notwithstanding the specific provisions relating to chemicals in the TSD and any amending legislation, under REACH:

(gg) if substances are not registered they cannot be used;

(hh) if they are registered, registration will be for a limited period of time;

(ii) If a safer alternative is available a substitution plan is mandatory;

(jj) If there is no alternative, an R&D plan to find a safer alternative is mandatory; and

(kk) If an alternative is developed after authorization is granted, then a substitution plan is mandatory.

A2.31 Finally when considering REACH it is necessary to make reference to the position with respect to waste and REACH. The Common position reached in 2006 on the REACH Regulation was that waste, as defined by Directive 12/2006/EC, should fall outside the scope of the Regulation.

A2.32 The Common Position states that substances covered by Annex II are exempted from registration as it is deemed inappropriate or unnecessary and their exemption from registration does not prejudice the aims of the Regulation.

A2.33 Article 11 makes the intention of REACH clear:

> To ensure workability and to maintain the incentives for waste recycling and recovery, wastes should not be regarded as substances, preparations or articles within the meaning of this Regulation

A2.34 The exemption[65] states that:

> 7. The following shall be exempted from Titles II, V and VI:
>
> (d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:
>
> (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
>
> (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery

A2.35 However whilst waste is exempted if substances are recovered on their own or in preparations or articles then these are only exempt from registration etc in accordance with Article 7(d). Any non-recovered material stays as waste.

A2.36 If substances such as metals or single chemical species are recovered then the definition works, .provided there is a valid safety Data Sheet (SDS) for the registered substance as required by Art 31/32.

A2.37 It is doubted whether this assists for example for an article recovered and used again perhaps after cleaning, since such an article does not come with a list of ingredients so that a check can be made to establish if it is registered. Such an article will never, in the foreseeable future, have such a full list of substances and so it appears that the recycling of all articles is banned for the simple reason of inability to comply with these legal requirements.

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[65] Article 7.

A2.38 In the case of plastics such as a plastic toy the article would first be granulated into plastic chips and so become a preparation. If it is then re-extruded to produce a plastics profile that is then cut and assembled into say a computer case, it will not come with a list of ingredients and so whilst the sort of substances are known it is not possible to prove on legal inspection that there is compliance with the requirements.

A2.39 It has been suggested that one of the REACH Implementation Projects (RIPs) might offer a way forward. The RIPS are designed to ensure an efficient implementation of REACH through the development of guidance documents and RIP 3.3 will develop a Guidance Document for industry on how they can fulfil the information requirements on intrinsic properties of substances.

A2.40 The problem however is that as a matter of law a RIP cannot amend the REACH Regulation. An analysis of article 7 indicates that:

(ll) It is necessary legally to show that that the substance recovered.....on its own, in a preparation or in an article.....is the same as the substance that has been registered in Title II. There is no requirement to prove that the recycler carried out the registration but simply that someone registered it.

(mm) It is then necessary to have a valid SDS for the substances present presumably from those who registered the substance.

(nn) Analysis is no way to show what additives are present in such polymer formulations. There is no way of knowing with certainty what is present and in addition older articles may contain substances that were not registered under REACH.

A2.41 So it seems that the recycling of any waste is in practice not allowed by REACH unless it is recovered as a single substance, which can clearly be shown to have been registered under REACH.

The TSD chemicals

A2.42 In Annex II, part 3 of the TSD, three requirements are listed with regard to the chemical properties of toys. They are in essence:

(oo) Toys placed on the market are so placed in the expectation that they are not hazardous if ingested, inhaled, or brought into contact with the skin, mucous tissues or eyes; and that they do not present any risk of physical injury. This includes the need to comply with relevant and related existing Community legislation.

(pp) Bioavailability, defined as the “soluble extract having toxicological significance”, of select substances must not exceed the levels as given in table 1.3.

(qq) Toys must comply with the requirements of Directives 67/548/EEC and 88/379/EEC, which identify and specify legal concentration limits of dangerous substances or preparations which may harm the health of children using them.[66] However, if such substances are deemed unavoidable by manufacturers, they may be permitted up to certain amounts if agreed to by the European Committee for Standardization (CEN).

A2.43 Directive 67/548/EEC deals with "the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances" (European Commission, 1967). It has been amended nine times as of the end of 2006, and adapted to technological progress no less than 28 times. It defines "substances" as "chemical substances and their compounds as they occur in the natural state or as produced by industry" (which is similar to that in REACH). Annex I contains a complete list of officially dangerous substances, of which there are about 5,000.

A2.44 Directive 88/379/EEC (amending directive 67/548/EEC) relates to "the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations" (European Commission, 1988). It was repealed and replaced in 1999 by Directive 1999/45/EEC. "'Preparations' are defined as "mixtures or solutions composed of two or more substances". Then, the dangerous preparations covered by Directive 88/379/EEC (also amending directive 67/548/EEC) are directly formed by combinations of the substances in Annex I of Directive 67/548/EEC. Given the extremely large number of combinations resulting from any of these 5,000 substances, Directive 88/379/EEC outlines methods for grouping and classifying different families of preparations, and in turn determining threshold amounts that may inform set migration limits. Not so surprisingly, Article 2 parts l and m of 1999/45/EEC label mutagenic and carcinogenic preparations, respectively, as dangerous ones.

A2.45 Directive 2006/1231/EC amends Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to REACH.

Other legislation, standards and guidelines relating to chemicals in toys

A2.46 The table below summarises other legislation that impact the toy industry with regard to chemicals.

[66] It is of some importance to note that, while the TSD dictates that "toys must not contain dangerous substances or preparations within the Meaning of Directives 67/548/EEC and 88/379/EEC in amounts which may harm the health of children using them", the limits specified by the said directives are not necessarily equivalent to the limits that may be acceptable for small children.

Table A2.1: Other legislation on chemicals in toys

Directive	References to Toys
93/68/EEC (The amendment of the Toys Directive)	Relates to CE marking
67/548/EEC (Dangerous Substances Directive)	Sets out harmonised EU rules for classification, packaging and labelling of dangerous chemical substances. This Directive is the responsibility of DG Environment
1999/45/EC (Dangerous Preparation Directive)	Relating to the classification, packaging and labelling of dangerous preparations
2002/96/EC (Waste Electrical and Electronic Equipment Directive)	Toys are mentioned in Annex IA and Annex IB of this Directive.
2002/95/EC (Restriction on Hazardous substances Directive)	The Directive applies to all toys to which the WEEE directive applies.
76/768/EEC (Cosmetics Directive)	This Directive applies to children's cosmetics.
2000/13/EC (Labelling Directive)	This Directive deals only with foodstuffs.
2005/84/EC (Phthalates Directive)	22nd amendment of Council Directive 76/769/EEC dealing with restrictions on the marketing and use of certain dangerous substances and preparations. Bans certain phthalates in toys.
76/769/EEC (Restrictions on the marketing and use of dangerous substances and preparations)	Benzene and Chrysotile are not permitted in toys. Specified azocolourants are not to be used in certain textiles and leather articles; nor may those textiles or leather articles be placed on the market unless they conform to Directive requirements.
2002/84/EC and 2003/3/EC (Azocolourants and Blue colourant)	Relates to restrictions on the marketing and use of blue colourant. by extension applies to toys.
2005/69/EC (Restrictions on marketing)	Restrictions on the marketing and use of polycyclic aromatic hydrocarbons (PAHs) applies to toys.
2006/122/EC (Restrictions on marketing)	Restrictions on the marketing and use of certain dangerous substances and preparations (perfluorooctane sulfonates) applies by extension to toys.
Regulation 2006/1907/EC (REACH)	Regulation adopted on 18 December 2006 It enters into force on 1 June 2007. concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH).
2005/59/EC (Restrictions on marketing)	Restrictions on the marketing and use of toluene and trichlorobenzene applies to extender oils and cars and by extension to toy cars.

CEN standards

A2.47 In addition and as previously noted there a number of guidelines to which toy manufacturers must adhere if they wish to affix the CE Mark to their products. These are the CEN EN71 guidelines. Within the EN71 series of standards EN71 1-8 have been approved by the EC. EN71 9-11 have been drafted by CEN and are not yet approved in the same way. However they enjoy a high level of support in the industry and most toy manufacturers ensure that their products meet these standards. It bears repeating that none are mandatory. The table below summarises the guidelines.

Table A2.2: EN71 guidelines

EN71 part	Description
EN71-1	Guidelines on toys' mechanical and physical properties
EN71-2	Guidelines on toys' flammability
EN71-3	Specifications for migration of certain substances
EN71-4	Specifications for experimental sets for chemistry and other related activities
EN71-5	Guidelines on chemical toys (sets) other than experimental sets
EN71-6	Graphical symbols for age warning labelling
EN71-7	Guidelines on finger paints and requirements for testing methods
EN71-8	Guidelines on swings, slides, and similar activity toys for indoor and outdoor family domestic use
EN71-9	Organic chemical compounds – requirements
EN71-10	Organic chemical compounds – sample preparations and extraction
EN71-11	Organic chemical compounds – methods of analysis

A2.48 Further details about the dates of amendments can be found in the Official Journal of the European Union (26.10.2006).

APPENDIX 3: THE CHEMICALS IN QUESTION

Introduction

A3.1 Epidemiological research has consistently demonstrated the human foetus, developing child, and the adult as vulnerable to exposures from various environmental toxicants that disrupt time-specific growth and developmental processes (for example see Brent & Weitzman, 2004; Makri et al., 2004; National Academy of Sciences, 1993; Selevan et al., 2000). In some situations and for certain toxic substances children may have greater exposure than adults because of their behaviour, diet, and metabolic and physiological characteristics (Moya et al., 2004). Children take in more air, water, and food per unit body weight per day than adults and they also have differences in the absorption, distribution, metabolism, and excretion of chemicals and chemical residues that are dependent on their age (National Academy of Sciences, 1993).

Elucidation of mechanisms for carcinogenicity

A3.2 Many of the metal substances being considered here still require elucidation of mechanisms to explain their potential for adverse effects on health. One mechanism for metal-induced toxicity and carcinogenicity is the generation and role of reactive oxygen and nitrogen species. Toxicity associated with iron, copper, chromium, vanadium and cobalt are mechanisms involving reduction-oxidation cycling reactions. The toxicity associated with the metals, mercury, cadmium and nickel are depletion of glutathione, (an antioxidant found in the body that protects cells from toxins such as free radicals) and bonding to sulfhydryl groups of proteins. Arsenic is thought to bind directly to such groups. Other mechanisms, involving formation of hydrogen peroxide under physiological conditions, have also been proposed. The factor that determines toxicity and carcinogenicity for all these metals is the generation of free radical molecules including reactive oxygen (ROS) and nitrogen species (RNS). (Valko et al, 2005).

A3.3 Free radical molecules are highly reactive and destructive and known to be important for human health and disease including atherosclerosis, diabetes and cancer, where free radical reactions are an underlying mechanism of injury and a final common pathway. The human body is continuously exposed to free radicals and other ROS and RNS from both external sources (sunlight, other forms of radiation, pollution) and also generated endogenously via normal cellular metabolism. Radicals of oxygen (superoxide anion, hydroxyl radical, and peroxy- radicals), reactive non-radical oxygen species such as hydrogen peroxide and singlet oxygen, as well as carbon, nitrogen, and sulphur radicals comprise a variety of reactive molecules that can damage cells (Flora, 2007).

A3.4 The nutrient status of the body is important in counteracting the effect of toxic metals. Antioxidants are involved in the prevention of cellular damage by terminating free radical chain reactions before vital molecules are damaged. Several enzyme systems within the body scavenge free radicals, but the principal antioxidants are vitamin E, vitamin C, n-acetylcysteine and -lipoic acid (Valko et al, 2006; 2007). The vitamins C and E are thought to protect the body against the destructive effects of free radicals. Additionally,

selenium, a trace metal that is required for proper function of one of the body's antioxidant enzyme systems, is also included in this category. Antioxidants interact safely with free radicals and neutralize free radicals. Antioxidant nutrients do not become free radicals because they are stable molecules acting as scavengers to prevent cell and tissue damage that could lead to disease.

A3.5 Trace substances, such as selenium, zinc, arsenic, cadmium, and nickel, are found naturally in the environment, and human exposure is from a variety of sources, including air, drinking water, and food. Trace substances are of particular interest given that the levels of exposure to them are potentially modifiable (Navarro and Rohan, 2007).

A3.6 The appendix describes the evidence on the potential adverse health effects of the specific substances named in the TSD and its proposed revision. It should be stressed that the evidence presented is not directly related to chemicals in toys and may not be immediately applicable, but in certain cases one can make inferences where appropriate and apply them to toys.

Glossary of terms

A3.7 A number of terms are used in the text and these are defined here to avoid them being repeated in each section.

A3.8 **Benchmark Dose (BMD)**: derived from modelling the exposure–response data, as an alternative to the NOAEL/LOAEL as the point of departure for non cancer risk assessments. BMD is the dose that corresponds to a specified level of increased response [the benchmark response (BMR)] compared with background. BMD is calculated by fitting a mathematical model to the dose–response data, which can be continuous or quantal. BMD allows for consideration of the dose–response over the entire exposure range. Actual risk levels can be calculated as an alternative to the hazard index (which is typically based on comparisons of human exposures with an RfD or RfC).

A3.9 **California Environmental Protection Agency (CalEPA):** The CalEPA reference exposure level is a concentration at or below which adverse health effects are not likely to occur.

A3.10 **Lowest Observed-Adverse-Effect Level (LOAEL):** lowest dose at which there are statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control group.

A3.11 Margin of Safety (MOS): the ratio of the RfD to the calculated human exposure. Therefore if the MOS is equal to or > 1 (that is the human exposure does not exceed the RfD) it is usually OK to assume that the exposure will not pose a health risk. MOS has no units.

A3.12 **Minimal risk level (MRL):** The MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non cancer

health effects over a specified duration of exposure. Exposure to a level above the MRL does not mean that adverse health effects will occur. The MRL is intended to serve as a screening tool.

A3.13 **No-Observed Adverse- Effect Level (NOAEL):** the highest dose for which there are no observed statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its control.

A3.14 **Reference Concentration (RfC) or Reference Dose (RfD):** defined as an estimate of daily or continuous exposure to the human population (*including sensitive subgroups*) that is likely to be without an appreciable risk of deleterious effects during a lifetime (U.S. EPA 1999a). The value of the RfD or RfC is derived by determining a point of departure divided by uncertainty factors (see below). The RfD not a direct estimator of risk, but rather a reference point to gauge the potential effects. At exposures increasingly greater than the RfD, the potential for adverse health effects increases. Lifetime exposure above the RfD does not imply that an adverse health effect would necessarily occur.

A3.15 The RfC is an estimate of a daily inhalation exposure to the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse health effects over a lifetime. It is derived from a statistical lower confidence limit on the benchmark concentration (BMCL), a no-observed-adverse-effect level (NOAEL), a lowest-observed-adverse-effect level (LOAEL), or another suitable point of departure, with uncertainty/variability factors applied to reflect limitations of the data used. The RfC considers toxic effects for both the respiratory system (portal-of-entry) and for effects peripheral to the respiratory system (extrarespiratory effects). The inhalation RfC (generally expressed in units of mg/m^3) is analogous to the oral RfD and is similarly intended for use in risk assessments for health effects known or assumed to be produced through a nonlinear (possibly threshold) mode of action.

A3.16 **Regional deposited dose ratio (RDDR):** accounts for pharmacokineticdifferences between species.

A3.17 **Uncertainty factors (UFs):** used to account for uncertainties in the available studies, such as limitations in the database, variability within humans, and differences in species response (i.e., animal-to-human extrapolation). $\mathbf{UF_A}$ is a threefold uncertainty factor to account for pharmacodynamicdifferences not addressed by the RDDR. $\mathbf{UF_F}$ is a threefold uncertainty factor to account for extrapolating from subchronic to chronic exposures. $\mathbf{UF_H}$ is a 10-fold uncertainty factor to account for the variation in sensitivity among members of the human population.

Aluminium

A3.18 Aluminium is the commonest metal in the earth's crust (8.1%) and is the third most common substance. Aluminium belongs to Group IIIa of the Periodic Table, along with boron, indium, gallium and thallium. It is reactive and, therefore, never occurs naturally in its substanceal form, but as insoluble compounds within minerals–including bauxite and

clay minerals. Aluminium metal is effectively non-reactive because of the rapid formation to aluminium oxide on any exposed surfaces. This protective layer, in addition to its' light weight makes aluminium metal an ideal material for many applications in the construction industry, in the transport industry and in the packaging industry.

A3.19 Priest reviewed the behaviour and bioavailability of aluminium in man (2004). Although aluminium is ubiquitous in the environment, the human body contains, at most, only a few tens of milligrams and no known essential function. This low level is due to the insolubility, at neutral pH, of most natural aluminium compounds and the protective barrier of the gut wall for the uptake from food of potentially toxic metal ions. Nevertheless, some aluminium crosses these barriers and enters the body. While these levels are likely to be small for most environmental aluminium compounds, such as aluminosilicate, they could be considerably greater for some manufactured compounds, which may be of high solubility–leading to increased uptake. This may be relevant in toy manufacturer. Metal ions enter the body via the gut wall, by inhalation and through wounds. All of these may be important for aluminium. Probably the most important route is via the gut wall, even so, by far the greatest fraction of ingested aluminium passes through the intestinal tract without being absorbed (Priest 2004)

A3.20 By comparison with the bioavailability of other trivalent metal ions, it may be predicted that only about 1.0×10^{-4} (or less) of the insoluble species (such as aluminium oxides and aluminosilicates), depending upon their physicochemical properties, will be absorbed. For the more soluble species, studies on other polyvalent metals would suggest that, fractional intakes will be higher (OECD, 1988). Studies of aluminium absorption by man consistently show enhanced aluminium uptake when the metal is present in the gut in association with citrate (or reduced pH)–although the relationship may be complex (Glynn et al 2001).

A3.21 Estimates of aluminium in the total diet (excluding aluminium from drinking water) have been made for the Food and Drugs Administration in the United States, by Pennington, (Pennington and Schoen, 1995; Pennington & Jones, 1989) and for the Ministry of Agriculture Fisheries and Food in the UK, by Sherlock(1989). These suggest daily aluminium intakes of between 0.7 and 14 mg–depending upon age and sex. In Finnish, Japanese, Swiss and UK studies,(WHO, 1997) daily intake of aluminium from food was calculated to be 6.7, 4.5, 4.4 and 3.9 mg, respectively. In general, it is likely that daily intakes of aluminium in North America are higher than in Europe. As for measurements of the aluminium content of individual foods, the measurement of total daily diets is complicated by the problems of analysis and of sample contamination. However, the WHO data are generally regarded as reliable. Aluminium concentrations are also higher in manufactured infant milk formulas than in human breast milk–although concentrations are very variable and product specific–suggesting a possible cause for concern, (Fernandez-Lorenzo, 2000)

A3.22 Bioavailability following intakes by other routes. Aluminium salts present in aerosol antiperspirant and "roll on" gel antiperspirant preparations–typically aluminium chlorohydrate–may enter the body either by trans-dermal absorption or from skin wounds

caused by the removal of pubic and axillary hair. A study using 26Al-labelled aluminium chlorohydrate undertaken using two volunteers at the Perdue University (Flarend et al, 2001) showed the uptake of 0.012% of the tracer applied. It is also known that the spraying of under-arm antiperspirants onto abraded skin produced during the process of razing axillary hair results in the intake of some aluminium: Freemont and his colleagues have described granulomas as resulting from this practice.(Williams & Freemont, 1984) .

A3.23 The literature demonstrates that the biokinetics and bioavailability of aluminium and its compounds are typical of those for other trivalent metals. Such metals are of low solubility, form insoluble hydroxides at neutral pH, have a low bioavailability and are retained by the skeleton. In the case of aluminium, studies with the isotope 26-Al, have shown that about 2% of aluminium entering the blood is retained within the body for years, but that the remainder is excreted–the vast majority in urine. Within blood, most aluminium is bound to the iron transport protein transferrin–but the strength of binding is low and the metal is readily removed from blood in the kidneys. As a consequence of the retention of some aluminium it is predicted that aluminium body-burdens will increase as a function of time. Incremental increases in body aluminium will be largest for aluminium workers–inhaling soluble aluminium fumes–and in patients given large oral doses of aluminium-containing antacids and phosphate binders (Priest 1984).

Health effects

A3.24 The embryo/foetal toxicity of aluminium administration, the potential reproductive toxicology of aluminium exposure, and the neuro-developmental effects of aluminium were reviewed by Domingo in 1995. At that time aluminium was known as a developmental toxicant when administered parenterally. (A parenteral route of administration is one where the desired effect is systemic, and the substance is administered by other routes than the digestive tract).

A3.25 Until recently, there was little concern about embryo/foetal consequences of aluminium ingestion because bioavailability was considered low. Now the importance of the route of exposure and the chemical form of the aluminium compound on developmental toxicity are well established. Although no evidence of maternal and embryo/foetal toxicity was observed when high doses of aluminium hydroxide were given orally to pregnant rats and mice during the formation of organs in early gestation, signs of maternal and developmental toxicity were found in mice when aluminium hydroxide was given at the same time as citric or lactic acids, that is, in an acidic environment (with a pH less than 7). Studies in rabbits have, on the other hand, shown that behavioural toxicity due to aluminium is greater in adult and aged animals than in young adults. However, maternal dietary exposure to excess aluminium during gestation and lactation that did not produce maternal toxicity would nevertheless be capable of causing permanent neurobehavioral deficits in weaning mice and rats. In the human this might be important for the developing infant. Adverse effects of parenteral aluminium administration on the mouse male reproductive system have also been reported.

Antimony

A3.26 Antimony is a metal found in natural deposits as ores containing other substances. The most widely used antimony compound is antimony trioxide, used as a flame retardant. It is also found in batteries, pigments, and ceramics/glass.

A3.27 The Maximum Contaminant Level Goals (MCLG) for antimony has been set at 6 parts per billion (ppb) because the US EPA believes this level of protection would not cause any of the potential health problems (described below).

A3.28 Based on this MCLG, the US EPA has set an enforceable standard called a Maximum Contaminant Level (MCL). MCLs are set as close to the MCLGs as possible, considering the ability of public water systems to detect and remove contaminants using suitable treatment technologies. The MCL for antimony has also been set at 6 ppb because EPA believes, given present technology and resources, this is the lowest level to which water systems can reasonably be required to remove this contaminant should it occur in drinking water.

Health effects

A3.29 *Short-term exposure*: Antimony has the potential to cause nausea, vomiting and diarrhoea at levels above the MCL for relatively short periods of time.

A3.30 *Long-term:* A lifetime exposure to antimony at levels above the MCL indicate that this substance may be a potential human carcinogen. No reliable data are available concerning health effects from long-term exposure to antimony in drinking water.

Genotoxicity

A3.31 Trivalent and pentavalent antimony compounds have generally been negative for genotoxicity in non-mammalian species. However mammalian genotoxicity test systems have usually shown positive results for trivalent antimony [Sb(III)] and negative results for pentavalent antimony [Sb(V)] compounds. Assessment of the in vivo potential of antimony trioxide (Sb2O3) to induce chromosome aberrations has given conflicting results. IARC concluded that Sb2O3 was carcinogenic from animal data. Human carcinogenicity data is difficult to evaluate given that antimony exposure usually occurs with arsenic exposure. The possible mechanisms of action including the potential to produce active oxygen species (ROS) and to interfere with DNA repair systems still need further investigation. (De Boeck et al 2003). Antimony has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

Arsenic

Health effects

A3.32 The most common effects of arsenic ingestion are gastrointestinal irritation, peripheral neuropathy, vascular lesions, anaemia, skin diseases, including skin cancer and other cancers of the internal organs like bladder, kidney, liver or lung. Relatively little information is available on the effects of direct dermal contact with inorganic arsenicals, but several studies indicate local irritation and dermatitis as the major ones. (Szymanska-Chabowska et al, 2002)

A3.33 The health effects of human exposure to arsenic have been re-evaluated by international government agencies leading to reduced levels of arsenic permitted in drinking water. Canada decreased maximum allowable levels from 50 to 25 microg/L and the U.S. from 50 to 10 microg/L. Canada is currently contemplating a further decrease to 5 microg/L. These changes result from studies that have shown deleterious effects at lower concentrations than previously thought. Factors combining to increase/decrease the ill effects of arsenic (As) include age, duration and magnitude of exposure, source of exposure, nutritional and general health status.

A3.34 Chronic ingestion of As and human health effects include an accumulation of As in tissues such as skin, hair and nails, resulting in various clinical symptoms such as hyperpigmentation and keratosis. Research shows that hyper-pigmentation in adults and childrenis associated with chronic ingestion of water containing high arsenic concentrations (National Academy of Sciences, 1999; Rahman et al., 2001). Arsenic related skin lesions were also reported to be associated with malnutrition. Cardiovascular disease and neuropathy have also been linked to As consumption. Verbal IQ and long-term memory can also be affected. As can suppress hormone regulation and hormone mediated gene transcription.

Reproductive effects

A3.35 Limited epidemiological evidence also exists for associations between maternal exposure to arsenic in drinking water at concentrations above 100 µg/L and early or late foetal deaths (Ahmad et al., 2001; Hopenhayn-Rich et al., 2000). Increases in fetal loss and premature delivery and decreased birth weights of infants, have been shown to occur at low (<10 microg/L) exposure levels (Kapai et al, 2006).

A3.36 Biological plausibility for associations of arsenic with ill health is supported by studies on experimental animals which show arsenic exposure resulting in foetal death and birth defects in four species (Golub et al., 1998). Arsenic has now been recognised as a reproductive toxicant in humans with potential to induce malformations, especially neural tube defects, (Wang et al, 2006).

A3.37 There is limited evidence for an association between childhood chromosomal abnormalities and single- and double- stranded DNA breaks and maternal/childhood residence in regions with elevated airborne or drinking water arsenic concentrations

(Yanez et al., 2003). Populations chronically exposed to drinking water containing high arsenic levels in Taiwan (350–1140 µg/L) showed greater risks of skin, liver, lung, kidney and bladder cancers. New water sources with low-arsenic levels were introduced in 1966–1967 followed by a decrease in the cancer death rate ratio (the ratio of local cancer death rates to national rates) among males and females less than 40 years, with a lag of about 15 years (Tsai et al., 1998).

Barium

A3.38 The database on the toxicity of inhaled barium compounds in humans consists primarily of studies of occupational exposure. Baritosis is considered a benign pneumoconiosis resulting from the inhalation of barite ore or barium sulphate.

Evidence for Human Carcinogenicity

A3.39 Under EPA's 1986 Guidelines for Carcinogen Risk Assessment, barium would be classified as Group D, not classifiable as to human carcinogenicity. Although adequate chronic oral exposure studies in rats and mice have not demonstrated carcinogenic effects, the lack of adequate inhalation studies precludes assessing the carcinogenic potential of inhaled barium. Under the Proposed Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1996), barium is considered not likely to be carcinogenic to humans following oral exposure and its carcinogenic potential cannot be determined following inhalation exposure.

Evidence for Noncarcinogenic Effects

A3.40 The kidney appears to be the most sensitive target of toxicity resulting from repeated ingestion of soluble barium salts. Chronic and sub-chronic rodent studies conducted by NTP (1994) and McCauley et al. (1985) provide evidence for an association between barium exposure and renal toxicity. However, chronic and subchronic rodent studies conducted by Tardiff et al., (1980) and Schroeder and Mitchener (1975a, b) were unable to detect adverse effects, including renal toxicity, following exposure to barium. Unfortunately, no human studies have investigated the effects of barium exposure on the kidneys. Nevertheless the NTP (1994) 2-year drinking water study in B6C3F1 mice was selected as the principal study and chemical-related nephropathy was identified as the critical effect for deriving a Reference Dose (RfD) for barium and its soluble salts. The primary reason for selecting this study and critical effect was that the nephropathy data provide the best evidence of a dose-response relationship.

A3.41 There is conflicting evidence whether or not barium exposure may induce hypertensive effects. There is some evidence that reduced dietary calcium is a risk factor for hypertension in humans (McCarron et al., 1984). Acute hypertension has been observed in humans following accidental or intentional ingestion of soluble barium salts (CDC, 2003; Downs et al., 1995). Two human studies have investigated the effects of longer-term barium ingestion on blood pressure (Brenniman et al., 1981; Wones et al.,1990). Coincidently, the same NOAEL of 0.21 mg/kg-day was identified for both studies. These

NOAELs were estimated by EPA using standard estimates for drinking water intake (2 L/day) and average body weight (70 kg). Neither Brenniman et al. (1981) nor Wones et al. (1990) provided sufficient data to support, or refute, the hypothesis that chronic barium exposure causes hypertension.

Additional Studies/Comments (Oral RfD)

A3.42 The uptake of barium in bone tissue was evaluated in F344/N rats sacrificed at the 15-month interim of the NTP (1994) 2-year drinking water study. Barium concentrations in upper, middle, and lower sections of the femur were increased by approximately three-orders of magnitude in the high dose groups. The biological implications of increased barium deposition in the bone tissue is unclear. It is possible that barium may interfere with the physiological processes of bone tissue including white blood cell production. A significant reduction in mononuclear cell leukemia was observed in treated male rats (NTP, 1994). Additional research is needed to fully investigate potential osteogenic effects of elevated barium exposure. Based on this limited data set it is not clear if barium is associated with reproductive toxicity.

Boron

Evidence for Noncarcinogenic Effects

A3.43 Developmental (decreased foetal weights) effects are considered to be the critical effect. The basis for calculating the RfD is the $BMDL_{05}$ of 10.3 mg boron/kg-day calculated from the developmental effects reported by Heindel et al. (1992) and Price et al. (1996a).

A3.44 Treatment with 0.8 per cent boric acid (gd 6-15) significantly increased prenatal mortality; this was due to increases in the percentage of resorptions per litter and percentage of late foetal deaths per litter. The number of live foetuses per litter was also significantly decreased at 0.8 per cent. Average foetal body weight (all foetuses or male or female foetuses) per litter was significantly reduced in all treated groups versus controls in a dose-related manner. The percentage of malformed foetuses per litter and the percentage of litters with at least one malformed foetus were significantly increased. Treatment with 0.2 per cent or more boric acid also increased the incidence of litters with one or more foetuses with a skeletal malformation. The incidence of litters with one or more pups with a visceral or gross malformation was increased at 0.4 and 0.8 per cent, respectively. The malformations consisted primarily of anomalies of the eyes, the central nervous system, the cardiovascular system, and the axial skeleton. In the 0.4 and 0.8 per cent groups, the most common malformations were enlarged lateral ventricles of the brain and agenesis or shortening of rib XIII. The percentage of foetuses with variations per litter was reduced relative to controls. Based on the changes in organ weights, a maternal lowest-observed-adverse-effect level (LOAEL) of 0.2 per cent boric acid in the feed (28.5 mg B/kg-day) can be established; the maternal no-observed-adverse-effect level (NOAEL) is 0.1 per cent or 13.6 mg B/kg-day. Based on the decrease in fetal body weight per litter, the level of 0.1 per cent boric acid in the feed (13.6 mg B/kg-day) is a LOAEL; a NOAEL was not defined.

A3.45 The NOAEL and LOAEL for phase II of the Price study were 12.9 and 25.3 mg B/kg-day, respectively.

A3.46 The Institute for Evaluating Health Risks (IEHR, 1997) concluded that there was a consistent correlation between boric acid exposure and the different effects on rib and vertebral development in rats, mice, and rabbits.

A3.47 The $BMDL_{05}$ based on the combined results of the two studies was 10.3 mg B/kg-day, which was very close to the NOAEL of 9.6 mg B/kg-day from the Price et al. (1996a, 1994) study.

A3.48 In addition to the rat studies, the developmental effects of boric acid were also studied in mice and rabbits. Heindel et al. (1994, 1992) and Field et al. (1989) identified a NOAEL and LOAEL of 43.3 and 79 mg B/kg-day, respectively, for decreased fetal body weight in mice exposed to boric acid in the feed. Increased resorptions and malformations, especially short rib XIII, were noted at higher doses. Price et al. (1996b, 1991) and Heindel et al. (1994) identified a NOAEL and LOAEL of 21.9 and 43.7 mg B/kg-day for developmental effects in rabbits. Frank effects were found at the LOAEL, including high prenatal mortality and increased incidence of malformations, especially cardiovascular defects.

Cadmium

A3.49 Cadmium occurs naturally in ores with zinc, lead and copper. The heaviest exposure to cadmium is from dust or fumes in work with cadmium nickel batteries and in the brazing of alloys with copper, silver and tin to increase their hardness. Cadmium in the substanceal form is used as an anticorrosion agent (cadmiation) and can be present in phosphate fertilizers as a pollutant. Cadmium salts are also used as stabilisers in plastics and as pigments and colouring agents for plastics, ceramics and glass. Thus cadmium exposure can occur after inhalation during heating, soldering, welding or burning of cadmium coated metal or other surface.

A3.50 Cadmium toxicity was disclosed as early as 1955 in Japan as Itai–itai disease. For the first time, cadmium pollution was shown to have severe consequences on human health. Cadmium poisoning within an occupational setting is a notifiable industrial disease.

A3.51 It is well known that many toxic effects of cadmium action result from interactions with essential substances, including zinc. Interactions with essential substances such as zinc can take place at different stages of absorption, distribution in the organism and excretion of both metals and at the stage of the biological functions involving zinc. Exposure to Cd leads to disturbance in Zn in the organism; dietary Zn intake also has an important effect on Cd absorption, accumulation and toxicity. Zn status in the body is important in relation to development of Cd toxicity. Thus the immuno-compromised or the immature organism (e.g. the neonate) may be particularly susceptible to Cd exposure (Brzoska et al 2001).

A3.52 A study by Hossn et al (2001) reported that in neonates, serum Cd was higher in babies with weights and heights below the 5th percentile for age. Breast-fed infants had a serum

Cd level (1.25 microg/l) that did not accord to their mothers' milk (0.52 microg/l, P < 0.001), suggesting alternative routes of exposure. Environmental tobacco-smoke exposure is known to be the most important determinant of Cd status in the school-aged children.

A3.53 Safe daily levels of Cd intake should be kept below 30 µg per person. Individual variations in Cd absorption and sensitivity to toxicity predicts that a dietary Cd intake of 30 µg /d may result in a slight kidney dysfunction in about 1 per cent of the adult population. The previous guideline for a maximum recommended Cd intake of 1µg/kg body weight per day is therefore seen to be too high to ensure that renal dysfunction does not occur as a result of dietary Cd intake.

A3.54 Results of a study of workers and other persons environmentally or occupationally exposed to low concentrations of cadmium showed renal tubular damage due to exposure to cadmium develops at lower levels of cadmium body burden than previously thought, (Jarup et al ,2000). WHO (1992) estimated that a urinary excretion of 10 nmol/mmol creatinine (corresponding to *circa* 200 mg Cd/kg kidney cortex) would represent a 'critical limit' below which kidney damage would not occur. However, WHO calculated that *circa* 10% of individuals with this kidney concentration would be affected by tubular damage. Other reports have shown kidney damage and/or bone effects may occur at lower kidney cadmium levels. European studies indicate signs of cadmium induced kidney damage in the general population at urinary cadmium levels around 2–3 µg Cd/g creatinine (Buchet et al, 1990; Jarup et al 2000).

A3.55 Schoeters and colleagues (2006) have reviewed cadmium exposure and effects on children. The abstract of their review is the following:

> Cadmium accumulation in the body starts at a young age. Exposure routes in children are similar to those in adults, that is mainly via food, environmental tobacco smoke and house dust. Excretion from the body is limited. Cadmium accumulation in the kidney is responsible for effects such as nephrotoxicity and osteoporosis which are observed at adult age. Cadmium exposure through inhalation is also associated with lung cancer in adulthood. Although transfer to the neonate through the placenta and through breast milk is limited, teratogenic and developmental effects were observed in experimental animals. The database on human studies involving children is limited, yet effects on motoric and perceptual behaviour in children have been associated with elevated in utero cadmium exposure. In school age children urinary cadmium levels were associated with immune suppressive effects. More studies are needed to confirm these results. Experimental data in vitro and in animals refer to effects of cadmium on the hypothalamus-pituitary axis at different levels. This may lead to disorders of the endocrine and/or immune system. Cadmium exposure at early age should be limited as much as possible to prevent direct effects on children and to prevent accumulation of cadmium which may have serious health effects only becoming manifest at older age.

Evidence for Human Carcinogenicity

A3.56 Cadmium is a human carcinogen of worldwide concern because it accumulates in the environment due to its extremely long half-life. Cadmium compounds are classified as

human carcinogens by several regulatory agencies. IARC classified cadmium as a human carcinogen (group I) in 1993 on the basis of sufficient evidence in both humans and experimental animals. IARC, however, noted that the assessment was based on few studies of lung cancer in occupationally exposed populations, often with imperfect exposure data, and without the capability to consider possible confounding by smoking and other associated exposures (such as nickel and arsenic). Occupational cadmium exposure is associated with lung cancer in humans. Studies reported in the literature indicate that cadmium may play a role in both the initiation of cancer, by activating oncogenes, and in the progression of cancer, by increasing the metastatic potential of existing cancer cells. (Jarup et al 1998)

A3.57 Recently, it has been shown that Cd has potent estrogen- and androgen-like activities in vivo and in vitro, by directly binding to estrogen and androgen receptors. However, the precise mechanisms underlying the effects of Cd as an endocrine disruptor remain to be elucidated.

A3.58 Cadmium exposure has on occasion, been linked to human prostate cancer with laboratory data implicating cadmium as a prostate carcinogen. The epidemiological data linking cadmium and lung cancer are however much stronger than for prostate cancer. Epidemiological studies concerning the association between cadmium and prostate cancer are inconclusive. Sahmoun and colleagues (2005) reviewed published data from exposed occupational cohorts from 1966 to 2002 and from cohorts highly exposed to cadmium in nickel-cadmium battery plants. Of 4 descriptive studies, 3 reported a positive association between cadmium and prostate cancer. Of 10 case-control studies, 5 (50%) reported a positive association. Of 11 cohorts studies, 3 (33%) found a positive association. The standardized mortality ratios (SMRs) from four cohort studies of exposed occupational nickel-cadmium battery workers were weak but not statistically significantly positive: 126 (95% confidence interval C.I.: 83-184). In contrast to laboratory studies, epidemiological studies do not convincingly implicate cadmium as a cause of prostate cancer. Future epidemiological studies that attempt to resolve the discrepancy between laboratory and epidemiological studies of cadmium carcinogenesis may benefit from incorporating biological measures of cadmium exposure (Sahmoun et al 2005).

Chromium (VI)

A3.59 Chromium is one of the most common contact sensitizers in males in industrialised countries and is associated with occupational exposures to numerous materials and processes, including chrome plating baths, chrome colours and dyes, cement, tanning agents, wood preservatives, anticorrosive agents, welding fumes, lubricating oils and greases, cleaning materials, and textiles and furs (Burrows and Adams, 1990; Polak et al., 1973). Solubility and pH appear to be the primary determinants of the capacity of individual chromium compounds to elicit an allergic response (Fregert, 1981; Polak et al., 1973). The low solubility chromium (III) compounds are much less efficient contact allergens than chromium (VI) (Spruit and van Neer, 1966). Dermal exposure to chromium has been demonstrated to produce irritant and allergic contact dermatitis (Bruynzeel et al., 1988; Polak, 1983; Cronin, 1980; Hunter, 1974). Primary irritant dermatitis is related to

the direct cytotoxic properties of chromium, while allergic contact dermatitis is an inflammatory response mediated by the immune system. Allergic contact dermatitis is a cell-mediated immune response that occurs in a two-step process. In the first step (induction), chromium is absorbed into the skin and triggers an immune response (sensitization). Sensitized individuals will exhibit an allergic dermatitis response when exposed to chromium above a threshold level (Polak, 1983). Induction is generally considered to be irreversible. The RfD was updated in 1998. The RfD is similar to the previous value on IRIS but now incorporates a threefold uncertainty factor to account for the less-than-lifetime exposure in the principal study and a threefold modifying factor to account for uncertainties related to reports of gastrointestinal effects following drinking water exposures in a residential population in China. The overall confidence in this RfD assessment is low. Confidence in the database is low because the supporting studies are of equally low quality and the developmental toxicity endpoints are not well studied.

A3.60 Nasal mucosal irritation, atrophy, and perforation have been widely reported following occupational exposures to chromic acid mists and dissolved hexavalent chromium aerosols. However, there is uncertainty regarding the relevance of occupational exposures to chromic acid mists and dissolved hexavalent chromium aerosols to exposures to Cr(VI) dusts in the environment. Lower respiratory effects have been reported in laboratory animals following exposures to Cr(VI) dusts. However, these studies have not reported on nasal mucosal effects following the exposures. The uncertainties in the database have been addressed through the development of two RfCs; one based on nasal mucosal atrophy following occupational exposures to chromic acid mists and dissolved hexavalent chromium aerosols, and a second based on lower respiratory effects following inhalation of Cr(VI) particulates in rats.

Evidence for Carcinogenicty

A3.61 Animal studies include one lifetime oral study of hexavalent chromium that shows a statistically significant increase in stomach tumours compared to controls. In a limited-term cancer study in mice, co-exposure to hexavalent chromium in drinking water and ultraviolet light produced skin tumours. A study of cancers in humans exposed to hexavalent chromium in drinking water has revealed a statistically significant increase in stomach tumours. A meta-analysis of occupational studies also showed a statistically significant increase in stomach cancers. The increases in stomach tumours in both human and animal studies with toxicokinetic, genotoxic, and mechanistic data, suggest oral exposure to chromium to be a carcinogenic risk (Sedman et al, 2006).

Human Carcinogenicity

A3.62 Studies of chrome pigment workers in the United States have consistently demonstrated an association between occupational chromium exposure (predominantly to Cr [VI]) and lung cancer. Studies of workers in the chrome-plating industry have demonstrated a positive relationship between cancer and exposure to chromium compounds (Royle, 1975; Franchini et al., 1983; Sorahan et al., 1987).

A3.63 Sufficient evidence from epidemiological studies has enabled the International Agency for Research on Cancer (IARC, 1990) and the U.S. EPA (1998) to classify hexavalent chromium as a human carcinogen. In contrast to hexavalent chromium, trivalent chromium (see below) is considered an essential substance, essentially non-toxic, and not posing a significant carcinogenic risk (ATSDR, 2000).

A3.64 Hexavalent chromium is converted rapidly in acidic conditions to trivalent chromium (Proctor, 2002). Sedman et al (2006) review the mechanism for the carcinogenicity of hexavalent chromium including the evidence for the acidic stomach medium being adequate to convert all hexavalent chromium to trivalent chromium. They find that toxicokinetic, genotoxicity, and general toxicity studies as well as the available epidemiological and animal cancer bioassay results are not consistent with the assertion that hexavalent chromium is completely converted to trivalent chromium in the animal or human stomach. This leads to the authors conclusion that exposure to hexavalent chromium in drinking water should be considered to pose an increased risk of cancer to humans. This conclusion should be incorporated into a risk assessment for oral exposure to hexavalent chromium.

Chromium III

A3.65 Trivalent chromium occurs naturally. It is an essential substance in humans. It is essential to normal glucose, protein, and fat metabolism and is thus an essential dietary substance. Chromium III is much less toxic than chromium (VI). The respiratory tract is the major target organ for chromium (III) toxicity, similar to chromium (VI). The body can detoxify some amount of chromium (VI) to chromium (III).

A3.66 The general population is exposed to chromium (generally chromium [III]) by eating food, drinking water, and inhaling air that contains the chemical. The average daily intake from air, water, and food is estimated to be less than 0.2 to 0.4 micrograms (µg), 2.0 µg, and 60 µg, respectively.

A3.67 Dermal exposure to chromium may occur during the use of consumer products that contain chromium, such as wood treated with copper dichromate or leather tanned with chromic sulphate.

A3.68 Occupational exposure to chromium occurs from chromate production, stainless-steel production, chrome plating, and working in tanning industries; occupational exposure can be two orders of magnitude higher than exposure to the general population.

A3.69 People who live in the vicinity of chromium waste disposal sites or chromium manufacturing and processing plants have a greater probability of elevated chromium exposure than the general population. These exposures are generally to mixed chromium (VI) and chromium (III).

A3.70 Although data from animal studies have identified the respiratory tract as the major target organ for chronic chromium exposure, these data do not demonstrate that the effects

observed following inhalation of chromium (VI) particulates are relevant to inhalation of chromium (III).

A3.71 The oral RfD for chromium (III) is 1.5 mg/kg/d based on the exposure level at which no effects were observed in rats exposed to chromium (III) in the diet. However the EPA has low confidence in the RfD based on the low confidence in the study on which the RfD for chromium (III) was based due to the lack of explicit detail on study protocol and results; and the low confidence in the database due to the lack of high-dose supporting data.

A3.72 No information is available on the reproductive or developmental effects of chromium (III) in humans. However, a study of mice fed high levels of chromium (III) in their drinking water has suggested a potential for reproductive effects, although various study characteristics preclude a definitive finding.

Cobalt

A3.73 Since the last IARC assessment in 1991, studies have been published on the genotoxicity, experimental carcinogenesis, and epidemiology of cobalt. Two different mechanisms of genotoxicity have been presented both of which may contribute to the carcinogenic potential of cobalt compounds. These are DNA breakage induced by cobalt metal particularly hard metal particles and inhibition of DNA repair by cobalt (II) ions. There is evidence that soluble cobalt (II) cations exert a genotoxic and carcinogenic activity in experimental systems but evidence in humans is lacking. While experimental data suggest evidence of a genotoxic potential for cobalt metal in vitro in human lymphocytes there is no available evidence of a carcinogenic potential. There is evidence that hard metal particles exert a genotoxic and carcinogenic activity in vitro and in human studies, respectively. However there is insufficient information for carcinogenicity associated with cobalt oxides and other compounds. There are many areas of uncertainty but these results may be important with respect to hard metal toy products that might contain cobalt (Lison et al 2001).

A3.74 Co(II) ions are genotoxic in vitro and in vivo, and carcinogenic in rodents. Co metal is genotoxic in vitro. Hard metal dust, of which occupational exposure is linked to an increased lung cancer risk, is proven to be genotoxic in vitro and in vivo. The mechanisms may be the production of active oxygen species and/or DNA repair inhibition. Given the recently provided proof for in vitro and in vivo genotoxic potential of hard metal dust, the mechanistic evidence of elevated production of active oxygen species and the epidemiological data on increased cancer risk, it may be advisable to consider the possibility of a new evaluation by IARC. (De Boeck et al 2003)

Copper

A3.75 Copper (Cu) is an essential substance for biological organisms, as a component of many Enzyme systems and proteins. Recommended daily allowances for human adults in the UK and USA range from 0.9 to 1.2 mg/day (SCF 2003). Based on the estimate for adults

of 0.03 mg/kg bw/day as given by RIVM (2001), children's normal exposure is estimated at 0.06 mg/kg bw/day (twice the adult value, as suggested by US data).

Health effects

Acute

A3.76 There are a number of case reports of acute Cu poisoning/toxicity. These case reports are instances when the acute toxicity is due to the ingestion of beverages (including water) that have been contaminated with Cu, or from the accidental or deliberate ingestion of high quantities of Cu salts. The largest literature base on acute Cu toxicity is comprised of case reports on single oral exposures to high levels of Cu. In many cases these exposures represent suicide attempts, and the dose often exceeds 20 g. A progression of symptoms have been reported in these subjects that includes abdominal pain, nausea, vomiting, headache, lethargy, diarrhoea, tachycardia, respiratory difficulties, haemolytic anaemia, gastrointestinal bleeding, liver and kidney failure and death (Davanzo et al., 2004, Srivastava et al., 2005 and World Health Organization, 1998). The mechanisms underlying the acute toxicity effects of Cu in humans are not well elucidated, but they probably represent oxidative stress at multiple points in the body, with marked variability in several components of the endocrine system (Gaetke and Chow, 2003, Handy, 2003 and Yang et al., 2004). It should be noted that Cu toxicity can also occur through the skin (Hostynek and Maibach, 2003 and World Health Organization, 1998)

Chronic effects

A3.77 Copper toxicity is not usually viewed as a significant human public health concern. Chronic effects are most pronounced on liver function and acute effects of copper toxicity are seen mainly in the gastrointestinal tract as an intestinal irritation effect. Acute copper toxicity in drinking water appears to have a threshold of approximately 6 mg/litre. Several human studies indicated absence of adverse liver effects after prolonged intake of 7 to 10 mg/day. A 12-week supplementation study by Pratt et al. (1985) was selected to calculate an overall NOAEL of 10 mg/day for liver effects. Mendez et al. (2004) investigated a copper supplement in an adult population representing a 3–10-fold increase of the typical dietary Cu intake. Although there were transitory increases in select liver transaminases, these were not considered to be clinically significant (Mendez 2004).

A3.78 Turnlund and colleagues (Turnlund et al, 1997) also carried out a metabolic research unit study. The studies by Mendez and Turnlund suggest that chronic dietary Cu intake of less than 10 mg Cu/day do not pose a significant health risk for normal healthy individuals. This finding agrees with the upper limit set for Cu by the Institute of Medicine (Institute of Medicine, 2002a). However, additional studies that use more sensitive markers for oxidative stress would be of value.

A3.79 Some investigators have suggested that the chronic consumption of drinking water with elevated Cu concentrations may represent a potential health risk for susceptible

populations including infants, young children, and individuals who are hetrozygotic for Wilson's disease (Brewer, 2000 and Eife et al., 1999). The above issue was recognized by the US National Research Council in its report on "Copper in Drinking Water" (US National Research Council, 2000) as an important question that needs to be addressed in the immediate future. With the above noted, it is important to recognize that to date there are no conclusive data linking the chronic consumption of water high in Cu with the occurrence of liver disease. This may be relevant for copper in toy products (Uriu-Adams & Keen (2005).

A3.80 Available data are limited for other toxicity endpoints. Poor quality studies of copper compounds in rats and mice suggest absence of carcinogenic activity. Genotoxicity data are inconclusive. In developmental and reproduction studies testicular degeneration and reduced neonatal body and organ weights were seen in rats at dose levels in excess of 30 mg Cu/kg body weight per day over extended time periods, and fetotoxic effects and malformations were seen at high dose levels (>80 mg Cu/kg body weight per day) (IPCS 1998, SCF 2003).

A3.81 The Upper Limit of 5 mg/day corresponding with 0.083 mg/kg bw/day, as derived by SCF (2003), is chosen as the most appropriate value.

Dermal effects

A3.82 Adverse direct dermal effects cannot be assessed due to lack of data. However, copper is used widely in various applications (water transport, electricity wires) without this leading to frequent reports of adverse skin effects, the potential to induce and therefore these effects probably is very low.

Lead

A3.83 Current knowledge of lead pharmacokinetics indicates that risk values derived by standard procedures would not truly indicate the potential risk, because of the difficulty in accounting for under-lying body burdens of lead. Lead bioaccumulates in the body, primarily in the skeleton. Lead body burdens vary significantly with age, health status, nutritional state, maternal body burden during gestation and lactation, etc. For this reason, and because of the continued apparent lack of threshold it is still inappropriate to develop reference values for lead.

A3.84 Predictive blood lead models generally distinguish between the intake of lead during exposure and the uptake of lead by the body. The fraction of lead that is absorbed and enters the blood by whatever route of entry compared with the total amount of lead acquired is termed the bioavailability. In the simple illustration of a PBK model (Figure 1), lead intake is represented as ingestion. Subsequently, a fraction of the lead present in the gastrointestinal tract is taken up into the bloodstream—a process that may vary with the age of the individual; the person's health, physiological, and/ or nutritional status; and whether ingestion occurred with or without food. Bioavailability of inhaled lead may differ from that of ingested lead. By either route of entry, biokinetic or pharmacokinetic models

incorporate a variable for the fraction of total lead that is actually absorbed and define it as the uptake of lead. In the 1999 EPA Guidance Document *IEUBK Model Bioavailability Variable* (EPA 1999), the following terms are defined and adopted:

A3.85 Exposure to high levels of inorganic lead during early childhood (with blood lead levels > 80 µg/dl) results in clinical neurotoxicity, abdominal colic, anaemia, and damage to the renal tubules of the kidney (see

A3.86). Severe neurotoxicity of young children from exposure to dust from lead-based paint was known in the 1890s. It was in 1979 that the first good evidence of cognitive deficits for low levels of exposure to lead was reported (Needleman et al., 1979). Most recently epidemiological studies have found neuropsychological deficits and other adverse health outcomes at prenatal maternal or childhood blood lead levels below 10 µg/dl, the current action level of the Centres for Disease Control and Prevention and the European action level.

A3.87 A case report in 2004 of a four year-old, previously healthy boy who experienced intermittent abdominal pain for several weeks found normocytic anaemia. An abdominal radiograph showed a metallic foreign body in the stomach. Endoscopy resulted in the retrieval of a quarter and a medallion pendant from the stomach. A venous blood lead level measurement was extremely elevated, at 123 microg/dL. The level of concern for lead is greater than or equal to10 microg/dL. The state environmental quality laboratory tested the medallion and was found to contain 38.8% lead (388,000 mg/kg), 3.6% antimony, and 0.5% tin. Similar medallions purchased from toy vending machines were analyzed and were found to contain similarly high levels of lead. State health officials notified the US Consumer Product Safety Commission, which resulted in a national voluntary recall of more than1.4 million metal toy necklaces. This case report illustrates the presence of lead hazards in objects routinely intended for use by children (see lead, below) but it also shows that lead may be found in objects with the substances of antimony and tin.

Pregnancy

A3.88 Low blood lead concentrations (Hertz-Picciotto, 2000),.with levels as low as 5–9 µg/dl measured in the first three months of pregnancy, have been associated with early death of the foetus (Borja-Aburto et al,1999). Preterm birth has also been associated with relatively low maternal prenatal blood lead levels (McMichael et al., 1986; Torres-Sanchez et al., 1999; Agency for Toxic Substances and Disease Registry, 2005). (see A3.89).

Neuropsychological function

A3.89 In 1892 the first overt childhood lead poisoning was reported (Gibson 1892), but clear evidence of sub-clinical neuro-toxicity at background lead exposure levels came to light nearly a century later. Middle-class children in Boston showed lead concentrations (greater than 24 versus less than 6 µg/g) in tooth dentine associated with deficits in IQ,

attention and auditory processing, and classroom problem behaviours (Needleman et al., 1979).

A3.90 Recent epidemiological reviews present strong evidence for cognitive deficits among school-age children at blood lead levels below 10 µg/dl (Bellinger, 2004; Koller et al., 2004; Lidsky & Schneider, 2003). Two longitudinal studies (research methodologies with the highest level of evidence) indicate children with blood lead concentrations not exceeding 10 µg/dl, (the current public health action level) have inverse dose-response relationships between cognitive function scores and blood lead concentration (Bellinger & Needleman 2003; Canfield et al., 2003). In a pooled analysis of seven prospective longitudinal studies, the average IQ deficit associated with an increase in concurrent blood lead concentration from <1 to 10 µg/dl was about three times that for an increase from 10 to 20 µg/dl (Lanphear et al., 2005). Birth cohort studies have also shown inverse dose response relationships between transplacental lead exposure and cognitive function scores among children below age 3 yr (Bellinger et al., 1988; Emory et al., 2003; Gomaa et al., 2002; Shen et al., 1998; Tang et al., 1999).

Other health outcomes (anthropometric measures, puberty, kidney damage, cancers)

A3.91 Three large, cross-sectional studies based on NHANES II and III found inverse dose-response relationships between height at ages 1–7 yr and 8–18 yr and current blood lead levels extending below 10 µg/dl with no evidence of a threshold, (Ballew et al., 1999; Schwartz et al., 1986; Selevan et al., 2003) (see below). There is some evidence for association between low-level lead exposure and delayed menarche in females (Selevan et al., 2003; Wu et al., 2003). Acute high-level lead exposure is known to result in renal tubular damage, dose-response relationships have also been found between childhood urinary protein levels and current or average lifetime blood lead levels, independent of potential confounders (Bernard et al., 1995; Fels et al., 1998; Staessen et al., 2001; Verberk et al., 1996; Factor-Litvak et al., 1999).

A3.92 Limited evidence supports associations between the childhood cancer neuroblastoma and self-reported paternal occupations likely to involve lead exposure (De Roos et al., 2001; Kerr et al., 2000). The potential role of lead exposure in childhood cancer remains almost unexplored (Wigle et al 2007). The US bio-monitoring program in the US (Centres for Disease Control and Prevention, 2001, 2003, 2005) has reported that the prevalence of blood lead concentrations at10 µg/dl among children age 1–5 yr decreased from 4.4 per cent in 1991–1994 to 1.6 per cent in 1999–2002. This may result from removal of lead from petrol.

Table A3.1: Associations between lead exposure and development outcomes

Health outcome	Type	Level of evidence	Blood lead (µg/dl)[a]	Reference
Adverse pregnancy outcomes	Early foetal death			
	Maternal exposure	L	5-9	Borja-Aburto et al., 1999
	Pre-ternal occupational exposure	L	>31[b]	Lindbohm et al., 1991
	Pre-term death			Torres-Sanchez et al., 1999
	Maternal occupational exposure	L	5-9[c] 14-32	McMichael et al., 1986
Neuropsychologic function	Acute encephalopathy			Agency for Toxic Substances and Disease Registry, 2005
	High-level childhood exposure	S	>80	
	Cognitive deficits, preschool-age children			Emory et al., 2003
				Canfield et al., 2003
	Transplacental exposure	L	<5[d]	
	Low-level childhood exposure	L	<10	
	Cognitive deficits, school-age children	S	<10	Agency for Toxic Substances and Disease Registry, 2005
	Low-level childhood exposure		<5	Schnaas et al., 2006
	Fine motor deficits, school-age children	L	<10	Chiodo et al., 2004
	Low-level childhood exposure			
	Visual-motor integration deficits			Chiodo et al., 2004
	Low-level childhood exposure	L	<10	
	Increased auditory threshold			Agency for Toxic Substances and Disease Registry, 2005
	Low-level childhood exposure	S	<10	
	Central auditory threshold			Rothenberg et al., 1994, 2000
	Maternal exposure	L	6-8	Zou et al., 2003
	Low-level childhood exposure	L	<10	

Health outcome	Type	Level of evidence	Blood lead (µg/dl)[a]	Reference
	Peripheral motor nerve condition			Schwartz et al., 1988
	Velocity deficits			
	Moderate childhood exposure	L	20-30	
	Problem behaviours			Chiodo et al., 2004
	Low-level childhood exposure	L	<10	
	Reading and arithmetic score deficits			Lanphear et al., 2000
			<5	Wang et al., 2002
	Low-level childhood exposure	L	<10	
Other outcomes	Reduced growth in heights			Ballew et al., 1999
	Low-level childhood exposure	L	<10	Schwartz et al., 1986
	Delayed onset of menarche and pubic hair growth			Selevan et al., 2003
				Wu et al., 2003
	Low-level childhood exposure (females)	L	<10	
	Anaemia			Agency for Toxic Substances and Disease Registry, 2005
	Moderate childhood exposure		>20	
	Urinary protein exposure			Agency for Toxic Substances and Disease Registry, 2005
	Moderate or high level childhood exposure	S	>30	
				Bernard et al., 1995
	Low-level childhood exposure	L	<10	Verberk et al., 1996
			<20	Fels et al., 1998
			10-20	
	Immune system dysfunction			Sarasua et al., 2000
	Low-level childhood exposure	L	>15	
	Dental caries			Agency for Toxic Substances and Disease Registry, 2005
	Low-level childhood exposure	L	>10	

Source: Wigle D, Arbuckle V, Walker M, Wade M, Liu S, Krewski D.I Environmental Hazards: Evidence for effects on child health. Journal of Toxicology and Environmental Health, 2007 Part B, 10:3–39.)

Manganese

A3.93 Manganese is a ubiquitous substance that is essential for normal physiologic functioning in all animal species. Several disease states in humans have been associated with both deficiencies and excess intakes of manganese. Thus any quantitative risk assessment for manganese must take into account aspects of both the essentiality and the toxicity of manganese. There are many reports of toxicity to humans exposed to manganese by inhalation; much less is known, however, about oral intakes resulting in toxicity. Rodents do not provide a good experimental model for manganese toxicity, and only one limited study in primates by the oral route of exposure is available. The following assessment, therefore, focuses more on what is known to be a safe oral intake of manganese for the general human population. Some individuals may, in fact, consume a diet that contributes more than 10 mg Mn/day without any cause for concern.

A3.94 While the NRC determined an "estimated safe and adequate daily dietary intake" ESADDI for manganese of 2-5 mg/day, some nutritionists feel that this level may be too low. Evaluations of standard diets from the United States, England, and Holland reveal average daily intakes of 2.3-8.8 mg Mn/day. Depending on individual diets, however, a normal intake may be well over 10 mg Mn/day, especially from a vegetarian diet. While the actual intake is higher, the bioavailability of manganese from a vegetarian diet is lower, thereby decreasing the actual absorbed dose. From this information taken together, EPA concludes that an appropriate reference dose for manganese is 10 mg/day (0.14 mg/kg-day). In applying the reference dose for manganese to a risk assessment, it is important that the assessor consider the ubiquitous nature of manganese, specifically that most individuals will be consuming about 2-5 mg Mn/day in their diet. This is particularly important when one is using the reference dose to determine acceptable concentrations of manganese in water and soils.

Oral RfD

A3.95 A review of the biochemical and nutritional roles of manganese in human health, as well as a list of disease states related to manganese deficiency or excess, is provided by Wedler (1994). Because of the ubiquitous nature of manganese in foodstuffs, actual manganese deficiency has not been observed in the general population. As reviewed by Freeland-Graves and Llanes (1994), several disease states have been associated with low levels of serum manganese. These include epilepsy, exocrine pancreatic insufficiency, multiple sclerosis, cataracts, and osteoporosis. In addition, several inborn errors of metabolism have been associated with poor manganese status (e.g., phenylketonuria, maple syrup urine disease). While a correlation has been shown for low levels of serum manganese and these disease states, a causal relationship has not been demonstrated, and this remains an area in which additional research is needed.

A3.96 While manganese is clearly an essential substance, it has also been demonstrated to be the causative agent in a syndrome of neurological and psychiatric disorders that has been described in manganese miners. Donaldson (1987) provides a summary of this documented toxicity of manganese to humans, which has been primarily limited to

workers exposed by inhalation. In contrast to inhaled manganese, ingested manganese has rarely been associated with toxicity. A review of manganese toxicity in humans and experimental animals has been provided by Keen and Zidenberg-Cherr (1994).

A3.97 A report by Kawamura et al. (1941) is the only epidemiologic study describing toxicologic responses in humans consuming large amounts of manganese dissolved in drinking water. The most severe symptoms were observed in elderly people, while children appeared to be unaffected. A few case studies have also pointed to the potential for manganese poisoning by routes other than inhalation. One involved a 59-year-old male who was admitted to the hospital with symptoms of classical manganese poisoning, including dementia and a generalized extrapyramidal syndrome (Banta and Markesbery, 1977). The patient's serum, hair, urine, faeces and brain were found to have manganese "elevated beyond toxic levels," perhaps a result of his consumption of "large doses of vitamins and minerals for 4 to 5 years." Unfortunately, no quantitative data were reported. Another case study of manganese intoxication involved a 62-year-old male who had been receiving total parenteral nutrition. A third case study involved an 8-year old girl with Alagille's syndrome (an autosomal dominant disorder) and end-stage liver disease (Devenyi et al., 1994). The patient had a stable peripheral neuropathy and for 2 months manifested with episodic, dystonic posturing and cramping of her hands and arms. Although conclusive evidence is lacking, some investigators have also linked increased intakes of manganese with violent behaviour.

A3.98 The soil in some regions is very high in manganese (40,000-50,000 ppm) and the fruits and vegetables grown in the region also are reported to be high in manganese. Elevated concentrations of manganese have been determined in the blood and hair of the Aborigines (Stauber et al., 1987). In addition to the high levels of environmental manganese, other factors common to this population may further increase the propensity for manganism: high alcohol intake, anaemia, and a diet deficient in zinc and several vitamins (Florence and Stauber, 1989).

A3.99 Another issue of great importance to consider in the risk assessment for manganese concerns the bioavailability of different forms of manganese consumed under different exposure conditions. Various dietary factors as well as the form of manganese can have a significant bearing on the dose absorbed from the GI tract. Many constituents of a vegetarian diet (e.g., tannins, oxalates, phytates, fiber) have been found to inhibit manganese absorption presumably by forming insoluble complexes in the gut. In addition, high dietary levels of calcium or phosphorus have been reported to decrease manganese absorption. Individuals who are deficient in iron demonstrate an increase in manganese absorption. It is also recognised that manganese uptake and elimination are under homeostatic control, generally allowing for a wide range of dietary intakes considered to be safe. These factors and others are described in a review by Kies (1987). In addition to the influence of extrinsic variables, significant inter-individual differences in manganese absorption and retention have been reported. In humans administered a dose of radio-labelled manganese in an infant formula, the mean absorption was 5.9 +/- 4.8 per cent, but the range was 0.8-16 per cent, a 20-fold

difference (Davidsson et al., 1989). Retention at day 10 was 2.9 +/- 1.8 per cent, but the range was 0.6-9.2 per cent, again indicating substantial differences between individuals.

A3.100 Neonates may be at increased risk of toxicity resulting from exposure to manganese because of a higher level of uptake from the GI tract and a decreased ability to excrete absorbed manganese. The uptake and retention of manganese have been reviewed by Lonnerdal et al. (1987). In rats, manganese absorption decreased dramatically as the animals matured. While 24-hour retention values are as high as 80 per cent in 14-day-old pups, this value drops to about 30 per cent by day 18. Low levels of manganese absorption (about 3-4 per cent) have also been reported for mature humans, but few data are available for infants.

A3.101 No reports of actual manganese toxicity or deficiency have been reported for infants. As with adults, however, the potential for effects resulting from excess manganese or suboptimal manganese appears to exist (reviewed by Lonnerdal, 1994). In particular, suboptimal manganese may be a problem for preterm infants given calcium supplementation, which is known to inhibit the absorption of manganese. Because manganese is required for adequate bone mineralization, it is suggested that insufficient absorption of manganese in preterm infants may contribute to poor bone growth. On the other hand, excess manganese may be a problem for infants with low iron status, as this is known to increase the absorption of manganese.

A3.102 An additional concern for infants has been expressed because of the often high levels of manganese in infant formulas, particularly compared with breast milk than in adults (Mena, 1974).

Elemental Mercury

A3.103 In the general population dental amalgam and fish consumption are the major sources of mercury exposure (Becker et al., 2002; Sweet & Zelikoff 2001). Elemental mercury is metabolised in vivo to inorganic mercury and thus these forms of mercury have similar toxicities. Neurotoxic symptoms reported in children acutely exposed to high levels of elemental mercury include headache, dizziness, memory loss, insomnia, hallucinations, peripheral neuropathy, tremors, irritability and seizures (Counter & Buchanan 2004; Counter et al., 2002). There have been no adequately conducted epidemiological studies of potential child health effects from use of dental amalgam. Phenylmercuric acetate, a fungicide once used in interior latex paint, released elemental mercury into indoor air and produced two reported cases of clinically overt acrodynia (Centres for Disease Control and Prevention 1990). A review noted that exposure to high levels of inorganic mercury during infancy or childhood produced acrodynia and renal tubular damage (Clarkson, 1997). Children with the *CYT19* genotype may have increased susceptibility to arsenic toxicity. (Yamanaka et al., 2004).

A3.104 There is little evidence of an association of amalgam restorations with neurodegenerative diseases, altered renal function, adverse pregnancy outcomes, or autoimmune diseases. There is a lack of data on neurobiological and neurodevelopmental effects on children

who may be exposed to mercury from maternal amalgam restorations during gestation (Mitchell et al 2005).

Nickel

A3.105 Nickel is an essential nutrient for some mammalian species, and has been suggested to be essential for human nutrition. By extrapolation from animal data, it is estimated that a 70-kg person would have a daily requirement of 50 µg per kg diet of nickel.

Health Effects (Non-cancer)

Acute effects:

A3.106 Gastrointestinal distress (e.g., nausea, vomiting, and diarrhoea) and neurological effects have been reported in workers who drank water on one shift that was contaminated with nickel as nickel sulphate and nickel chloride. Pulmonary fibrosis and renal oedema were reported in humans and animals following acute (short-term) exposure to nickel carbonyl. Acute animal tests in rats have shown nickel compounds to exhibit acute toxicity values ranging from low to high. The soluble compounds, such as nickel acetate, were the most toxic, and the insoluble forms, such as nickel powder, were the least toxic.

Chronic effects

A3.107 Dermatitis is the most common effect in humans from chronic dermal exposure to nickel. Cases of nickel dermatitis have been reported following occupational and non-occupational exposure, with symptoms of eczema (rash, itching) of the fingers, hands, wrists, and forearms.

A3.108 Chronic inhalation exposure to nickel in humans also results in respiratory effects, including a type of asthma specific to nickel, decreased lung function, and bronchitis. Animal studies have reported effect on the lungs and immune system from inhalation exposure to soluble and insoluble nickel compounds (nickel oxide, subsulphide, sulphate heptahydrate). Soluble nickel compounds are more toxic to the respiratory tract than less soluble compounds.

A3.109 The Reference Dose (RfD) for nickel (soluble salts) is 0.02 milligrams per kilogram body weight per day (mg/kg/d) based on decreased body and organ weights in rats. (in glossary) The California Environmental Protection Agency (CalEPA, 1997) has calculated a chronic inhalation reference exposure level of 0.00005 milligrams per cubic meter (mg/m^3) for nickel based on respiratory and immune system effects reported in rats exposed to a soluble nickel salt. The CalEPA reference exposure level is a concentration at or below which adverse health effects are not likely to occur.

A3.110 ATSDR has calculated a chronic-duration inhalation MRL of 0.0002 mg/m^3 for nickel based on respiratory effects reported in rats exposed to a soluble nickel salt. The MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be

without appreciable risk of adverse non-cancer health effects over a specified duration of exposure.

Reproductive/Developmental Effects

A3.111 No information is available regarding the reproductive or developmental effects of nickel in humans.

A3.112 Animal studies have reported reproductive and developmental effects, such as a decreased number of live pups per litter, increased pup mortality, and reduction in foetal body weight, and effects to the dam from oral exposure to soluble salts of nickel.

A3.113 Sperm abnormalities and decreased sperm count have been reported in animals exposed to nickel nitrate orally and nickel oxide by inhalation, respectively.

Cancer Risk

A3.114 Nickel sulphate via inhalation and nickel acetate in drinking water were not carcinogenic in either rats or mice.

Selenium

A3.115 Selenium in the earth's crust is often found with minerals containing sulfur and is found in four different oxidation states (-2, 0, +4, +6), either as the substance or as selenites or selenates (inorganic salts). The combustion of coal is the main source of environmental selenium while the diet and water are main sources for human populations. Organic forms of selenium as the amino acids selenomethionine and selencysteine make up most of the dietary exposure from grains and cereals, more readily absorbed than the inorganic salts (ATSDR 2003).

A3.116 European study data (SCF 2000) for non-vegetarians indicate daily intake levels up to about 1 µg/kg bw/day. Results from a dietary intake study carried out in the USA indicate that children up to age 6 years have almost twice the intake of adults on a body weight basis (ATSDR 2003) i.e. 2 µg/kg bw/day. Worldwide levels of selenium in public tap water samples are usually much less than 10 µg/litre. However a high-selenium area in China has revealed selenium in drinking water between 50-160 µg/litre. Selenium in the air is mostly bound to particles and urban studies have shown ranges from 0.1 to 10 ng/m3. Higher levels may be found in certain areas such as near copper smelters (WHO 1996).

Health Effects

A3.117 Selenium is an essential substance in humans and animals and involved in enzyme systems. Daily requirements for adults range from 40 to about 50 µg/day with a lower limit of 20 µg/day. SCF (2000). Selenium compounds are readily absorbed from the human gastrointestinal tract. The physical state of the compound (solid or in solution) the chemical form of selenium (e.g., organic, inorganic), and the dosage are factors

influencing absorption. Generally absorption percentages of 80% and higher have been observed in human volunteers (ATSDR 2003).

Acute effects

A3.118 Oral exposure to very high levels of selenium (e.g., several thousand times greater than normal daily intake) results in nausea, vomiting, and diarrhea in humans and laboratory animals. In humans acute exposure has occasionally caused cardiovascular symptoms but no EEG abnormalities were found in a human population chronically exposed to selenium.

Chronic effects

A3.119 Between 1989 and 1994, studies of humans from certain areas in China with high levels of selenium, and chronic oral intake from food and water (10–20 times more than normal) have shown selenosis. Symptoms of this condition are skin (diseased nails) and neurological (unsteady gait) effects. The minimum daily dietary intake sufficient to cause symptoms of selenosis was about 1200 µg Se (range: 913-1907 µg Se). No clinical signs of selenosis were recorded in individuals with blood selenium below 1000 µg/l, corresponding to an intake of about 850 µg/day, which has been taken as a NOAEL for clinical selenosis. (SCF 2000).

Sensitisation

A3.120 Limited data suggest that selenium and compounds have only low potential for inducing irritation and sensitisation (ATSDR 2003).

Evidence for carcinogenicity

A3.121 IARC concluded there was inadequate evidence for classification. In fact evidence suggests that some forms of selunium exert an anti-tumour action in animals and humans. Selenium sulfide however appears an exception, producing increased tumor incidences after oral administration. The relevance of this compound for toy-related exposures seems limited. In genotoxicity tests selenium compounds have shown both genotoxic and anti-genotoxic effects. Generally the genotoxic effects were observed at high dosages and the anti-genotoxic at low dosages (RIVM 1998).

A3.122 Overall, the evidence currently available appears to support an inverse association between selenium exposure and prostate cancer risk, and possibly also a reduction in risk with respect to lung cancer, although additional prospective studies are needed. Most studies have reported no association between selenium and risk of breast, colorectal, and stomach cancer (Navarro and Rohan, 2007).

A3.123 There are limited human data that suggest children may be less sensitive for selenium toxicity than adults (ATSDR 2003).

A3.124 The US EPA used results from Yang et al. (1989) to establish a human NOAEL for selenosis. The LOAEL derived from this study was 1.26 mg Se/day and the NOAEL 0.85 mg/day (0.015 mg/kg bw/day). An uncertainty factor of 3 to account for sensitive individuals was applied, leading to an RfD of 5 µg/kg bw/day. RIVM (1998) concurred with the approach developed by US-EPA and a TDI of 5 µg/kg bw/day was proposed. ATSDR (2003), like US-EPA, concluded to an NOAEL from the Chinese studies of 0.015 mg/kg bw/day. With an uncertainty factor of 3 a chronic MRL of 0.005 mg/kg bw/day was proposed (ATSDR 2003).

A3.125 SCF (2000) also used an NOAEL of 0.85 mg/day as derived from the Chinese epidemiology studies. It was pointed out that other studies from the USA and Venezuela supported this NOAEL. Application of an uncertainty factor of 3 to allow for the remaining uncertainties of the studies used led to Tolerable Upper Intake Level (UL) of 300 µg/day. No specific UL for children was derived because of lack of appropriate data

Silver

A3.126 The critical effect in humans ingesting silver is argyria, a medically benign but permanent bluish-gray discoloration of the skin. Argyria results from the deposition of silver in the dermis and also from silver-induced production of melanin. Although silver has been shown to be uniformly deposited in exposed and unexposed areas, the increased pigmentation becomes more pronounced in areas exposed to sunlight due to photoactivated reduction of the metal. Although the deposition of silver is permanent, it is not associated with any adverse health effects. No pathologic changes or inflammatory reactions have been shown to result from silver deposition. Silver compounds have been employed for medical uses for centuries. In the nineteenth and early twentieth centuries, silver arsphenamine was used in the treatment of syphillis; more recently it has been used as an astringent in topical preparations. While argyria occurred more commonly before the development of antibiotics, it is now a rare occurrence.

A3.127 Humans are exposed to small amounts of silver from dietary sources. The oral intake of silver from a typical diet has been estimated to range from 27-88 ug/day (Hamilton and Minski, 1972/1973; Kehoe et al., 1940). Tipton et al. (1966) estimated a lesser intake of 10-20 ug/day in two subjects during a 30- day observation period. Over a lifetime, a small but measurable amount of silver is accumulated by individuals having no excessive exposure. Gaul and Staud (1935) estimated that a person aged 50 years would have an average retention of 0.23-0.48 g silver (equivalent to 1-2 g silver arsphenamine). Petering et al. (1991) estimated a much lower body burden of 9 mg over a 50- year period based on estimated intake, absorption, and excretion values; however, it is not clear how the final estimate was calculated.

A3.128 In addition to silver arsphenamine, any silver compound (silver nitrate, silver acetate, argyrol, Neosilvol and Collargol, etc.), at high dose, can cause argyria. Another important factor predisposing to the development of argyria is the exposure of the skin to light.

Human Carcinogenicity Data

A3.129 No evidence of cancer in humans has been reported despite frequent therapeutic use of the compound over the years.

Strontium

A3.130 The biological role of strontium has been reviewed most recently by Pors Nielson (2004). The oral toxicity was reviewed by RIVM in 2006 (Van Engelen et al ,2006). Strontium comprises 0.02–0.03% of the earth's crust and is widely available. in soil and drinking water with concentration between 0.001 and 39 mg/l. In the US the concentration of strontium in drinking water is <1 mg/l. A normal adult diet contains 2–4 mg per day, mostly from vegetables and cereals. Dutch data indicate a mean total daily intake of 1.3 mg/person (maximum 3.6 mg/person) (RIVM, 1998). The oral toxicity of strontium and its compounds was reviewed by ATSDR (2004) and summarized by RIVM in 2006. Specific data for children are lacking. Based on the above information background daily intake of strontium for a child is estimated to be 18 mg/kg bw/day. This is the maximum of the mean adult range as reported in RIVM (1998).

A3.131 Strontium is able to replace calcium in its physiological role and is taken up in bone. Abnormal skeletal development is the most important toxicological effect produced by strontium. Human toxicity data are lacking. Abnormalities of the skeleton were found in weanling rats after 20 days of dosing with 550 mg Sr/kg bw/day (LOAEL). The NOAEL in weanling rats was 140mg/kg bw/day. In adult rats the NOAEL was 690 mg/kg bw/day in the same study (ATSDR 2004). Experimental data show that 20% of ingested strontium in humans is absorbed from the gastrointestinal tract. (Van Engelen et al ,2006)

A3.132 Animal data indicate young animals as more sensitive to strontium than adults but human data are scarce. Strontium adversely affects bone development and therefore children are at increased risk.

A3.133 Based on an NOAEL of 140 mg/kg bw/day (above) ATSDR (2004) proposed an intermediate MRL of 2mg/kg bw/day was calculated with an uncertainty factor of 90, (10 for extrapolation from animal to human and 3 for human variability, 3 for short study duration and limited endpoint examination). A partial uncertainty factor was used to account for human variability because the selected NOAEL was based on the response of juveniles. ATSDR did not calculate a chronic MRL due to lack of data were. The US-EPA proposed an RfD of 0.6 mg/kg bw/day (US-EPA, 1996) with a total uncertainty factor of 300 (10 for interspecies extrapolation, 10 for an incomplete database, including a lack of developmental and reproductive data, 3 for for sensitive subpopulations). Again a low intra-species factor was used because the NOAEL was for a sensitive subgroup. (Van Engelen et al ,2006)

A3.134 The RfD 0.6 mg/kg bw/day as proposed by US-EPA (1996) has been chosen as an appropriate value for toy-related exposures. There have been no more recent data on the toxicology of strontium

Tin

A3.135 . Metals exist in both organic and inorganic species and it is necessary to obtain substance-specific data for risk assessment and management. This is due to the varying bioavailability and toxicity of the different species. Only recently laboratory techniques and protocols have existed to allow speciation on a large scale.

Tin (inorganic)

A3.136 RIVM (1991) reviewed the oral toxicity of inorganic tin and compounds [WHO/JECFA (1982, 1989, 2001), IPCS (2005), EFSA (2005) and ATSDR (2005)]. Tin occurs naturally in the earth's crust at approximately 2–3 ppm concentration. Humans have been exposed to inorganic tin mainly from migration from tin cans to foods. The European Union permits tin chloride (SnCl2) as a food additive (E512) for bottled and canned white asparagus. (Van Engelen et al ,2006)

A3.137 Data on mean inorganic tin intake from food for populations of Australia, France, Japan, Netherlands, New Zealand, the United Kingdom, and the USA indicate intakes of inorganic tin ranging from <1 up to 15 mg/person per day. Certain individuals could ingest up to 50–60 mg of tin daily if they normally eat tinned fruit, vegetables, and juices from unlacquered cans (IPCS 2005). The JECFA (2001) cites a UK study of 97 pre-school children (age 1.75–2.2 years) in which average daily intakes of 1.7-2.9 mg/day were found. Intake showed strong correlation with consumption of canned foods. An Australian study among two-year-olds showed a mean intake of 1.3 mg/day (JECFA 2001). Based on the above information background daily intake of inorganic tin for a child was estimated to be 290 mg/kg bw/day. This figure is calculated from the maximum mean of 2.9 mg/day of the range for young children as reported in JECFA (2001), assuming a child body weight of 10 kg. (Van Engelen et al ,2006).

Toxicity

A3.138 There is no evidence that tin is essential for humans or animals. There are no data on deficiency effects from inadequate intake of inorganic tin. Inorganic tin has a low systemic toxic potential due to low absorption in the gastrointestinal tract. The only reported effect in humans is acute irritation of the mucosa of the gastrointestinal tract (no known chronic effects), found in consumers drinking fruit juices containing high concentrations of tin (about 200 mg/kg product). In toxicology experiments animals fed inorganic tin have shown anemia, liver and kidney damage. In a sub-chronic feeding study in rats the NOAEL was 32 mg/kg bw/day. In a chronic feeding study in rats the NOAEL was 400 mg/kg diet (equivalent to 20 mg/kg bw/day).

A3.139 No data are available for oral toxicity of tin in children.

A3.140 There is no data on dermal toxicity (ATSDR, 2005).

A3.141 The absorption of inorganic compounds of tin from the gastrointestinal tract in humans and animals is very low with as much as 98% being excreted directly in the faeces (EFSA 2005). Therefore toxicity from oral exposure would be expected to be low.

A3.142 The JECFA proposed a TDI of 2 mg/kg bw/day as the appropriate value for toy-related exposures. (JECFA, 2001). Based on an NOAEL of 32 mg/kg bw/day from a subchronic feeding study in rats, ATSDR (2003) proposed an intermediate MRL of 0.3 mg/kg bw/day. In this derivation an uncertainty factor of 100 (10 for animal to human extrapolation and 10 for human variability) was applied. ATSDR derived no chronic MRL because appropriate data were lacking. EFSA (2005) noted that because of their limited absorption, orally ingested inorganic tin compounds have low systemic toxicity in man and animals but concluded the available evidence was insufficient for deriving an Upper Level for inorganic tin.

Tin (Organic)

A3.143 The oral toxicity of organic tin compounds has been reviewed (EFSA 2004; JMPR, 1992; US-EPA, 1997; IPCS, 1999 and RIVM 1999).

Occurrence

A3.144 Organotin compounds include the trisubstituted tributyltin (TBT) and triphenyltin (TPT) both commonly used as biocides in wood preservatives, in antifouling paints for boats and as pesticides. Mono-and di-substituted compounds such as monomethyltin (MMT), dimethyltin (DMT), dibutyltin (DBT), mono-n-octyltin (MOT) and di-n-octyltin (DOT) are used in mixtures in various amounts as PVC stabilizers, a use that includes food contact materials.

A3.145 The major source of human exposure to organotins is fish and seafood. The EFSA (2004) presented data on dietary exposure from eight European Countries (Belgium, Denmark, Germany, France, Italy, Netherlands, Greek and Norway). In Norway the high mean fish/seafood consumption of organotin compounds is 80 grams/day. This level and the *median* international concentrations of TBT, DBT, and TPT, enabled a total daily intake of 0.018 µg/kg bw/day to be calculated. If *mean* international concentrations were used, the calculated intake was 0.083 µg/kg bw/day. For the 95th percentile for fish/seafood consumption by Norwegians of 165 grams/day combined with the *median* international concentrations of TBT, DBT, and TPT, the total intake of organotins was calculated to be 0.037 µg/kg bw/day. This level combined with the *mean* international concentrations of TBT, DBT, and TPT led to 0.17 µg/kg bw/day. For high fish/seafood consumers from Norway, consuming products at the 95th percentile level of organotin concentrations, an intake of 0.30 µg/kg bw/day was calculated. Based on this information a background daily intake of organic tin for a child was estimated to be 0.083 mg/kg bw/day. This is the mean calculated for adults in Norway as the EU country with highest fish consumption.

A3.146 Organotin compounds are sparingly soluble in water but soluble in fats and easily adsorbed to particulate matter in the aquatic environment. They accumulate in fish and in sediments where they are relatively persistent and can be taken up by organisms such as clams.

Health effects

A3.147 Tributyltin (TBT) and triphenyltin (TPT) cause masculinization in female molluscs, by increasing the levels of unconverted androgens. Organotin compounds are therefore potential endocrine disrupters (Nakanishi et al, 2006). Organotin exposure has also been linked to adipocyte differentiation suggesting an important new area of research into the potential environmental influences on obesity. (Grun and Blumberg 2006).

A3.148 TBT and TPT have been studied extensively in animals and results suggest these chemicals are neurological and reproductive toxicants and also associated with the development of tumours. TBT, DBT, TPT and DOT were also associated with immunotoxicity producing thymus atrophy and depletion of lymphocytes in the thymus, spleen and peripheral lymphoid tissues. Decreases in immunoglobulin concentrations, lymphopenia and decrease in white blood cells in rodents were also seen. Because of their adverse effects on the aquatic ecosystem the use of TBT and TPT as biocides in antifouling paints for boats has been restricted (EFSA 2004).

Toxicity

A3.149 Mechanistic data indicate a similar mode of action for the different organotins. An overall NOAEL of 0.025 mg/kg bw/day was derived from a chronic rat study with TBTO in which reduced resistance to *T. spiralis* infection was the critical effect. The same NOAEL was observed in a 2-year study in rats carried out by the same laboratory (EFSA 2004).

A3.150 As is pointed out in US-EPA (1997), rat data indicate young animals are more susceptible to TBT immunotoxicity. The overall NOAEL, however, already includes this factor because it stems from a study using weanling rats.

Dermal contact and sensitisation

A3.151 Some organic tin compounds also have sensitizing properties. TBTO is an irritant of the eyes and skin in experimental animals. These effects were observed at concentrations of ³0.5% (skin) and 0.15% (eyes). A NOAEL for these endpoints is lacking. In human beings, TBTO may cause severe dermatitis after direct skin contact (conclusion based on *case studies*). This reaction has a delayed character, i.e. the symptoms develop only several hours after the start of contact. The dose-effect relation for this effect is unknown. The lowest effect concentration reported is 0.01 g/litre (value derived from a *case study*). A NOAEL for this endpoint is lacking. The observed dermatitis is probably not a hypersensitivity response. No effect was seen in a standard test for dermal sensitization in guinea pigs with tributyltinoxide. In skin irritation tests triphenyltin showed only a mild response at high concentrations (RIVM 2000).

A3.152 Human data are lacking for absorption. In rat studies with TBT, TPT and DOT absorption after oral administration ranged form 20 to 55% (EFSA 2004).

Zinc

A3.153 Zinc is an essential substance required as part of a healthy diet. The zinc content of a typical mixed diet of North American adults is approximately 10-15 mg/day (IOM, 2001). The FDA's Total Diet Study (Pennington et al., 1989) found zinc intakes of 7.25, 9.74, 15.42, 9.38, and 15.92 mg/day in children (2 years of age), girls (14-16 years), boys (14-16 years), women (25-30 years), and men (25-30 years), respectively. The recommended dietary allowances (RDAs) for zinc for the year 2000 (IOM, 2001) are 11 mg/day for adult males and 8 mg/day for adult females (not pregnant or lactating).

A3.154 Zinc is essential for the function of more than 300 enzymes, including alkaline phosphatase, alcohol dehydrogenase, Cu, Zn-superoxide dismutase, carboxypeptidase, delta-aminolevulinic acid dehydratase, carbonic anhydrase, ribonucleic acid polymerase, and reverse transcriptase (Vallee and Falchuk, 1993; Sandstead, 1994). Zinc is also involved in DNA and RNA synthesis and cell proliferation. Zinc coordinates with cysteine and histidine residues of certain peptides and produces a tertiary structure which has an affinity for unique segments of DNA in promoter gene regions, including zinc finger protein domains, the most common zinc motif, and the zinc thiolate cluster (Prasad and Nath, 1993; Walsh et al., 1994). Other physiological roles of zinc include enhancement of the affinity of growth hormone for its binding receptors, modulation of synaptic transmissions by interacting with specific sites on ionotrophic neurotransmitter receptor proteins, and induction of metallothionein (Walsh et al., 1994).

A3.155 The RfD for zinc is based on human clinical studies to establish daily nutritional requirements. Zinc is an essential trace substance that is crucial to survival and health maintenance, as well as growth, development, and maturation of developing organisms of all animal species. Thus, insufficient as well as excessive oral intake can cause toxicity and disease and a quantitative risk assessment must take essentiality into account. The principal studies examine dietary supplements of zinc and the interaction of zinc with other essential trace metals, specifically copper, to establish a safe daily intake level of zinc for the general population, including pregnant women and children, without compromising normal health and development.

A3.156 A wide range of clinical symptoms have been associated with zinc deficiency in humans (Abernathy et al., 1993; Prasad, 1993; Sandstead, 1994; Walsh et al., 1994). As reviewed by Mahomed et al. (1989), severe zinc deficiency in animals has been associated with reduced fertility, fetal nervous system malformations, and growth retardation in late pregnancy. In humans, labor abnormalities, congenital malformations, and preterm labor have been reported in otherwise healthy women with low maternal serum zinc concentrations.

A3.157 Pregnancy outcome and zinc supplementation Numerous studies have examined pregnancy outcomes following zinc supplementation. Simmer et al. (1991) found

significant intrauterine growth retardation and fewer inductions of labour (generally associated with poor fetal growth), and non-statistically significant increases in birth weight and placental weights in zinc-deficient women receiving a supplement containing 100 mg zinc citrate (22.5 mg zinc) (these women were receiving the supplement because they were believed to be at risk of delivering small-for-gestational age babies). However, Mahomed et al. (1989) did not find any statistically significant differences in gestation duration, details of labour and delivery, fetal development, or neonatal health among 246 randomly selected pregnant women receiving 20 mg Zn/day as zinc sulfate tablets beginning before the 20th week of pregnancy as compared to 248 women receiving placebo tablets. While the zinc supplement and placebo group had marginal zinc intake (approximately 10 mg/day) prior to supplementation, the zinc supplementation did not appear to influence pregnancy outcome.

Human Carcinogenicity Data

A3.158 Under the *Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), there is inadequate information to assess carcinogenic potential* of zinc, because studies of humans occupationally-exposed to zinc are inadequate or inconclusive, adequate animal bioassays of the possible carcinogenicity of zinc are not available, and results of genotoxic tests of zinc have been equivocal.

A3.159 There are no reports on the possible carcinogenicity of zinc and compounds per se in humans. Case studies have been used to evaluate the effects of zinc administered for therapeutic reasons. There are reports which compare zinc levels in normal and cancerous tissue. Studies of occupational exposure to zinc compounds have also been conducted, but have limited value because they do not correlate exposure with cancer risk.

Some supporting Data for Carcinogenicity

A3.160 Zinc deficiency or excessively high levels of zinc may enhance susceptibility to carcinogenesis, whereas supplementation with low to moderate levels of zinc may offer protection (Mathur, 1979; Woo et al., 1988). Thus, zinc has a modifying effect on carcinogenesis that may depend both on the dose and the identity of the carcinogen being affected.

APPENDIX 4: ORGANIC COMPOUNDS

A4.1 This appendix details the organic compounds contained in EN71-9, many of which will be covered in the three revision approaches. The table below sets out solvent migration limits.

Table A4.1: Solvents Migration

Compound	CAS Number	Limit
*Trichloroethylene (trichloroethene)	79-01-6	Action Limit
*Dichloromethane	75-09-2	0.06 mg/l
2-methoxy-ethylacetate	110-49-6	0.5 mg/l
*2-ethoxy-ethanol	110-80-5	0.5 mg/l
*2-ethoxy-ethylacetate	111-15-9	0.5 mg/l
Bis(2-methoxy ethyl) ether	111-96-6	0.5 mg/l
2-methoxy-proplyacetate	70657-70-4	0.5 mg/l
*Methanol	67-56-1	5mg/l
Nitrobenzene	98-95-3	Action
Cyclohexanone	108-94-1	46 mg/l
3, 5, 5, tri-methyl-2-cyclohexene-1-one	78-59-1	3 mg/l
*Toluene	108-88-3	2 mg/l
*Ethylbenzene	100-41-4	1 mg/l
Xylene (all isomers)	various	2 mg/l (total)

A4.2 The following text presents toxicological profiles for seven organic compounds from the above table. These compounds were not considered in the RIVM SIR report 001027801 (Van Engelen et al 2006).

A4.3 EN 71-9 provides requirements for certain organic chemical compounds in toys and toy materials. Migration limits are derived for some compounds and absolute limits for others. EN 71-10 provides information on the sample preparation and extraction procedure to determine migration for these compounds. Various migration and extraction tests exist to determine the release of organic compounds such as phthalates and nitrosamines from toy articles. The RIVM method for migration is based on human physiology and applied independently of the matrix of contaminant. However research with in vitro digestion models has shown the amount extracted in the acid environment of the stomach is not representative of a 'worst case' situation for the bioavailable amount of an organic substance (Oomen et al, 2001). The method in EN 71-3 to determine bioavailable amounts is suitable as a 'worst case' for bioavailable amount of substances (metals) but is not applicable for bioavailable amounts of organic compounds. Tests to simulate ingestion of organic substances are under development (Brandon et al, 2006).

General background

A4.4 Children have internal exposure attributes during inhalation of volatile organic compounds (VOCs) that are different from adults and important for systemic effects. These are: i) greater energy expenditure and breathing rate for body-weight, leading to relatively greater uptake; ii) increased circulation rates leading to faster metabolism and distribution within the body; iii) different relative organ volumes, particularly the brain and the liver that may result in higher or lower internal concentrations; iv) immature metabolism, e.g. renal function (Mielke et al 2005).

A4.5 The US EPA developed the Integrated Risk Information System (IRIS) for values of potency factors for selected VOCs for risk assessment. The VOCs, including 1,1-dichloroethene, dichloromethane, chloroform, benzene, *trichloroethylene, tetrachloroethene, and styrene were selected for risk calculation due to the availability of potency factors, high frequency of occurrence, and carcinogenicity. The cancer potency factors for inhalation of selected VOCs are shown in Table A4.2.

Table A4.2: Potency factors for selected VOCs according to the IRIS system

Volatile organic compounds	Potency factor $(mg/kg/day)^{-1}$
1,1 Dichloroethene	1.16
Methylene chloride	0.014
Chloroform	0.081
Benzene	0.029
Trichloroethene	0.013
Tetrachloroethene	0.0033
Styrene	0.00057

[Source Guo et al 2004]

A4.6 In the IRIS system factors are adopted to calculate lifetime cancer risk (USEPA, 1998). Inhalation exposure is a multiple of the mean concentration of the specific VOC and the duration of exposure. Risk assessment requires assumptions for average body weight and the amount of air breathed. The USEPA suggests standard values for adults and children (Gratt 1996; USEPA, 1994). For adults exposures were converted to a daily dose by assuming 20m3 inspired air/day and average body weights of 70kg for men and 60kg for women. For children the average body weight was assumed to be 10kg and an average of 5m3 of air/day inspired. A lifetime of 70 years was applied to all individuals. The absorption factor of VOC for humans was assumed to be 90 per cent (Guo et al 2004).

Trichloroethylene

Synonyms

A4.7 1,1,2-trichloroethylene, 1,2,2-trichloroethylene, tri-clene, acetylene trichloride , algylen, anamenth, benzinol, blacosolv, 1-chloro-2,2-dichloroethylene, chlorylea, chlorylen, chorylen, circosolv, ethylene trichloride, the numerous synonyms indicating that it is ubiquitous.

Uses

A4.8 1,1,2-trichloroethylene is mainly used for vapour degreasing of metal parts and as a solvent for extraction of greases, oils, fats, waxes, and tars. It is used as an intermediate in the production of other chemicals, and as a refrigerant. In consumer products trichloroethylene is a constituent in typewriter correction fluids, paint removers/strippers, adhesives, spot removers and carpet-cleaning fluids. In the past it has been used as a general anaesthetic. (ATSDR, 1997)

Chronic Health Hazard Assessments for Non carcinogenic Effects

A4.9 The oral (**RfD**) and inhalation (**RfC**) reference doses are presently being calculated. Trichloroethylene can be measured in the breath for personal exposure assessmentand breakdown products can be measured in urine or blood. (ATSDR 1997)

Acute Health Effects

A4.10 Acute inhalation exposure in humans affects the central nervous system; symptoms include sleepiness, fatigue, headache, confusion and euphoria. Effects on the liver, kidneys, gastrointestinal system and skin have also been reported. (ATSDR, 1997).

Chronic Effects (Non cancer):

A4.11 Chronic inhalation exposure in humans also affects the central nervous system (symptoms after occupational exposure include dizziness, headache, sleepiness, nausea, confusion, blurred vision, facial numbness, and weakness). Simultaneous alcohol consumption and trichloroethylene inhalation has also been found to increase trichloroethylene toxicity in humans (ATSDR, 1997). Effects on human liver, kidneys, immune and endocrine systems have been reported from occupational exposure or contaminated drinking water (US EPA 2001).

A4.12 ATSDR (1997) calculated an intermediate-duration inhalation MRL of 0.1 parts per million (ppm) (0.5 milligrams per cubic meter, mg/m^3) for trichloroethylene based on neurological effects in rats (ATSDR, 1997). The California Environmental Protection Agency (CalEPA, 1997) has calculated a chronic inhalation reference exposure level of 0.6 mg/m^3 based on neurological effects in humans. This level is a concentration at or below which adverse health effects are not likely to occur.

Reproductive/Developmental Effects

A4.13 Two epidemiological studies found increases in the incidence of miscarriages: nurses exposed via inhalation to trichloroethylene and other chemicals in operating rooms, and women exposed either occupationally or non-occupationally to trichloroethylene and other solvents. In both studies other chemicals were also present thus limiting any conclusions specific for trichloroethylene exposure. (ATSDR, 1997).

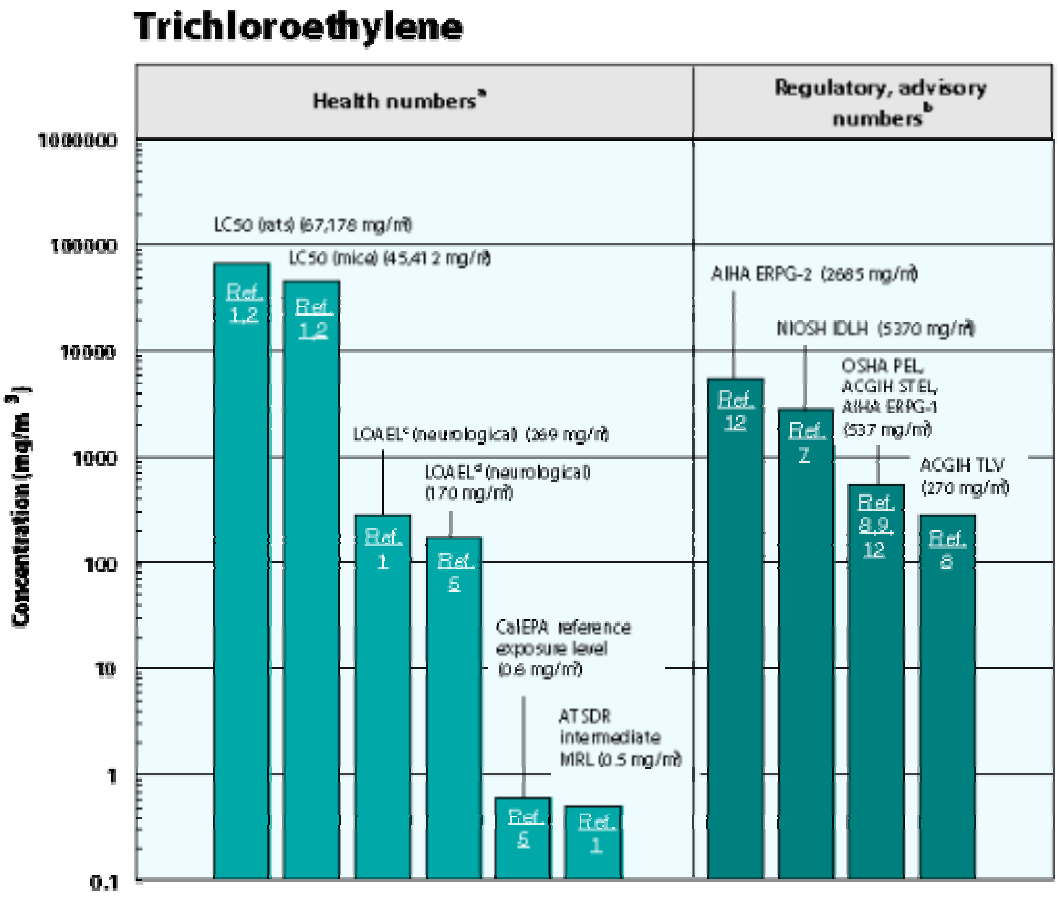
A4.14 An epidemiological study of 2,000 male and female workers exposed to trichloroethylene via inhalation found no increase in malformations in babies born following parental exposure (ATSDR, 1997). Several studies of exposure to trichloroethylene present in contaminated drinking water have not found an association with adverse reproductive effects in humans. Congenital heart disease in children was found associated with a drinking water contaminated with trichloroethylene and similar chemicals. However, no causal relationship with trichloroethylene could be made (ATSDR, 1997). Animal studies have reported developmental effects from exposure to trichloroethylene and its metabolites (ATSDR, 1997;US EPA 1985; US EPA 2001)

Carcinogenicity Assessment for Lifetime Exposure

A4.15 Several large epidemiological studies indicate trichloroethylene exposure is associated with cancers in humans, particularly kidney, liver, cervix, and the lymphatic system. Consistency of evidence is strongest for an association with kidney cancer supported by molecular epidemiology studies (US EPA 2001). Inhalation and oral exposure studies in rats and mice have shown increases in tumours of the lung, liver, kidney, testes and lymphoma (ATSDR, 1997; US EPA 1985; US EPA 2001)

A4.16 A provisional inhalation unit risk estimate of 1.7 x 10-6 $(\mu g/m^3)^{-1}$ has been calculated for trichloroethyelene. This value is currently being reassessed by the EPA (US EPA 1995). A provisional oral cancer slope factor of 0.011 $(mg/kg/d)^{-1}$ is also currently being reassessed (US EPA 1995). New data suggest that trichloroethylene is a likely human carcinogen. (US EPA 1998; US EPA 2001)

Figure A4.1: Health Data from Inhalation Exposure (data obtained in 1999)



[a] *Health numbers are toxicological numbers from animal testing or risk assessment values developed by EPA.*

[b] *Regulatory numbers are values that have been incorporated in Government regulations, while advisory numbers are non regulatory values provided by the Government or other groups as advice. OSHA numbers are regulatory, whereas NIOSH, ACGIH, and AIHA numbers are advisory.*

[c] *LOAEL is from the critical study used for the ATSDR intermediate MRL.*

[d] *LOAEL is from critical study used for the CalEPA chronic reference exposure level. (see glossary for definition of terms)*

Refs in figure: 1=ATSDR 1997; 2=US DHHS, 1993; 5= Cal EPA 1997;

7 = NIOSH 1997; 8 = ACGIH 1999; 9 = OSHA 1998; 12 = AIHA 1998

Note: Conversion Factors: *To convert concentrations in air (at 25°C) from ppm to mg/m^3: mg/m^3 = (ppm) × (molecular weight of the compound)/(24.45). For trichloroethylene: 1 ppm = 5.37 mg/m^3. To convert concentrations in air from µg/m^3 to mg/m^3: mg/m^3 = (µg/m^3) x (1 mg/1,000µg). [www.epa.gov/ttn/atw/hlthef/]*

Dichloromethane

Uses

A4.17 Dichloromethane is the industrial solvent of choice for cellulose acetate production, with uses in consumer products such as paint strippers and in the decaffeinating process of coffee. In response to questions about the long-term effects of exposure to DCM, several chronic toxicity/oncogenicity studies were conducted in the late 1970s.

Acute Exposure

A4.18 The operating procedure for assessment of risk for acute exposure to volatile organic compounds (VOCs), has been developed with international cooperation, by the US Acute Exposure Guideline Level (AEGL) committee. The 3 levels are: (AEGL-1: discomfort; AEGL-2: irreversible or other serious, long-lasting adverse effects; AEGL-3: life-threatening effects or death with different exposure times (10 and 30 min, and 1, 4 and 8 h). The AEGL values represent threshold levels in order to protect the human population. Mielke et al (2005) reports the methodology for deriving AEGL values with sensitive sub populations such as children addressed in more detail. Such populations would be expected to suffer stronger effects when exposed to a given external concentration. DCM was used to quantify the higher internal exposure of children compared to a healthy, young adult. Differences depend on age, dose, and duration of exposure. These models result in AEGL values that are biologically justified (Mielke et al, 2005).

Chronic Health Hazard Assessments for Noncarcinogenic Effects

A4.19 The Chronic Oral Exposure (RfD) was last revised for the US EPA in 03/01/1988. The National Coffee Association, studies (1982) calculated NOAELs from animal liver toxicity studies at experimental doses of 5.85 and 6.47 mg/kg/day for males and females, respectively with an UF of 100 and an MF of 1. The oral RfD was calculated at 6E-2mg/kg/day. The LOAEL was calculated at 52.58 and 58.32 mg/kg/day for males and females, respectively from a 2 year rat drinking water bioassay.

A4.20 A NOAEL of 87 mg/m^3 was reported by Haun and colleagues (Haun et al, 1972). The equivalent oral dose is about 28mg/kg bw/day (87 mg/m^3 x 0.5 x 0.223 m^3/day/0.35 kg (rats). The uncertainty factor was 100 for the oral RfD. The 100-fold factor accounts for both the expected intra- and interspecies variability to the toxicity of this chemical in lieu of specific data. No modifying factor was used.

A4.21 A screening-level review conducted in September 2002 of recent relevant toxicology for the RfD for dichloromethane did not identify any critical new studies.

A4.22 A reference concentration for chronic inhalation exposure (RfC) is not available.

Carcinogenicity Assessment for Lifetime Exposure

A4.23 Evidence for dichloromethane as a probable human carcinogen is based on inadequate human data but sufficient evidence of carcinogenicity in animals; increased incidence of liver and lung neoplasms in male and female mice, and increased incidence of benign mammary tumors in both sexes of rats, salivary gland sarcomas in male rats and leukemia in female rats. The classification of dichloromethane as a probable carcinigen is supported by some positive genotoxicity data, although results in mammalian systems are generally negative.

A4.24 *Human carcinogenicity data include* two studies of chemical factory workers exposed to dichloromethane showing an excess of cancers (Ott et al., 1983; Friedlander et al., 1978;

Hearne and Friedlander, 1981. The Ott et al. (1983) study was designed to examine cardiovascular effects, and therefore the study period was too short to allow for latency of site-specific cancers. In the Friedlander et al. (1978) study, exposures were low, but the data provided some suggestion of an increased incidence of pancreatic tumors. This study was recently updated to include a larger cohort, followed through 1984, and an investigation of possible confounding factors (Hearne et al., 1986, 1987). A non-significant excess in pancreatic cancer deaths was observed, which was interpreted by EPA (1987a) as neither clear evidence of carcinogenicity in humans, nor evidence of noncarcinogenicity. An update of the Ott et al. (1983) study (in 1989), based on longer follow-up, indicated possible elevation of liver and biliary tract cancers.

Animal Carcinogenicity Data

A4.25 Two DCM inhalation studies have shown increased incidence of benign mammary tumors in both sexes of Sprague-Dawley F344 rats. Male rats had increased salivary gland sarcoma and female rats had increased leukemia incidence (Burek et al, 1984). Both sexes of mice developed liver and lung tumors after dichloromethane treatment (NTP, 1986).

A4.26 In the National Coffee Association study (1982, 1983), male mice had an increased incidence of combined neoplastic nodules and hepatocellular carcinoma. The increase was not dose-related, but the pairwise comparisons for the two mid- dose groups were statistically significant (U.S. EPA, 1985a). Female mice had no increased liver tumor incidence. The EPA (1985b) regarded this study as suggestive but not conclusive evidence for carcinogenicity of dichloromethane.

A4.27 Current EPA cancer risk assessment guidelines include a caveat to evaluate the risk of sensitive sub-populations, such as children. Clewell et al, (2004) recently reviewed these guidelines and their analysis and review indicate that neonatal children up to age 5 years *are less likely to be exposed to carcinogenic metabolites of dichloromethane* than are adults. This was based on the pharmacokinetics of blood dichloromethane and metabolism to the reactive metabolite using the GST pathway. Furthermore, their analysis did not demonstrate significant differences in kinetics between men and women. Thus, the assessment presented by David et al (2006) represents a conservative estimate of risk for all likely sensitive sub-populations.

A4.28 Starr et al (2006) describe a new cancer risk estimation model utilizing probabilistic methodology similar to that employed recently by U.S. EPA for other chemicals

A4.29 Starr et al report that the epidemiological studies gave little evidence, positive or negative, about coherence with the predictions of the physiologically based pharmacokinetic (PBPK) model, and probabilistic risk-assessment models. The case-control studies were flawed, including using deceased subjects and indirect methods for determining the potential for DCM exposure in cases and controls. Small cohort studies had little statistical power to detect excess risks of rare cancers, such as human liver cancer. The resulting reduction in estimated risks, some 40-fold (in addition to the 12.6-fold reduction

due to elimination of the interspecies body surface area adjustment factor), may not be an exact representation of the true risk differences, but it nonetheless argues for much lower risks than those indicated in the most recent U.S. EPA (1991)http://toxsci.oxfordjournals.org/cgi/content/full/91/1/20 - BIB14#BIB14 assessment. The panel agreed that the current state of the science for DCM should lead to substantial reductions in potential human cancer risks expected from DCM exposure. (Starr et al, 2006).

Ethoxyethanol

Synonyms

A4.30 Ethanol, 2EE, 2-ethoxy- , beta-ethoxyethanol, cellosolve, ethylene glycol monoethyl ether,

Uses

A4.31 Glycol ethers are versatile solvents, miscible with both aqueous and organic media with widespread use in industrial and household applications. Ethoxyethanol, also referred to as an ether alcohol, and described as a solvent and viscosity-decreasing agent, has been used in cosmetics (Wenninger and McEwen 1997). Data from a hazard survey showed that large amounts of E-series ethylene glycol ethers are imported and used in Taiwan. The annual consumption of 2-EE is 1200–1800 tons (Lin et al, 1993)

A4.32 At present ethoxyethanol can be safely used as a diluent in colour additive mixtures for food use that are exempt from certification. Additionally, ethoxyethanol is listed among the components of rubber articles intended for repeated use that can be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food. The total amount of ethoxyethanol is not to exceed per cent% by weight of the rubber product (21CFR177.2600).

Chronic Health Hazard Assessments for Noncarcinogenic Effects

A4.33 The reference dose for oral exposure (RfD)is not available at this time.

A4.34 The reference dose for chronic inhalation (RfC) was last revised 05/01/1991.

A4.35 A NOAEL of 380 mg/m^3 (103 ppm) was calculated for the critical effect of decreased testis weight, seminiferous tubule degeneration and decreased hemoglobin. (UF = 300, MF =1). The RfC was calculated as 2E-1 mg/m^3. (Barbee et al 1984)

A4.36 An uncertainty factor of 10 was used to account for intraspecies extrapolation, 10 for use of a sub-chronic study and 3 to account for interspecies extrapolation. The reproductive and developmental studies for ethylene glycol monoethyl ether are considered to be of sufficient number and quality in various species exposed both by oral and inhalation exposure. Thus, an uncertainty factor for an incomplete database is not needed. A modifying factor was not needed.

Adverse Reproductive Outcomes

Animal studies

A4.37 Doe (1984) exposed groups of 24 pregnant rabbits to varying ppm of ethylene glycol monoethyl ether for 6 hours/day on gestational days 6-18. Maternal toxicity was not observed; hematological parameters were not measured. The offspring exposed to 645 mg/m^3 had an increased incidence of skeletal defects and skeletal variants. The NOAEL (HEC) for this study is 188 mg/ m^3. Other studies have also shown that ethoxyethanol has demonstrable reproductive (Hardin et al. *1984*), haematological (Aasmoe et al. *1998*) and developmental effects (Hardin *1983*) in laboratory animals,

Human Studies

A4.38 The potential for testicular toxicity in workers exposed to ethylene glycol monoethyl ether vapors was assessed by Clapp et al. (1987) and Ratcliffe et al. (1989). Exposure levels ranged from not detectable to 24 ppm, with average levels 11 ppm (41 mg/m^3) (Clapp et al., 1987). Exposure was via inadvertent skin contact, inhalation or airborne vapour condensation on the skin.

A4.39 Ratcliffe et al. (1989) obtained semen samples from exposed and unexposed workers. Mean sperm count in exposed workers showed a marginal statistically significant decrease compared with controls (corrected for confounders). No statistically significant differences in other sperm characteristics were observed. Sperm counts of both exposed workers and controls were significantly different from historic values, suggesting that controls may also have had some exposure to ethylene glycol monoethyl ether or that both groups may have been exposed to another compound that affects spermatogenesis. Most of the workers in the control and some in the exposed group may have been exposed to metal fumes and dusts, solvents (tetrachloroethylene) or heat and vibration. Analysis of sperm parameters by duration and potential intensity of exposure did not reveal an exposure-related effect. Ethylene glycol monoethyl ether was not identified in the blood of exposed or control workers, although ethoxyacetic acid (primary metabolite of ethylene glycol monoethyl ether) was found in the urine of exposed but not control workers. Ratcliffe et al (1989) suggest a possible effect of ethylene glycol monoethyl ether exposure on sperm quality in the workers, but noted that the study is limited by the small sample sizes and the large interpersonal variation in the examined parameters.

A4.40 Studies by Figa-Talamanca et al. (1997) have also shown adverse reproductive effects in exposed workers.

A4.41 Other studies have also shown that the low molecular weight E-series glycol ethers (including 2-ME, 2-MEA, 2-EE, and 2-EEA) have haematological (Welch and Cullen, 1998) and teratogenic toxicity, (Shia et al, 2000, 2003).

Skin absorption

A4.42 The glycol ethers penetrate skin rapidly (Kezic et al. *1997a*,*1997b*; Filon et al. *1999*) and dermal absorption of these compounds may therefore present a significant health risk. Kezic et al (*1997a*) suggest the contribution of skin absorption to be around 55% and 42% total uptake for 2-methoxyethanol and 2-ethoxyethanol, respectively. Wilkinson and Wilkinson (2002) report on the vehicle, dose, skin thickness and receptor fluid on the dermal absorption of the glycol ethers including 2-ethoxyethanol. Their findings also indicate a high degree of skin absorption. Results from Venier and colleagues (2004) confirm the good ability of these solvents to permeate the skin and therefore represent a risk for potential dermal absorption both for workers and for occasional exposures. This is important for children's exposure to these chemicals in toys. Johnson (2002) in a final report of the Cosmetic Ingredient Review Expert panel on the safety assessment of ethoxyethanol and ethoxyethanol acetate, suggest that the adverse health effects associated with these chemicals indicates that they are unsafe as ingredients for use in cosmetic formulations via dermal exposure. (Johnson 2002)

Skin Irritation:

A4.43 Patch tests were performed on one to 20 patients with or suspected of having contact allergy to cosmetic products. Ethoxyethanol was tested at a concentration of 2% in petrolatum. Details concerning the experimental procedure were not stated but no irritant reactions were observed for ethoxyethanol (de Groot 1994).

Carcinogenicity Assessment for Lifetime Exposure

A4.44 This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

Ethoxy ethyl acetate

Synonyms

A4.45 These include Ethanol 2-Ethoxy- acetate; 2-EEA; 2-Ethoxyethanol Acetate; and Ethylene Glycol Monoethyl Ether Acetylated

A4.46 The 'Final Report on the Safety Assessment of Ethoxyethanol and Ethoxyethanol Acetate (Johnson, 2002) describes this chemical as a volatile water-white liquid (with mild, characteristic odour) that is soluble in water (Nikitakis and McEwen 1990).

Uses

A4.47 Both the ester 2-ethoxy ethyl acetate (2-EEA) and 2-Ethoxy ethanol (see above) have been commercially available for the past four decades primarily used as an industrial solvent for coating materials.(NIOSH 1991;Veulemans et al, 1987a, 1987b; Kim et al, 1999; Cullen et al, 1983; Welch & Cullen et al 1988; Welch et al, 1988; Angerer et al, 1990; Chia et al 1997; Lowry et al 1993, Vincent et al, 1994). Data from a hazard survey

showed that large amounts of E-series ethylene glycol ethers are imported and used in Taiwan. The annual consumption of 2-EEA is 5000–8000 tons (Lin et al, 1993) About 90% are used in the coating industries—that is, in the manufacture of paints, thinner, and inks. 2-EEA is used especially in the silk screening shop as a diluent or detergent (Loh et al, 2003).

Use in Cosmetics

A4.48 Product formulation data submitted to the Food and Drug Administration (FDA) in 1998 indicated no reported uses of Ethoxyethanol or Ethoxyethanol Acetate in cosmetic products (FDA 1998). However, data submitted to FDA in 1984 included use concentration ranges for Ethoxyethanol in the following product types: hair conditioners (1 product, 10% to 25%), nail polish and enamel (1 product, 0.1% to 1%), and nail polish and enamel removers (1 product, 10% to 25%). Ethoxyethanol Acetate was used in two nail polish and enamel removers (1% to 5%) and in two other nail polish and enamel removers (25% to 50%) (FDA 1984).

Use in Non cosmetics

A4.49 Glycol Ethers, such as Ethoxyethanol, are useful as solvents for lacquers, paints, varnishes, dyes, inks, resins, cleaning formulations, and liquid soaps. Glycol ethers also have utility as coupling agents for a variety of chemical specialties, and are used as intermediates in the production of plasticizers and other solvents. The higher molecular weight glycol ethers are the primary components of most brake fluids (Miller 1987).

A4.50 The uses for the acetates of glycol ethers include: deicers in jet fuel, in inks and coatings, photography, dyeing, and the manufacture of printed circuit boards and plasticizers (Wess 1992). Ethoxyethanol acetate has been used as a blush retardant in lacquers, as a solvent for nitrocellulose, oils, and resins, in wood stains and varnish removers, and in products for the treatment of textiles and leathers (American Conference of Governmental Industrial Hygienists [ACGIH] 1991). It is also used as a solvent in the processes of welding nose pads to eyeglass frames and laminating plastic sheets (Fisher 1973; Rietschel and Fowler 1995). Ethoxyethanol Acetate (and Ethoxyethanol) are listed among ingredients in adhesives that can be safely used as components of articles for use in packaging, transporting, or holding food (21CFR175.105).

Adverse health evidence

Absorption route

A4.51 The major route of exposure to 2-EEA is inhalation, but skin absorption is often overlooked. Lack of recognition of the potential toxic effects of these chemicals as well as the potential toxic effects from skin absorption are common among workers (Lin & Chen 1991).

A4.52 Specifically 2- ethoxyethanol acetate has been reported to cause hematological toxicity, infertility, and teratogenesis. Toxic effects have been reported from animal experiments.

Limited subacute and chronic overexposure in humans via inhalation or percutaneous absorption has been reported to result in haematological abnormalities (NIOSH 1991; Kim et al 1999) and oligospermia (NIOSH 1991).

A4.53 A study by Loh et al (2003) investigated haematological effects in 2-EEA exposed workers in a silk screening shop. Workers were defined as a high exposure group where 2-EEA was used as the major cleaning and printing solvent and those with indirect and non-exposure to 2-EEA were used as the comparison group. Blood and urine were samples were collected. Air samples were measured by eight hour personal sampling. Mean exposure of female workers was significantly higher than male workers. The haemoglobin and haematocrit levels in the female high 2-EEA exposure workers were significantly lower than those of female workers in the comparison group. No difference was found between male workers with high exposure to 2-EEA and a comparison group of workers. The haemoglobin, haematocrit, and RBC count in the study population had a significant dose-response relation with air 2-EEA levels. These results suggest that 2-EEA is a haematological toxicant, which leads to anaemic status at high exposure among female workers.

Methanol

Synonyms

A4.54 Carbinol, Methanol, methyl alcohol, wood alcohol, wood-spirit.

Uses

A4.55 Methanol is produced in high volumes with approximately 70% worldwide used as feedstock for the production of chemicals such as formaldehyde, methyl tertiary butyl ether (MTBE), acetic acid, methyl methacrylate, and dimethyl terephthalate. Methanol is also used as an industrial solvent. According to the EPA TRI, methanol ranks amongst the highest in terms of environmental releases.

A4.56 Methanol is found widely in consumer products such as varnishes, shellacs, paints, antifreeze, antifreeze, cleaning solutions, and adhesives. It is used in race-car fuels and there is potential for an automobile fuel in the new hydrogen fuel cell vehicles.

Human exposure routes: inhalation, oral and dermal

A4.57 Humans can be exposed to methanol by inhalation, oral intake, and dermal contact. Human exposure to methanol from the above uses is mainly through inhalation. Methanol is a natural component of the human diet. For oral ingestion, the major sources of exposure are consumption of adulterated alcoholic beverages or fermented spirits containing wood alcohol, as well as accidental or intentional consumption of pure methanol. Methanol occurs naturally in fresh fruits and vegetables as either free alcohol, methyl esters of fatty acids, or methoxyl groups on polysaccharides. The population is also exposed to methanol through two direct food additives: aspartame and DMDC

(dimethyl dicarbonate). DMDC is a yeast inhibitor used in tea beverages, sports drinks, fruit or juice sparklers, wines, and wine substitutes.

A4.58 Dermal contact with methanol solutions can also lead to rapid absorption and manifestations of toxicity or lethality under some conditions. (IPCS, 1997). Although dermal contact with methanol can be anticipated among the general public as well as occupational groups, population exposures to methanol by the dermal route have not been described quantitatively.

Poisonings

A4.59 In the year 2000, 2474 incidents of methanol poisoning were reported to poison control centers with 613 of those incidents involving children under 6 years of age. The incidents frequently involve young children who ingest methanol in consumer products.

A4.60 The Oral RfD was 5E-1 mg/kg/day derived from the NOAEL of 500 mg/kg/day (UF of 1000) for increased SAP and SGPT, and decreased brain weight (sub-chronic study of rats) (U.S. EPA, 1986). The LOAEL was 2500 mg/kg/day.

A4.61 Butchko and Kotsonis (1996) estimated the methanol intake through ingestion of aspartame, data shown in the following table.

Population	90th percentile methanol intake mg/kg/bw/day	99th percentile methanol intake mg/kg/bw/day
General population	0.16-0.30	0.64
Children (all ages)	0.26-0.52	0.52-0.85
Diabetics	0.21-0.34	0.82
Dieters	0.16-0.33	0.58
Women of child bearing age	0.2-0.42	0.87
Pregnant women	0.13-0.27	0.27

Chronic Health Hazard Assessments for Noncarcinogenic Effects

A4.62 Methanol is metabolised by alcohol dehydrogenase to formaldehyde, which in turn is converted to formate. Toxic effects include severe abdominal pain, retinal toxicity, acidosis, convulsions, and coma.

A4.63 The principal study to support the oral RfD was well-designed with adequate toxicological endpoints; the method of administration was not ideal, therefore confidence is medium. The overall data base is weak, lacking data on reproductive, developmental, or other toxicological endpoints and therefore confidence in this database is low. The RfD is given a medium confidence rating because of the strengths of the principal study.

Inhalation route

A4.64 Most environmental exposures to methanol vapour are orders of magnitude below the occupational time-weighted average threshold limit value of 200 ppm (260 mg/m^3) for an 8-h day and 40-h week (ACGIH 2000). The ACGIH short term exposure level for methanol is 250 ppm. Assuming worker exposure levels within the TLV and PEL, an 8-h work day, an inhalation rate of 20 m^3 per day and a 70 kg body weight, CERHR estimated worker exposures to methanol to be below 25 mg/kg bw/day: (260 mg/m^3)×(20 m^3 per day)×(8 h/24 h)×(1/70 kg)=<25 mg/kg bw per day

Oral exposure to aspartame

A4.65 A study monitored the blood disposition of methanol in fasted human adults given varying mg/kg (34-200 mg/kg) aspartame in 300 ml orange juice. No significant effects on blood were observed. (Stegink, 1981). Stegink et al (1983), presents a useful comparison of blood methanol levels in 1-year-old infants and adults where 24 one-year-old infants had blood methanol concentrations measured after oral exposure to aspartame. Blood levels following high doses of aspartame were not significantly different from those in adults receiving similar doses indicating that aspartame is metabolized to methanol in a similar manner. Leon et al (1989) monitored the general health of 53 adults after an oral dose of 75 mg/kg bw/day aspartame (divided into three doses) for 24 weeks. No differences in health parameters were reported between this group and a group of 55 adults given a placebo.

Human Inhalation data

Adverse health effects

A4.66 Two controlled studies examined the neurotoxic effects associated with methanol inhalation in humans Cook et al (1991) and Chuwers et al (1995). The NTP-CERHR expert panel (2004) suggested that although Cook et al reported the majority of their results to be negative, the differences seen all tended to be in the direction favouring the control condition over the methanol condition (self-ratings of vigor, concentration, and fatigue; reaction time, slope and intercept measures on the Sternberg memory task; P200 latency and N1-P2 interval on the auditory event-related potential task). This study raises the possibility of more serious findings or effects at lower exposure level in possibly sensitive subpopulations. Chuwers et al (1995) also studied the neurotoxic effects of acute methanol inhalation in human subjects exposed to the occupational threshold limit value of 200 ppm for 4 hr in a randomized double-blind study. The authors concluded that methanol exposure at this concentration had little effect on neurobehavioral performance. Results from a single dose study in healthy young adults may not however predict effects in sensitive populations such as children.

A4.67 Case studies describing effects of acute methanol exposure in humans date back to the early 1900s. The majority of human methanol poisonings have resulted from consumption of adulterated alcohol beverages (IPCS, 1997). However, acute methanol toxicity has

been noted in adults and children following percutaneous or inhalation exposures, and symptoms have been similar to those observed with oral exposure. The progression of methanol-induced toxicity in humans has been well characterized in reviews by Kavet and Nauss (1990) and IPCS (1997). Kavet and Nauss describe case studies involving repeated exposure to methanol. Such studies mostly provide little or no information with respect to levels and duration of exposure. However, they demonstrate consistent symptoms with acute intake (visual toxicity, headache and vomiting), effects noted after inhalation, oral, and dermal exposure.

Genotoxity

A4.68 The NTP-CERHR expert panel (2004) summarized the main findings of the IPCS (1997) comprehensive review of genetic toxicity information for methanol to be negative but with some positive genotoxic results. The IPCS had stated "The structure of methanol (by analogy with ethanol) does not suggest that it would be genotoxic"

Carcinogenicity

A4.69 Kavet and Nauss (1990) and IPCS (1997) reviewed methanol studies by the Japanese New Energy Development Organization (NEDO). Critical review of the NEDO studies was not possible due to insufficient technical data and histopathological results.

Genetic factors

A4.70 Mechanisms underlying varying susceptibility to methanol may also be related to genetic differences in ethanol metabolism through polymorphisms in the alcohol dehydrogenase (ADH2*2) and P450 2E1 (CYP2E1) genes. Population studies inicate significant ethnic differences in these genes with greater ethanol susceptibility in Asian and Native American populations. Given that human methanol metabolism is similar to ethanol, these polymorphisms in the alcohol dehydrogenase allele may lead to greater susceptibility to methanol toxicity. This would result from decreases in metabolism leading to higher peak-blood levels.

A4.71 Children may receive higher doses than adults at the same exposures for any air pollutants due to higher baseline breathing rates and their greater physical activity. Children's surface area/bodyweight ratio is greater than adults, making dermal also absorption potentially greater. Hand-to-mouth behaviour as well as indiscriminate ingestions increase childhood risk by the oral route (Bearer, 1995; US EPA, 1997). Alcohol dehydrogenase activity is 3–4% of adult levels in the 2-month old fetus and increases linearly until reaching adult values at about 5 years of age. This lower enzyme activity may offer a level of protection against acute poisoning because it may reduce the rate of formate production (a toxic breakdown product of methanol). However, susceptibility to the effects of methanol itself may be enhanced. In humans, formate levels increase and cause serious toxicity (i.e., blindness, death) before significant increases in blood methanol are seen.

Reproductive and developmental outcomes

A4.72 The Expert Panel (Shelby et al NTP CERHR Expert panel, 2004) judged that there are insufficient human data upon which to evaluate the reproductive toxicity of methanol.

A4.73 This caveat is especially important since the Expert Panel recognized that there are limited human exposure data for pregnant women and other potentially susceptible subpopulations. The Expert Panel concluded that developmental toxicity was the most sensitive endpoint of concern with respect to evaluating the risk to reproduction posed by methanol exposure in humans.

Teratogenicity and neurodevelopmental outcomes

A4.74 Methanol is believed to be the proximate toxicant for teratogenesis in experimental animals and because methanol and ethanol metabolism are similar in humans, there is real concern about potentially similar adverse neurodevelopmental outcomes. The current data for ethanol is robust for neurodevelopmental effects with altered cell proliferation, migration, differentiation, and apoptosis. These endpoints have had limited assessment in experimental animals following developmental methanol exposure. The current methanol literature does not adequately address these more mechanistic endpoints. There is some limited support for the hypothesis that the mode of action of methanol and ethanol has some overlap, supported by effects on cell proliferation and neural markers associated with migration and differentiation (NCAM). (Shelby et al NTP CERHR, 2004). The Expert Panel also concluded that there was insufficient evidence to determine if the human fetus is more or less sensitive than the most sensitive rodent species (i.e. mouse) to methanol teratogenesis. Other factors such as genetic polymorphisms in key metabolizing enzymes and/or maternal folate status, that alter methanol metabolism, may predispose some humans to developmental toxicity at lower blood methanol concentrations (<100 mg/l).

A4.75 The CERHR conclusions will have regulatory impact. Based on the CERHR report methanol will be classed as a developmental toxicant, resulting in labeling issues, dietary recommendations, changes in workplace exposure recommendation, and changes in ambient air standards. While methanol causes developmental effects in rodents exposed at high doses, no developmental effects are noted in humans or nonhuman primates. The mechanism(s) of action for developmental effects of methanol remains unknown. The relevance of these developmental studies in rodents to humans is unproven. Therefore it is suggested that methanol should not be considered a developmental hazard to humans Clary (2003).

Toluene

Chronic health hazard assessments for noncarcinogenic effects

The reference dose for chronic oral exposure (RfD)

A4.76 An oral RfD for chronic exposure was caluclated as 0.08 mg/kg-day with an uncertainty factor of 3000. Supporting research for the RfD was a 13 week gavage subchronic study where the critical effect was increased kidney weight in rats. The BMDL was calculated as 238 mg/kg/day and the BMD as 431 mg/kg/day (NTP, 1990). No studies for the chronic or subchronic effects of oral exposure to toluene in humans are available. A lifetime gavage study in rats (Maltoni et al., 1997) reported only carcinogenic endpoints and is, therefore, not suitable for use as the principal study for derivation of an RfD.

Evidence from human studies

A4.77 The choice of increased kidney weight as the critical effect is supported by several acute oral and inhalation human toxicity studies, indicating renal tubule toxicity. Case reports include a lethal oral exposure to 625 mg/kg toluene (Ameno et al., 1989) and a nonlethal case report of paint thinner ingestion (Caravati and Bjerk, 1997); both reported acute tubular necrosis and acidosis.

A4.78 A leather worker exposed to toluene for 40 years presented with focal segmental glomerulosclerosis (Bosch et al., 1988). Toluene sniffing has been associated with the formation of renal stones (Kroeger et al., 1980), proteinuria (Streicher et al., 1981), hepato-renal damage (O'Brien et al., 1971) and a case of glomerulonephritis reported in a woman who sniffed glue for several weeks (Bonzel et al., 1987). Several studies involving painters (Askergren, 1982; Franchini et al., 1983) or printers (Gericke et al., 2001) with toluene exposure have reported no effect on renal function.

A4.79 The choice of increased kidney weight as a critical effect is based on the above data and the available animal data. Postulated modes of action for toluene-induced kidney toxicity are described in Section 4.5.3 of the Toxicological Review (U.S. EPA, 2005).

A4.80 The RfD of 0.08 mg/kg-day was derived by the benchmark dose approach using EPA's (U.S. EPA, 2001) benchmark dose software (BMDS, Version 1.3). The benchmark response (BMR) was defined as the change of one control standard deviation from the control mean (U.S. EPA, 2000). Benchmark analysis was performed for absolute kidney weight changes in male rats (NTP, 1990).

A4.81 A BMDL of 238 mg/kg-day corresponds to the lower bound on the dose associated with a 10% increase in individuals having a kidney weight greater than the 98^{th} percentile of kidney weights in the control group (and the SD corresponding to 9% increase in kidney weight from control).

A4.82 The RfD for toluene was calculated as follows: RfD = BMDL ÷ UF, which gives 238mg/kg/day ÷ 3000 = 0.08 mg/kg-day

The reference concentration for chronic inhalation exposure (RfC)

A4.83 The current IRIS assessment for toluene takes into account a number of available human studies (mostly occupational) and incorporates new methodologies. The critical effect considered is neurological impairment.

A4.84 The average NOAEL was 34 ppm (128 mg/m^3) with UF of 10. An RfC of 5 mg/m^3 was derived by adjusting the average NOAEL for continuous exposure and application of a 10-fold UF for intrahuman variability. Evidence from multiple studies with neurological effects as the critical effect derived an adjusted NOAEL of 46 mg/m^3. Confidence in the database is high; multiple chronic studies in humans are available that examine neurotoxic effects and numerous animal reproductive and developmental studies, as well as a two-generation reproductive toxicity study, exist. There is high confidence in the resulting RfC

Evidence for RfC

A4.85 The available studies in humans indicate a relationship between neurological effects and toluene exposure at the lowest occupational exposure levels measured. There is no single study able to characterize neurological effects or specify a single critical effect. The studies used were considered to have adequate design and methods. Ten occupational studies of neurological effects from toluene inhalation include Abbate et al. 1993 (effects on hearing); Boey et al. 1997 (specific neuropsychological effects); Cavalleri et al. 2000 (colour vision impairment); Eller et al. 1999 (cognitive function and verbal and nonverbal learning and memory); Foo et al., 1990 (neurobehavioral effects); Murata et al., 1993 (motor and sensory nerve conduction velocity); Nakatsuka et al., 1992 (colour vision impairment); Neubert et al., 2001 (psychophysiological and psychomotor effects); Vrca et al., 1995 (visual evoked potentials); Zavalic et al., 1998a (color vision impairment). Not all studies examined all neurotoxicity endpoints.

A4.86 This subset of studies presents a cluster of NOAELs for neurological effects which are *generally below reported LOAELs for all endpoints.* A deficit in neurological function was chosen as the critical effect based on these neurological studies due to the overall evidence for this endpoint at low doses. Studies with known co-exposure to other solvents, studies lacking adequate exposure information or without an adequate reference group or where questionnaires were the only assessment of toxicity or exposure are not included as supporting studies

A4.87 The NOAEL (average) of 34 ppm (128 mg/m^3) was adjusted from an occupational exposure scenario to continuous exposure conditions as follows:

$$\text{NOAEL (adj)} = \text{NOAEL (average)} \times \text{VEho/VEh} \times 5 \text{ days/7 days}$$

$$= 128 \text{ mg/m}^3 \times 10\text{m}^3/20\text{m}^3 \times 5 \text{ days/7 days}$$

$$= 46 \text{ mg/m}^3$$

Where: VEho = human occupational default minute volume (10m^3 breathed during an 8 hr workday) VEh = human ambient default minute volume (20 m^3 breathed during the entire day)

A4.88 A total uncertainty factor of 10 was applied to the adjusted average NOAEL (i.e., 10 for consideration of intraspecies variation). A 10-fold uncertainty factor for intraspecies differences (UF_H) was used to account for potentially susceptible human subpopulations and life-stages.

Uncertainty for exposure of children

A4.89 This 10-fold uncertainty factor includes consideration of the model employing pharmacokinetic information to derive a chemical-specific intraspecies UF for toluene that accounts for childhood exposure only (Pelekis et al, 2001). Pelekis et al. (2001) suggest an informed quantitation of adult-to-child variability to be in the 3-fold range. The Pelekis model is based on the pharmacokinetic differences between adults and children. However, differences in human susceptibility may also be due to lifestage (e.g., advanced age) differences among the adult population, genetic polymorphisms, decreased renal clearance in disease states, and unknown pharmacodynamic variations in response to toluene exposure. Since the variability defined in the Pelekis model may not account for these additional differences in pharmacokinetics and pharmacodynamics, a full factor of 10 is used. An uncertainty factor to account for laboratory animal-to-human interspecies differences was not necessary because the point of departure is based on human exposure data.

A4.90 An uncertainty factor to account for extrapolating from less than chronic results (UF_S) was not necessary. Most of the studies used in the analysis were of chronic duration.

A4.91 An uncertainty factor was not needed to account for extrapolating from a LOAEL to a NOAEL because a surrogate NOAEL, i.e., an average NOAEL from a subset of studies, was used to derive the point of departure.

Reproductive and developmental effects

Animal studies

A4.92 Animal studies have demonstrated reproductive and developmental effects of toluene at exposure levels higher than those used for the determination of the point of departure. In addition, neurotoxicity studies and a two-generation reproductive toxicity study are available. There is some uncertainty regarding potential immunological effects of toluene via the inhalation route of exposure. Uncertainties are from conflicting immunotoxicity data on toluene following oral exposure in animal studies.

Immunologic effects

A4.93 Stengel et al. (1998) assessed several immunological parameters in blood following chronic inhalation occupational exposure to 50 ppm toluene but no statistically significant effects were observed. Aranyi et al. (1985) examined the effects of inhalation exposure on pulmonary host defenses in animals and found transient effects at low doses but no dose-response relationship. These results indicate additional research is needed to evaluate the immunological potential of toluene by inhalation.

Irritation

A4.94 In addition to neurologic effects in humans, the previous RfC on the IRIS database was based on irritation of the upper respiratory tract, (chronic study in rats, NTP 1990). However, these effects occurred in rats exposed to high concentrations (600 ppm or greater) of toluene and did not show an appreciable increase with increasing concentration (i.e., the incidence of the lesions was greater at 600 ppm than at 1200 ppm).

Human studies

A4.95 Acute studies in humans have demonstrated that subjective reports of irritation of the nose and/or eyes occurs at exposure levels of 100 ppm or greater (Baelum et al., 1985, 1990; Echeverria et al., 1989; Andersen et al., 1983) but not at exposures below 100 ppm (Echeverria et al., 1989; Andersen et al., 1983). Because neurologic effects are a more sensitive endpoint for exposed humans, neurological deficits were selected as the critical endpoint in this assessment.

Possible Childhood Susceptibility

A4.96 The US EPA (2005) suggest toluene susceptibility in children may be different to that in adults but there is only limited supporting data. Children have differences in levels of CYP enzymes and in several detoxification enzymes relative to adults (Leeder and Kearns, 1997; Nakajima et al., 1992; Vieira et al., 1996), as well as other physiological differences (see general background below Table 1. above). Toluene is lipophilic and therefore expected in breast milk high in lipids. Most absorbed toluene is rapidly eliminated from the body while a much smaller portion that gets into fatty tissue is eliminated slowly.

Evidence for Human Carcinogenicity

A4.97 Under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005), *there is inadequate information to assess the carcinogenic potential* of toluene because studies of humans chronically exposed to toluene are inconclusive. Toluene was not carcinogenic in adequate inhalation cancer bioassays of rats and mice exposed for life (NTP, 1990; Huff, 2003), and increased incidences of mammary cancer and leukemia were reported in a lifetime rat oral bioassay at a dose level of 500 mg/kg-day but not at 800 mg/kg-day (Maltoni et al., 1997). In the NTP (1990) and Huff (2003) studies, no neoplasms were

noted in male rats, and one nasal, two kidney, and two forestomach neoplasms observed in female rats were considered not to be associated with toluene exposure.

A4.98 Toluene has generally not been genotoxic in short-term testing. The previous IRIS assessment classified toluene as *not classifiable as to human carcinogenicity* under the *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 1986) based on inadequate data on the carcinogenicity of toluene in humans and inadequate evidence of carcinogenicity in animals. Toluene is not included in the *10th Report on Carcinogens* (NTP, 2002). IARC has classified toluene as Group 3 (*not classifiable as to its carcinogenicity in humans*) with a supporting statement that there is inadequate evidence in humans and evidence suggesting a lack of carcinogenicity of toluene in experimental animals (IARC, 1999).

A4.99 Available studies in toluene-exposed workers have reported very limited or no evidence suggesting carcinogenic effects of toluene exposure.

Ethylbenzene

Synonyms

A4.100 Ethylbenzol, NCI-C56393, Aethylbenzol , Ethylbenzene , Benzene, ethyl EB, Etilbenzene, Phenylethane, Etylobenzen , Ethylbenzeen , UN 1175

Uses

A4.101 Results from several chamber studies show that toluene, ethylbenzene, and xylenes are the main compounds emitted from photocopiers (Brown, 1999; Leovic et al, 1996; Tu 2003).

Chronic Health Hazard Assessments for Noncarcinogenic Effects

Oral RfD

A4.102 The oral RfD (1×10^{-1} mg/kg/day) is derived from the NOEL of 136 mg/kg/day (converted to 97.1 mg/kg/day) with an MF of 1 and a UF of 1000. The critical adverse effect is liver and kidney toxicity from rat subchronic to chronic oral bioassay studies (Wolf et al 1956). The confidence in the Oral RfD is low due to confidence in the study and the database being low.

Inhalation RfC

A4.103 The inhalation RfC (1 mg/m^3) was derived from the NOAEL of 434 mg/m^3 (100 ppm) with an UF of 300, and MF of 1. The critical effect is developmental toxicity from rat and rabbit developmental inhalation studies (Hardin et al., 1981). The confidence in the Oral RfD is low due to confidence in the studies and the database being low.

Carcinogenicity Assessment for Lifetime Exposure

A4.104 The weight of Evidence in the 1986 US EPA Guidelines did not classify ethylbenzene as a human carcinogen due to lack of animal bioassays and human studies. Neither the quantitative estimate of carcinogenic risk from oral or inhalation exposure was assessed under the IRIS Program.

Overall Summary

A4.105 The above profiles for the seven organic substances in Table A4.1 are an attempt to present the most recent research evidence with respect to adverse health effects associated with exposure to these specific organic compounds. An increasing body of published research now exists on health effects for infants and children but for only a very small fraction has any complete testing been undertaken. The rapid proliferation of new chemical compounds over the past fifty years has brought over 80,000 new chemicals into the environment with about 2,000 to 3,000 new chemical compounds added each year. Unfortunately, only 43 per cent of the existing chemicals have been tested for their toxicity, and only 7 per cent have been fully investigated in the context of neurodevelopmental toxicity (Landrigan et al, 2002).

APPENDIX 5: LITERATURE SUMMARY

A5.1 A summary of journal articles and published studies enables us to better grasp the complex nature of the topic with which we are dealing. We have tried to keep our approach comprehensive, as the dynamics of the question we are facing span beyond pure economic analysis: importantly they extend into the social, and environmental realms. Therefore, the literature we consult is holistic, and a full list of literature used for this study is placed in the bibliography, and a partial list relevant to this section, at the end of this appendix. Our report draws heavily — but not exclusively, from the below (referenced) publications, which are discussed chronologically.

A5.2 Phthalates have been addressed by the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and subsequently in their EU Directive.[67] They remain a controversial issue in the toys discussion; among consumers and firms. Certain plastics[68] used for toy parts can be built from harmful polymers and/or monomers and producers use phthalate-containing plasticisers[69] as final additives that help to soften the end plastic product, and increase its flexibility. Phthalates are thought to cause damage to the kidneys, liver and male reproductive system.[70] The CSTEE recommends that guideline values for extractable amounts of individual phthalates in toys be produced, incorporating a safety margin of at least 100 between exposure and the NOAEL values for the respective phthalates (1998).[71] We discuss phthalates in more detail later in this chapter.

A5.3 The Netherlands Inspectorate for Health Protection North conducted a study on "Plasticisers in soft PVC toys" (Bouma and Schakel) in 2001. The inspectorate did a market surveillance to evaluate the degree of compliance of toys with phthalates legislation. The results of the study showed that the market products are in compliance with legislation. Moreover, in comparison with a similar basket of toys from 1999, the majority of restricted plasticisers have been replaced with alternatives. Perhaps the most interesting result of the study highlights a vast segment of PVC toys not accounted for by the phthalate legislation but which may in fact be "very likely to be placed in the mouth" by children.

A5.4 Many of the serious health threats facing children today are not within their control—that is, they are products of the environmental surroundings. An article published in the American journal *Environmental Health Perspectives*, entitled "Environmental pollutants and diseases in American children" (Landrigan et al) hypothesises a fundamental "tide

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67 See EU Directive 1999/815/EC on the use of phthalates in children's toys.

68 Plastics are all polymers, although all polymers are not plastic.

69 Primarily diisononylphthalate (DINP) and di(2-ethylhexl)phthalate (DEHP).

70 BIBRA (1985) Project No. 3.0495.1. Report No. 0495/1/84. A 21-day feeding study of butyl benzyl phthalate to rats; effects on the liver and liver lipids. Dated October 1985; Wine RN, Li LH, Barnes LH, Gulati DK, Chapin RE (1997). Reproductive Toxicity of di-n-butyl phthalate in a continuous breeding protocol in Sprague-Dawley rats. Environ Health Perspective 105, 102-107.)

71 CSTEE. Phthalate migration from soft PVC toys and childcare articles. Opinion expressed at CSTEE 3rd Plenary Meeting Brussels 1998

change" in the nature of child illness.[72] While traditionally the main threats to children's health were infectious diseases, the current threats appear to come increasingly from the environment including chemicals in air, food, water, and from proximity to individual exposures.

A5.5 The article explains that chronic illness including asthma, paediatric cancer, neurodevelopmental and behavioural disorders, congenital defects, etc. are becoming increasing burdens on society. The rapid proliferation of new chemical compounds over the past fifty years has brought over 80,000 new chemicals into the environment. In any given year the American Environmental Protection Agency (EPA) is faced with about 2,000 to 3,000 new chemical compounds. Unfortunately, only 43 per cent of the existing chemicals have been tested for their toxicity, and only 7 per cent have been fully investigated in the context of neurodevelopmental toxicity. The article examines in detail the incidence of a few major environmental chemicals, using a detailed methodology aimed at formulating a better strategy to deal with this ongoing problem.

A5.6 In 2004 the Inspectorate for Health Protection North carried out a "Market surveillances on toy safety", which, similar to the 2001 report, examined toys on the market for relative levels of safety. This study was broader in scope, as it consisted of five market surveillances: for isophoron and phenol in floatable toys; lead and cadmium in wooden toys; wood preservatives in wooden toys; azo dyes in textile toys; and flammability of textile toys. Toys sampled came from the EU Member States, as well as locations in the Far East such as China and Indonesia.

A5.7 The results of the market surveillance were generally reassuring, although of the five examinations, only the floatable toys were all in perfect compliance. In the case where toys did not meet standards, "official measures were taken against the importers" of the toys.

A5.8 Another market surveillance study in the Netherlands, this time carried out by the Food and Consumer Product Safety Authority, examined plastic toys. They do not regard monitored phthalates as the only threat presented to children from plastic toys, and the authors highlight the presence of several other dangerous plastics and plasticisers. Furthermore, they chose not to overlook the presence of non-phthalate/plasticiser additives, and noted the presence of monomers, oligomers, compounds for dyes and inks, flame retardants, etc. in the self-same group of plastic toys. Despite an ambitious analysis, the authors were conservative in their suggestions: and no action was taken against industry stakeholders. Rather, the study should be used as input for future market surveillances once further closure can be taken from the conclusions.

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

A5.9 The Netherlands Food and Consumer Product Safety Authority also conducted a specialised investigation on the "Migration of n-nitrosamines and n-nitrosatable substances from latex balloons" in 2004. The inquiry arose as a response to a German investigation into a Dutch balloon supplier in 2002 that yielded very poor results. Due to the imminent carcinogenicity of nitrosamines and nitrosatable substances, legislation was passed in the Netherlands which requires strict labelling of balloons, and mandates the complete phasing out of these substances in the long term.

A5.10 While the compliance levels had improved on average, the results were still poor: in 2002 only one out of 57 tested balloons complied with the migration limits as set for teats and soothers;[73] in 2004 eight balloons out of 58 complied. The implications of this result may imply a larger problem for the balloon industry. Page 55 of the RPA report (discussed below) maintains that

A5.11 Information received from industry indicates that…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.

A5.12 This implies the need, if the EU balloon market is to survive, for a significant investment in research and development.

A5.13 Scrutinising plastics once more, the Danish Ministry of the Environment conducted a rigorous "Survey, migration and health evaluation of chemical substances in toys and childcare products produced from foam plastic" (Borling et al., 2006). (Foamed toys are mainly produced from ethylene vinyl acetate [EVA] and polyurethane [PUR].) The overarching strength of this study springs from its detailed quantitative analysis of the content, migration rates, chemical properties and risks, and migration limits of a range of compounds found in plastic toys.

A5.14 The methodology was divided into three phases: a survey of toys and childcare articles from the Danish market and their chemical composition; determination of whether the content of eight selected products included hazardous substances, and of what amounts; and setting up toxicological profiles of five primary phthalates[74] and their subsequent exposure assessment (see Table A5.1).

[73] See EU Directive 93/11/EEC.

[74] Diisobutylphthalate (DIBP), di-n-butylphthalate (DBP); diisononylphthalate (DINP); monobutyltin (MBT); and dibutyltin (DBT).

Table A5.1: Plastic products surveyed

Product No.	Product
1	Sword
2	Floor puzzle 1
3	Swim board
4	Activity carpet
5	Mask
6	Book
7	Floor puzzle 2
8	Ball

Source: Danish Environmental Protection Agency, 2006

A5.15 The article carefully outlined all of its calculations. The study found two out of eight of the products to contain concentrations above 0.05 per cent, which is the permitted limit value for phthalates in toys for children between 0-3 years. It recommended therefore that more attention be given to foamed toys and childcare products.

A5.16 In addition to studies with specialised focus, our work has been informed by a number of recent reports on how best to approach the problem of safeguarding toys from dangerous chemicals, both commissioned by the EU DG Enterprise. One report, "Chemicals in toys: a general methodology for assessment of chemical safety in toys with a focus on substances" (Van Engelen et al.), deals directly with the problem of chemical analysis in toys. The stated objective of the report is to review and assess the migration limit values for the chemicals catalogued in the Annex of the TSD. Additionally, it attempts to determine whether other substances not included in the TSD should be.

A5.17 The study is extensive and gives a background for many substances, a review of exposure to chemicals in toys, a proposed methodology for determining migration limits, and a discussion of how to best apply this methodology. The study concludes by reviewing what it considers to be the most prominent substances and recommending maximum migration limit values. For the latter task the study refers to and discusses limits set by major international government policies and recommendations, including the Food Contact Material legislation. An interesting, perhaps admirable aspect of the approach of this study is in its risk-based methodology: the study rests heavily on the assumption that since children are exposed to many harmful substances in their living environment—independent of the toys they play with--on a daily basis, this unspecified exposure must not be overlooked when determining appropriate migration limits for toys to comply with a child's Tolerable Daily Intake.

A5.18 The other DG Enterprise report, by RPA, is a "Study on the impact of the revision of the Council Directive 88/378/EEC on the safety of toys". This report is more economic and contextual in its approach, although it does not focus exclusively on chemical properties. After providing a detailed economic analysis of the EU toy sector, as well as an expansive explanation of the TSD, RPA reported on the results of a study they conducted whereby a number of stakeholders were consulted about possible modifications they would like to

see in the revised TSD. Further to this, RPA carried out a cost-benefit analysis of the impact of these proposed modifications. Stakeholders comprising of consumers, producers, and regulatory powers proposed that possible areas for modification include the definition of toys, toy marking and labelling regulations, third party verification, chemical safety requirements, etc.

A5.19 Because it was yet unclear which modifications would be adopted, the report selected a range of changes and used sensitivity analysis to derive results for three different cost scenarios. Some of the many notable results from the analysis include the expectation that the burden of costs to the proposed revision would fall disproportionately on smaller companies, who arguably comprise of the backbone to the EU toy economy. Of interest was also the prediction that very minor policy changes in order to increase vigilance for counterfeit toys may well lead to significant benefits to the industry.

A5.20 The proposed modifications to the chemical properties policy were not well defined, probably because of the complexity of the issue, and the failure of the existing TSD to provide a sufficient framework within which to think about this. According to the report, "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". Also noted was uncertainty over the need to restrict Category 1, 2, and 3 CMR substances, as well as a general demand for a unanimous EU compliance testing procedure.

A5.21 A concurrent development with the decision to revise the TSD has been the formulation of a new system for chemical regulation in the EU, REACH (Registration, Evaluation, and Authorization of Chemicals). Although REACH is not exclusively aimed at children, it has definite implications for children's health. Prior to this, the Children's Environment and Health Action Plan for Europe (CEHAPE) was adopted in 2004. According to Tamburlini in his article, "New developments in children's environmental health in Europe",

A5.22 The rationale of the CEHAPE is based on a thorough review of the scientific evidence on children's environmental health and on a study that quantified for the first time the burden of disease related to the main environmental exposures of children and adolescents in Europe. The Action Plan suggests actions and policies to achieve the four main priority goals: clean air, safe water, chemical and physical agents, and injuries. Over the same period, the European Commission has strengthened its focus on environment and health issues, has supported research on children's environmental health, and has developed a proposal for a new EU regulatory framework for chemicals that has clear implications for children and for the reproductive period.

A5.23 Tamburlini's article details the policy measures of REACH, CEHAPE, and other campaigns. It explains that CEHAPE was formed after the 1999 Third Ministerial WHO Conference on Environment and Health concluded that

A5.24 all developing organisms, especially during embryonic and foetal periods and the early years of life, are often particularly susceptible and may be more exposed than adults to

many environmental risks [that] despite differences in sensitivity and exposure to many toxic agents, safety standards for chemicals and maximum doses of exposure are still based mostly on criteria used for adults.

A5.25 In light of this notion, the author shows that REACH has perhaps a more significant role in dealing with the need for attention to children's chemical policy than it seems. It places the burden of proof for chemical compliance on industry, not consumers. This takes into account the relative lack of power enjoyed by children in representing themselves, and enables legislation to act on their behalf. Ultimately REACH would "hasten the end of the vast ongoing toxicologic experiment in which chemicals are being tested on children worldwide instead of in the laboratory". It goes without saying that for it to achieve this success, a cooperative effort and forceful determination on the part of many parties will be required.

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APPENDIX 6: STAKEHOLDER CONSULTATION

Introduction

A6.1 In this section we aggregate the views and opinions of stakeholders we have consulted during the writing of this report. Stakeholder views have been gathered via pilot interviews, a questionnaire programme, and more in depth stakeholder interviews. For the purposes of this report all respondents remain anonymous.

A6.2 The views presented here are clustered around certain themes relevant to the assessment of impacts. They have been useful in assisting us develop our assessment framework and model, as well as pointing out current industry practices and future challenges.

A6.3 This section also includes stakeholders' views on the proposed revision options. We should stress that the views expressed below are those of stakeholders and we do not necessarily agree or endorse any or all of them. Further, we stress that this stakeholder consultation was done in a short timescale and should not be regarded as a substitute for a full European Commission consultation on revising the chemical requirements of the TSD.

A6.4 A summary of results from the questionnaire survey is placed in the next appendix.

Consultation

Views on the toys industry

A6.5 Stakeholders directly involved in the manufacture and distribution of toys informed us that it is misleading to think of toys as a homogenous product, and that it is not possible to speak about a "generic" toy for analytical purposes. Indeed, as the list below shows, there is a wide range of toy types currently available in the EU.

Table A6.1: Toy categories

Main category	Examples of sub-categories
Action Figures & Accessories	Action figures, action figure accessories and action figure role play.
Arts & Crafts	Reusable compounds, sculpture kits, mechanical design, paint supplies, craft kits, paint kits, and crayons/markers/pencils/chalk.
Building Sets (02)	Building sets
Dolls	Nurturing dolls and accessories, fashion themed dolls and accessories, play-sets, and display dolls.
Games/Puzzles	Card games, trading card games, travel games, preschool games, children's games, family games, adult games, table-top games, plug 'n' play games, and puzzles.
Infant/Preschool Toys	Mobiles, rattles, walkers, play gyms, bath toys, musical instruments, figures and play-sets, learning toys, role-play toys, and push and pull toys.
Youth Electronics	Including hardware, software and accessories and robotic/interactive playmates.
Outdoor & Sports Toys	Tricycle/pedal ride-ons, non-pedal ride-ons, battery operated ride-ons, skates, skateboards, scooters, winter sports toys, pools, water and sand accessories, water guns, bubble toys and solution and playground equipment.
Plush	Traditional and special feature plush toys and puppets.
Vehicles	Powered vehicles such as radio controlled vehicles and non-powered vehicles.
All Other Toys	Models and accessories and pretend play and educational/musical toys.

Source: NPD Group Inc.

Note: not all categories are classed as toys for purposes of the TSD.

A6.6 However, it should be noted that some manufacturers do not think of toys in this way either; preferring instead to class their toy along age ranges.

A6.7 Stakeholders noted that while the larger toy manufacturers will typically produce toys in multiple categories (either branded or not); smaller companies tend to produce only in one category, operating in niche markets. Further, the revenues of toy companies are predominately based on toy sales through third party retailers, meaning that toy companies are not conglomerates having a diverse set of revenue streams.[75]

A6.8 In terms of manufacturing locations, stakeholders revealed that most toys are now produced in the Far East (predominately China). However, there are notable exceptions.

[75] Our questionnaire survey also revealed that at most 10 per cent of revenue for toy companies is generated directly via their own online stores.

Some large manufacturers still retain significant production in the EU and other toy products such as outdoor activities are still regarded as economically viable in the EU.[76]

A6.9 It was noted that while the development cycle of a new toy is relatively short, the development cycle of a new chemical input is much longer; the implication being that having to research for new chemical substitutes might delay new toys coming to market.

Toy testing and standards

A6.10 The European toy industry, in general, is in favour of well defined standards. Stakeholders claimed that the toys industry has a very good safety record with relation to chemicals and adheres to very strict safety standards. It was noted that for many toy manufacturers and importers a limit on a chemical is often regarded as equivalent to a ban on it (unless the chemical is indispensable to the product). Thus, lowering limits for many manufacturing and importers will not have any material difference on chemical amounts as they are not used in any case.

A6.11 We were informed that, in general, the industry regards all parts of EN71 (including EN71 9-11) as mandatory and compliance with the standard is said to be high.

A6.12 Most toy manufacturers self-certify their toys using the EN71 series of standards. Self-certification remains popular for technical information about raw materials and the production processes. If a toy company knows that a particular substance is not used in its manufacture then it is not tested for it. The testing is normally done on-site or at the companies' headquarters in Europe.

A6.13 However, there are a large number of toy companies (mostly importers and smaller manufacturers) who do require external testing by third-party labs. It was reported that labs are set up to do the testing specified and to interpret the standard and its requirements according to the written standards. For additional chemicals (e.g. phthalates, azo dyes etc.) specific tests have been developed and some labs can do these tests also (but not all). There is said to be no history in the toy world for testing other CMRs etc.

A6.14 Where testing is done externally, the cost varies considerably between toy type. The cost is seen as more a reflection of the number of materials used to make the toy, rather than the particular traits of the toy. For example a soft toy with several differently coloured fabrics would be more expensive than one made with only a few fabrics. We were informed that testing is usually done on each different (and differently coloured) material.

[76] Other Member States identified in our questionnaire in which there is significant toy manufacturing industries include Cyprus, Denmark, Ireland, the Czech Republic, Hungary, the Netherlands, and Spain.

Views on the chemicals in toys

The use of chemicals

A6.15 Like most durable products, the manufacturing of toys does involve the addition of specific chemicals. Our current understanding, based on stakeholder discussions, is that chemicals enter into toys through a number of different channels. In some cases, the chemicals are added very early in the process as part of the raw material, whereas in other cases, added chemicals are used in the toy manufacturing process to "stabilise" the toy, i.e. to preserve some characteristic such as the colouring and physical integrity. Other chemicals used to produce toys have preservative properties which help to prolong the life of the toy.

A6.16 Most potentially harmful chemicals are used for their ability to help shape the physical properties of toys such as structure and colour. The majority of substances that fall into this category are used to produce textiles and plastics for toy parts, although manufacturers of wooden toys may also use some azo dyes or leaded paints as colourants. Because of the usefulness of such chemicals, there is significant overlap between chemicals used in textiles and plastics. Manufacturers also use plasticisers as additives that help to soften the final plastic product, and increase its flexibility.

A6.17 Stakeholders further reported that certain plastics used for toy parts are built from known harmful polymers and/or monomers. Some also require the use of solvents in their production processes.

A6.18 However, we were informed that these potentially harmful substances are normally "trapped" in the toy material during production and so cannot normally migrate to users. Generally plastics are inert and are not known to give off chemicals. The exceptions to this are phthalates, which are governed by their own legislation.

A6.19 Finding out what chemicals are actually being used in a given toy was regarded as not a trivial task, especially for smaller manufacturers and importers. Toy importers and some manufacturers were said to be loath often to precisely define precisely what exact chemicals (and their amounts) are in toys (beyond saying they comply with legislation), as often they do not know themselves because of the length of supply chains. It was noted that in some cases chemicals may also have different names in different jurisdictions (e.g. DHP has multiple names) or that the trade name of the chemical is not the same as its scientific name. However, we were told that the factories ultimately producing the toys will know the additional chemicals added.

A6.20 It was also alleged that some importers have brought in toys from the Far East which have not been checked properly, despite having a CE marking — raising the issue of compliance and counterfeiting of toys (which is seen as a growing problem).

A6.21 Of the additional chemicals contained in the three proposed approaches, it was thought that other heavy metals are rarely used in toys, e.g. silver is not a common toy

component. Indeed, it was noted that out of all the heavy metals stated, only aluminium, lead, chromium and zinc are ever found in toys.

Chemical safety

A6.22 Stakeholders raised the point that data relating to migration of chemicals from toys is very limited. Stakeholders were unable to point to evidence or data on specific impacts on children from chemicals in toys. It was also noted that while consumer groups and some governments have expressed dissatisfaction with the use of certain chemicals in toys, no complaints relating to chemicals in toys have yet been received.[77]

A6.23 However, despite not identifying specific conditions associated with the chemicals, stakeholders did report possible effects stemming from excessive exposure to certain chemicals.

Table A6.2: Possible safety issues with certain chemicals

Chemical	Safety issue identified
Lead	Neuro-toxicity
Arsenic	Possible carcinogen
Mercury	Neuro-toxical potential
Cadmium	Nephrotoxical and can cause skin allegories
Nickel	Can cause skin allegories
Strontium	Radioactive
Antimony	Antibacterial

A6.24 A number of these issues are detailed further in the 2006 RIVM Advisory Report to the EC and studies carried out by the Danish Consumer Council (2004 and 2006).

A6.25 However, there is no consensus on scientific studies and their results, as some stakeholders noted however that while most of the chemicals named in TSD and the three revision approaches are toxic theoretically, the exposure from toys is virtually non-existent.

A6.26 Data do exist for formaldehydes and solvents, and these are seen as a particular risk for children, especially in confined spaces such as children's tents.

A6.27 A further potential risk was highlighted: that of a given chemical coming into contact with another and becoming contaminated.

[77] However, in should be noted that the RAPEX system has flagged up a number of issues relating to chemicals in toys.

A6.28 No stakeholder expressed concerns about the use of the chemicals currently named in the TSD (both in terms of their use and use amounts). It was noted that the current safety guidelines are more stringent now than in the 1970s, but the incidence of accidents related to chemicals has not changed (virtually zero). However, some concerns were raised about phthalates and the fact there is a large area of phthalates (800 possible) chemicals, many of which were not regulated before the new Phthalates Directive.

A6.29 In terms of actual cases known, we were informed that the Swedish Poison Information centre reported a 10 year old boy was poisoned by cadmium in crayons and that a 6 year old boy was poisoned by cobalt contained in liquid used in a chemicals toy set — but these cases would appear to be isolated.

A6.30 During tests of toys, formaldehydes, flame retardants, CMRs and some heavy metals (lead and chromium) have all been found.

Alternative chemicals

A6.31 If certain chemicals were banned or restricted, then the use of substitutes may be required.[78] However, we were informed that chemical substitutes for those chemicals in the Directive are less well defined, and could potentially pose their own risks. A further competition substance was raised in that banning certain substances will mean that only the larger, well resourced companies can afford to conduct research to find substitutes.[79]

A6.32 For some chemicals, such as Bisphenol A, it was reported that it would difficult or nearly impossible to find a substitute. The example of San Francisco was given, where in 2006 the city banned the sale of products with any level of Bisphenol A, meaning that a wide range of products could no longer be sold in the area. The ban was later repealed.[80]

Chemical safety challenges

A6.33 The following challenges for the toys industry were identified regarding chemicals and safety:

(rr) To ensure that any potentially harmful chemicals contained in toys remain trapped in the toys, and if released, may only be released in amounts that are safe for children;

(ss) From a safety point of view maintaining the definition of toys and products shaped and designed like toys;

(tt) To find and use safe chemicals and to find alternatives to the dangerous and classified chemicals; and

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[78] Where banned was understood to not be the same as allowing for trace substances.
[79] Although this should not be overstated, if there are externalities and other firms can licence the chemicals.
[80] See http://www.bisphenol-a.org/whatsNew/20070531SanFranciscoRepeal.html

(uu) Complying with chemical requirements in the absence of meaningful exposure data.

A6.34 A general challenge to the toys industry (not related to safety) was commonly given as the threat of electronic video games.

Criticisms of the existing TSD

A6.35 Generally speaking, we did not hear many criticisms of the current TSD. Those that we did hear included that:

(vv) at present the TSD only refers to heavy metals;

(ww) currently, surveillance and enforcement of the TSD is said to be poor; and

(xx) the current EN71 standards are not comprehensive enough.

A6.36 We note that the three proposed approaches all address the first concern.

A6.37 The REACH Directive was argued not to affect toys much due to the low amounts of chemicals in them. However, it was also argued by some experts that REACH does not address a number of chemicals and will be not fully effective until 2018 when it will be wholly enacted.

A6.38 A concern was also raised that potentially there may be some confusion between a multiplicity of standards applicable to toys coming from the TSD, REACH, Food Contact Directive and other directives/regulations.

A6.39 One further concern was that currently there is no reporting system of adverse chemical effects of toys. There is no efficient post-marketing system, where consumer (and health professionals) awareness of potential adverse effects of toys are elicited. It was claimed that most of the adverse reactions are neither reported nor recorded. The quality of collected data is often poor, mainly due to insufficient involvement of manufacturers, dermatologists, authorities and even affected consumers.

Views on the proposed revision approaches

A6.40 Unsurprisingly, there was a wide range of opinions on the three proposed approaches for revising the chemical requirements in the TSD. One common concern among those directly involved in the toy industry was a lack of consultation over changes to chemical requirements in the TSD.

A6.41 Within stakeholders, there were advocates for both the risk-based approach and the hazard/risk-based approach with authorisation by Comitology procedure. It should also be noted that there was a body of opinion which argued for the current status quo, claiming the existing EN71 regulations are sufficient.

A6.42 One hope expressed was that any new approach should be linked to the one already in place. Some interviewees suggested harmonisation with food safety regulations, which would also minimise costs. Indeed, the cost of monitoring and enforcement for safety agencies was raised — more chemicals in the TSD would require more monitoring.

A6.43 On the side of industry, it was contended that the toy industry has already complained of the risk of too many regulations and some argued the Commission should try to reduce the cost of compliance for producers and not increase it.

A6.44 The cost of the options was also a point of concern for industry stakeholders. Currently, manufacturers do not actively look for the additional chemicals included in the three proposed approaches, and so this will necessitate a new level of testing. For some of the larger companies this will be a minor expense, but for smaller companies the costs of additional testing were reported to be far from trivial and the chemical requirement revision may disproportionately affect SMEs. Further, testing for CMRs was reported to be extremely difficult, unless one was investigating for specific CMRs, i.e. one must test a toy for a particular CMR rather than test it for its chemical make-up.

A6.45 Manufacturers also noted that it is impossible to guarantee against the possibility of trace substances in toys. An absolute ban on CMRs 1 and 2 was regarded as unacceptable, and it was suggested that a better word would read along the lines “trace substances will still be allowed unless the level exceeds 0.1 per cent w/w of the toy material”.

A6.46 It was also that the ban of CMR 3 under approach 3 goes beyond the safety requirement regime of the Food Contact Materials Directive and the Cosmetics Directive.

A6.47 On the specific chemicals and limits, certain industry stakeholders had particular concerns:

Table A6.3: Industry views on chemical limits

Chemical	Comment
Cadmium	The reduction in the allowable amount is seen as a cause for concern, due to potential traces of the substance.
Organic tin	The limit given is not regarded as feasible.
Chromium VI	The proposed limit is regarded as too small to be detectable.
Zinc and Aluminium	There is concern about a lack of testing methods for these substances.

A6.48 Particular concern was voiced over the new zinc limits, given that zinc is a vital component for die-cast toys. The proposed limit was contended to be too high for die-cast toy makers and their viability would be threatened.

A6.49 A general concern was raised that unless new testing standards were developed (along the lines of EN71-3) there may be some confusion in having harmonised testing regimes.

Indeed, other respondents argued that the EN71 standards themselves would need to be revised in light of new chemical requirements in the TSD.

A6.50 A further concern raised by some stakeholders was the uncertainty surrounding the scientific base. This was reported to be constantly evolving and it was deemed not good practice to base new legislation on an evidence base which has conflicting studies and no consensus.

A6.51 It was argued that regardless of the approaches chosen by the EC, the only way that toy companies will be able to comply with the new TSD would be to have much more extensive product information files, which will contain information on those chemicals known to be deliberately added — trace substances may still exist. Unlike other essential requirements (e.g. mechanical) which rely on the quality of manufacture, the presence of certain chemicals can be ascertained using product and raw material knowledge.

A6.52 A practical consideration was raised that the implementation of each approach might take many years. The example of the Phthalates Directive was citied — which took over eight years to be agreed.

A6.53 It should also however be noted that a view was expressed by a minority of stakeholders that approach 3 did not go far enough and that all CMRs should be banned and no trace substances allowed.

Views on what should be included in any revised TSD chemicals requirements regime

A6.54 As with views on the three proposed approaches, there was a diversity of opinion on what should and should not be included in any revision of the TSD chemicals requirement regime.

A6.55 A small proportion of stakeholders were of the strong opinion that all CMRs should be banned and that a hazard based approach was preferable as risk assessment is underdeveloped for a number of chemicals. In contrast, others argued for contain a mixture of a risk-based approach (where limits are set for known dangers) and a hazard-based approach for CMRs.

A6.56 A number of further chemicals were identified as problematic and in need of attention. Rubber products and latex rubber were identified as additional chemicals to be included in the revised TSD. In addition, sensitising substances and substances dangerous to the environment were suggested to be included. The former should also be included, and possibly banned as the risk assessment on these is limited, and the latter would include bio-toxic substances in toys.

A6.57 One stakeholder argued that further regulation was required, especially for organic chemicals — but it should not always be the responsibility of the producer to test for these chemicals.

A6.58 Many stakeholders also requested that any revision of the TSD should take into account the EN71 standards and other voluntary arrangements currently enjoying support in the industry. A large number of respondents advocated the harmonisation of the remaining EN71 standards (9-11).

A6.59 Many stakeholders accepted that new regulations should not bring undue additional costs to manufacturers, although a minority did argue that safety concerns should always trump economic ones.

A6.60 A small number of stakeholders expressed the desire to have comprehensive legislation that covers all dangerous chemicals. It should be comprehensive to ensure complete consumer protection and have effective market surveillance mechanisms.

A6.61 It was also argued by a few stakeholders that environmental requirements should be explicitly be written into any revisions on the TSD.

A6.62 It was noted that fragrances are already regulated, e.g. through the Cosmetics Directive and the Medics Directive. Thus it was suggested that labelling for toys could be improved to account for fragrances so that parents are aware at the point of purchase of potential allergy-inducing chemicals contained in the toy.

Summary of stakeholder views heard

A6.63 We note again that time constraints prohibited us from conducting a complete stakeholder consultation. From our limited discussions, the following are the most salient observations:

(yy) The industry currently follows a number of standards, a number of which are voluntary, but are regarded as mandatory. However, concerns were raised that there are still toy companies that are not in compliance with standards and that surveillance systems were weak.

(zz) Currently the use of the additional named chemicals mentioned in all three proposed revision approaches is rare. The use of CMRs is more common, but the migration risk to children is seen as low to non-existent. However, it was acknowledged there will always be (harmless) trace substances in toys.

(aaa) It will be difficult to find alternatives for certain chemicals if they are banned. The example of San Francisco was given where Bisphenol A was banned and toys were no longer available in the city.

(bbb) The costs of testing vary, and requirements for substantially new levels of testing will be particularly onerous on SMEs.

(ccc) In general, the current TSD is regarded favourable and is said, along with the EN71 standards, to be effective.

(ddd) There is a wide range of opinion on the proposed approaches for revision with no clear consensus, even between common stakeholder groups.

(eee) A number of practical concerns have been raised about the three approaches, e.g. costs of testing.

(fff) The benefits of the proposed approaches are not well known amongst many stakeholders.

(ggg) A minority of stakeholders feel the proposed approaches do not go far enough.

APPENDIX 7: SUMMARY OF QUESTIONNAIRE RESPONSES

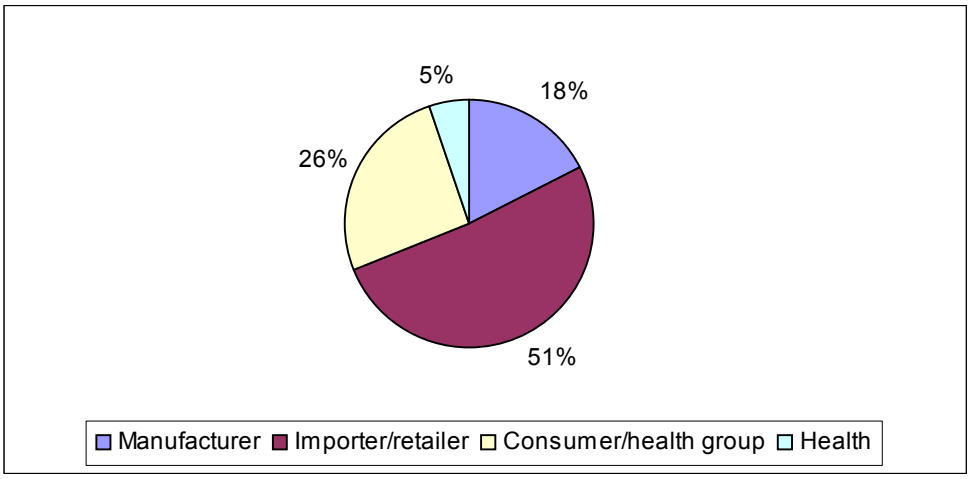
A7.1 This appendix presents an overview of the results from our online questionnaire.

General responses

Breakdown of respondents

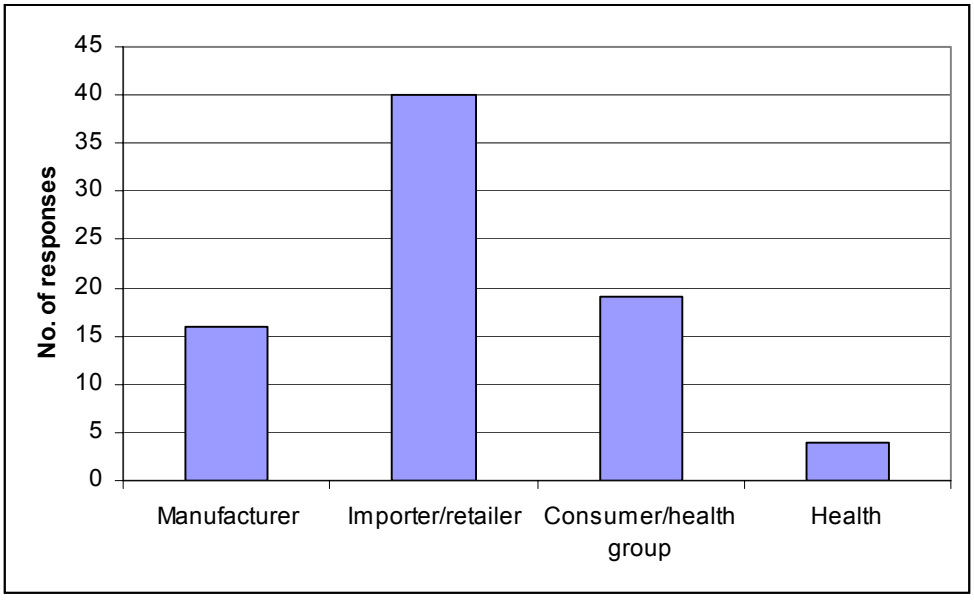
A7.2 As the chart below shows, the majority of responses to our questionnaire came from those directly involved in the toys industry as manufacturers, importers and retailers.

Chart A7.1: Breakdown of response by type



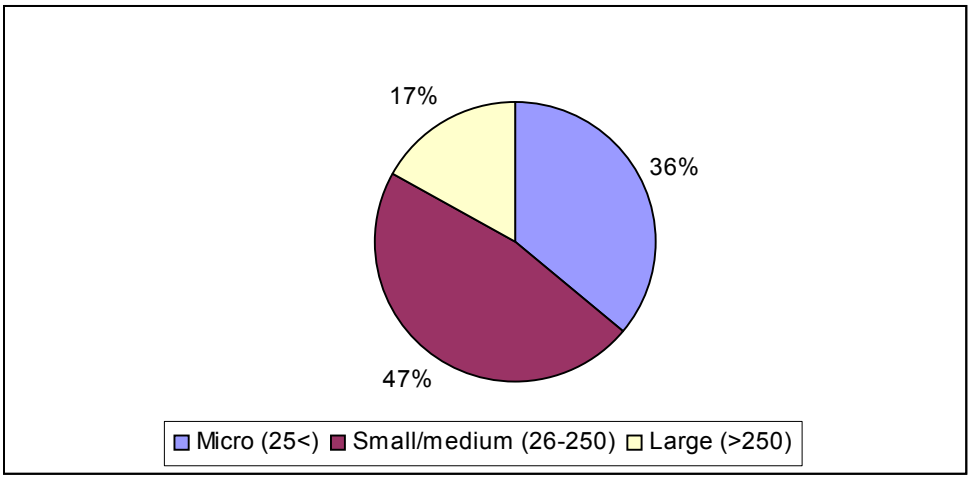
A7.3 The chart below shows the breakdown of actual responses by category type:

Chart A7.2: Number of responses



A7.4 When examined by company size, the type of importers and manufacturers broadly coincided with the structure of the European toys industry, i.e. most firms being SMEs.

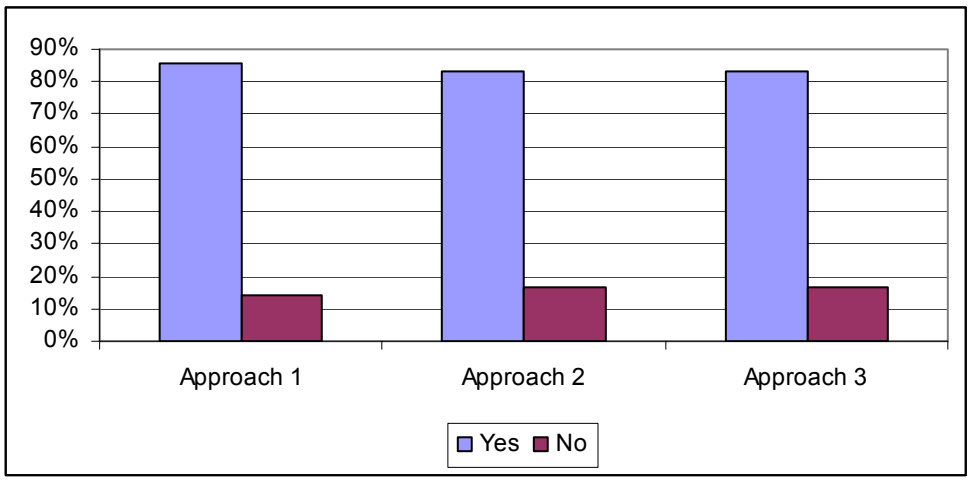
Chart A7.3: Size of companies



Manufacturers

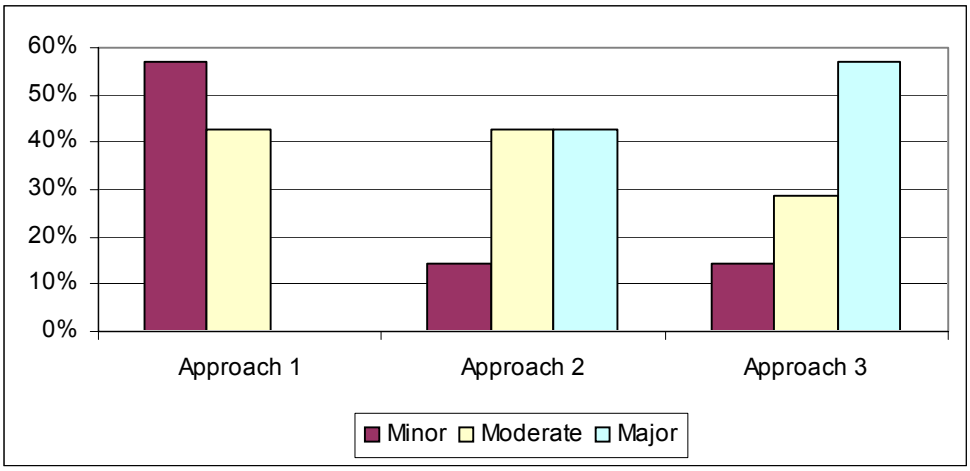
A7.5 The charts below set out manufacturers' responses to questions regarding the expected impact of the three approaches. As Chart A7.4 shows a large proportion of manufacturers believe each of the three approaches would lead to changes in their processes. However, one should add the caveat that these responses are perceptions and in actuality the impact of the three approaches may be much less than initially predicted as firms are able to react and adapt.

Chart A7.4: Would any of these approaches entail a change in your manufacturing processes?



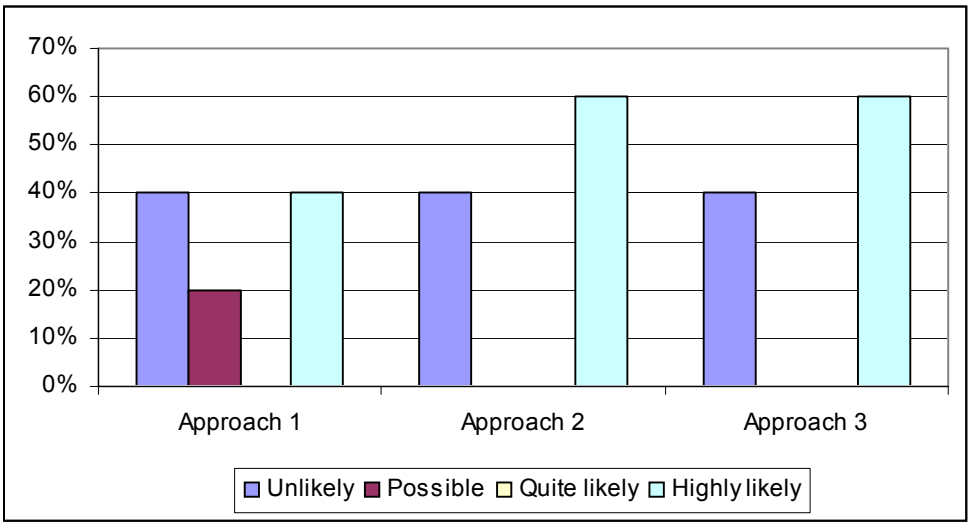
A7.6 In terms of the actual magnitude, approach 1 is seen as having the smallest change, while approaches 2 and 3 are associated with major changes to the manufacturing process.

Chart A7.5: If there were to be a change in the overall manufacturing process, how large would this change be?



A7.7 As the above chart shows number of respondents felt that their manufacturing processes would have to change, and this is reflected in the chart below on any one off capital expenditures.

Chart A7.6: Would the change involve any significant capital expenditure?



A7.8 The following charts break down the change to manufacturing companies by task. While respondents reported that there would be minor to moderate change in administrative processes, there would be a strong (over 20 per cent) increase in time spent doing quality assurance — this is perhaps not surprising as this is where the main impact of the three approaches are most directly felt.

Chart A7.7: If there were to be a change in the overall administrative process, how large would this change be?

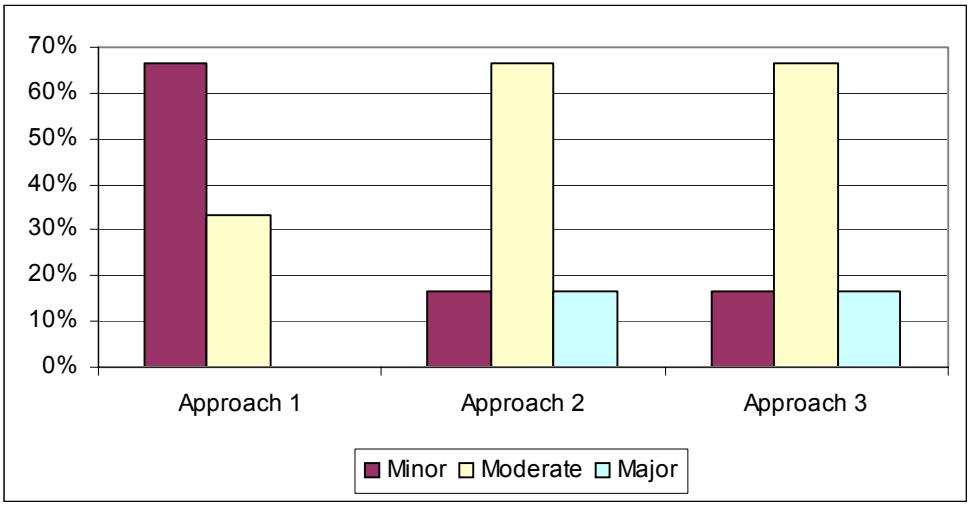
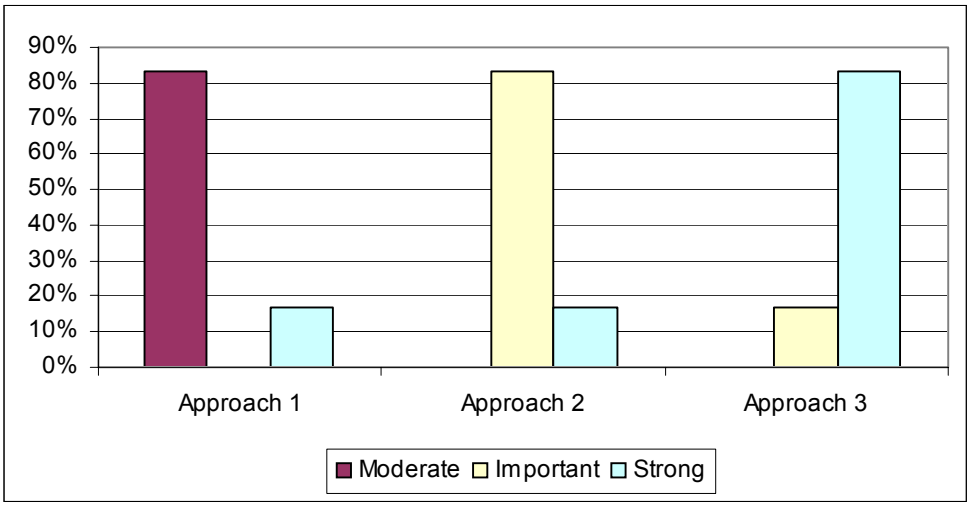
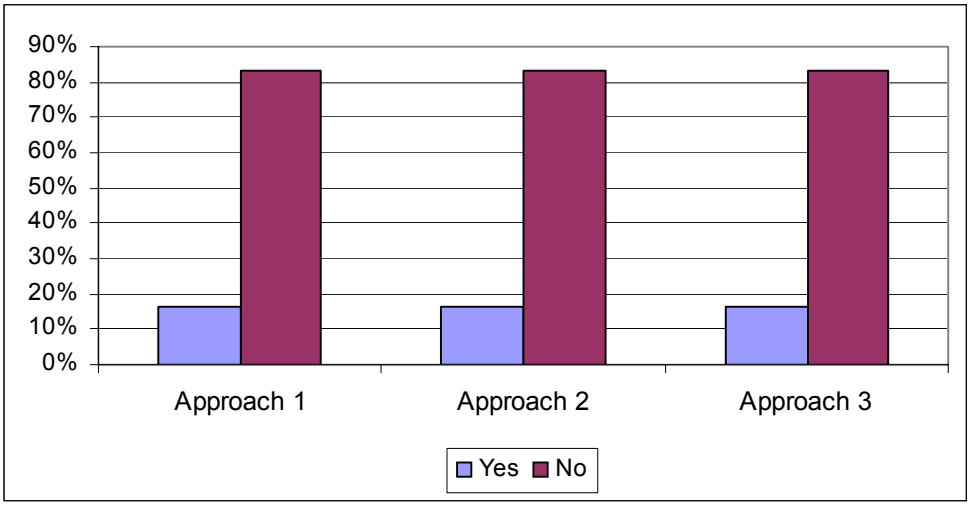


Chart A7.8: What would be the change in the amount of time needed for quality control?



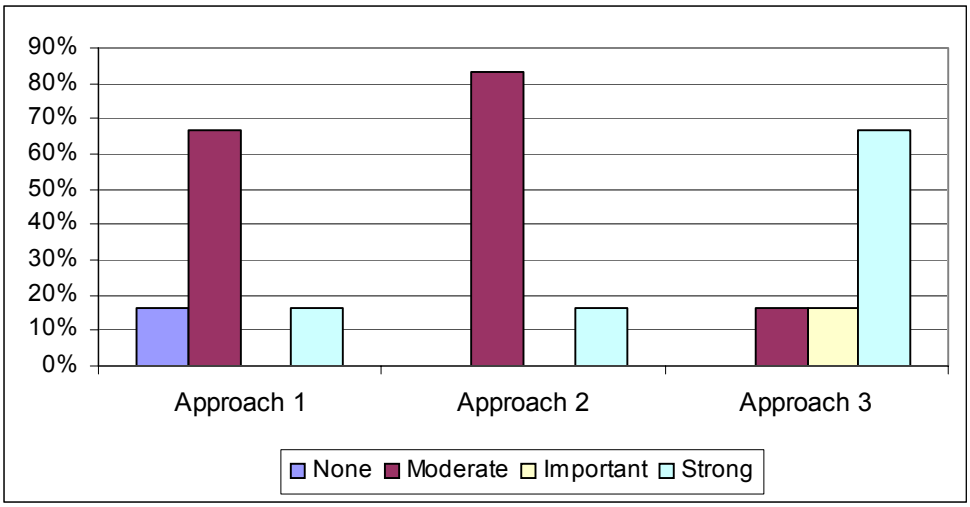
Where: strong (+20%), important (10-20%), moderate (0-10%) relative to existing procedures

Chart A7.9: Would your distribution procedures have to change?



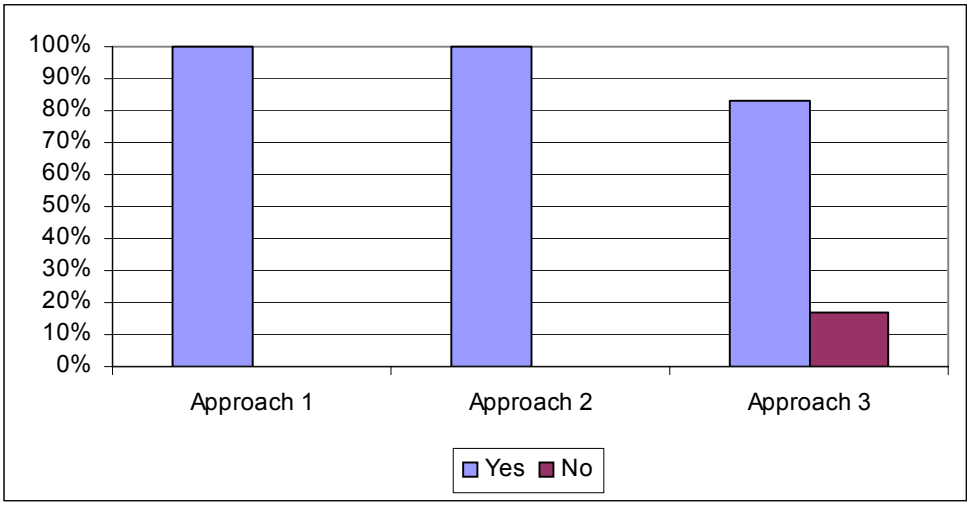
A7.9 The expected final impact on the price of toys was reported to range from none to moderate for approaches 1 and 2, and strong for approach 3.

Chart A7.10: What impact would you expect on the price of your toy?



A7.10 Encouragingly, overwhelmingly, manufacturers indicated a willingness to adapt and keep manufacturing their toys.

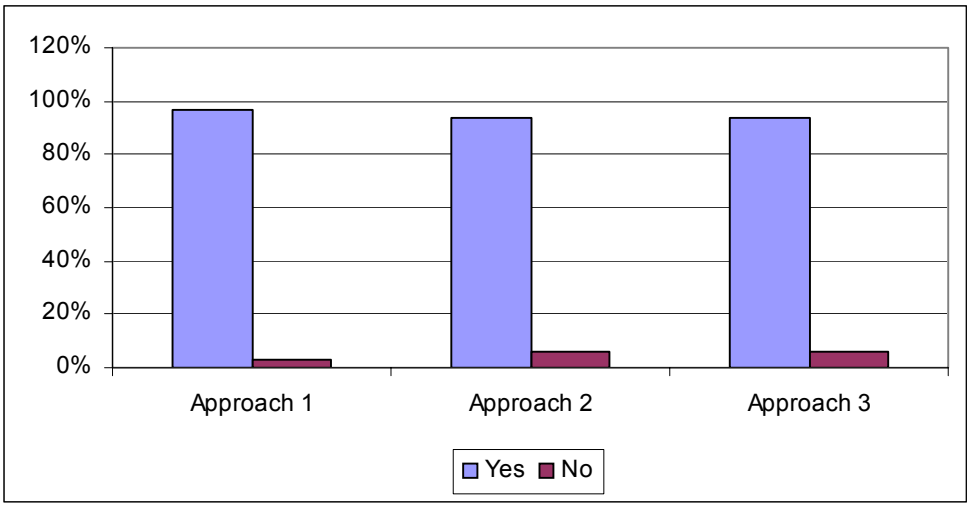
Chart A7.11: Would you continue to manufacture and/or distribute the toy?



Importers/retailers

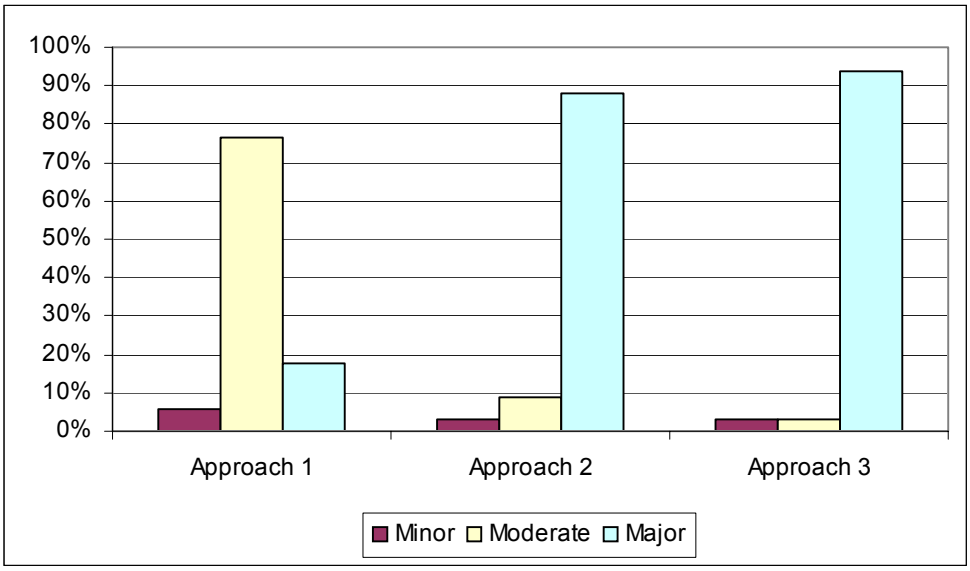
A7.11 A similar series of questions were asked of importers and retailers. Regarding the questionnaire as to whether approaches to importing and retailing would change, most firms replied in the affirmative. It should also be recalled that most importers are small firms.

Chart A7.12: Would any of these approaches entail a change in your importing or retailing processes?



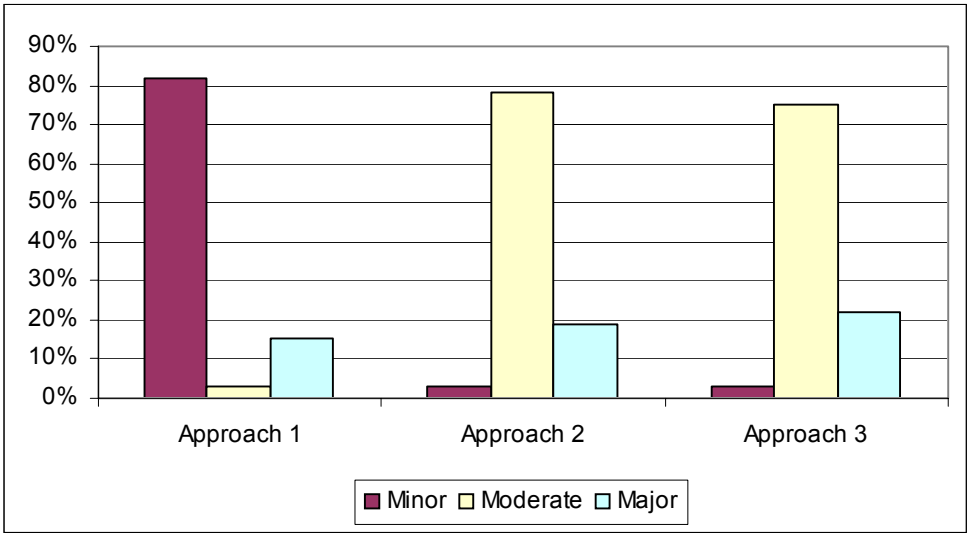
A7.12 In contrast to manufacturers, all approaches were said to entail moderate to major changes in the process.

Chart A7.13: If there were to be a change in the retailing/importing processes, how large would this change be?



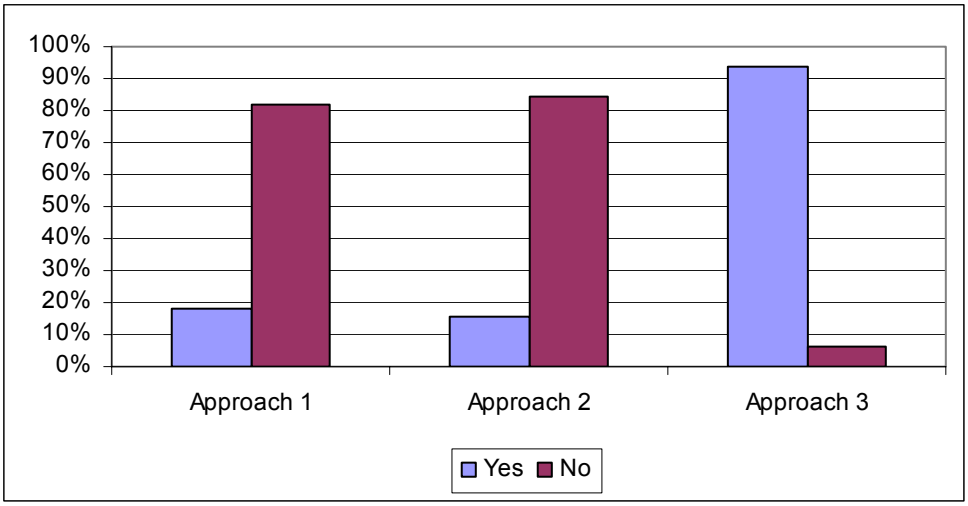
A7.13 Approaches 2 and 3 were felt to lead to the biggest changes in importers/retailers' administrative processes.

Chart A7.14: If there were to be a change in the overall administrative process, how large would this change be?



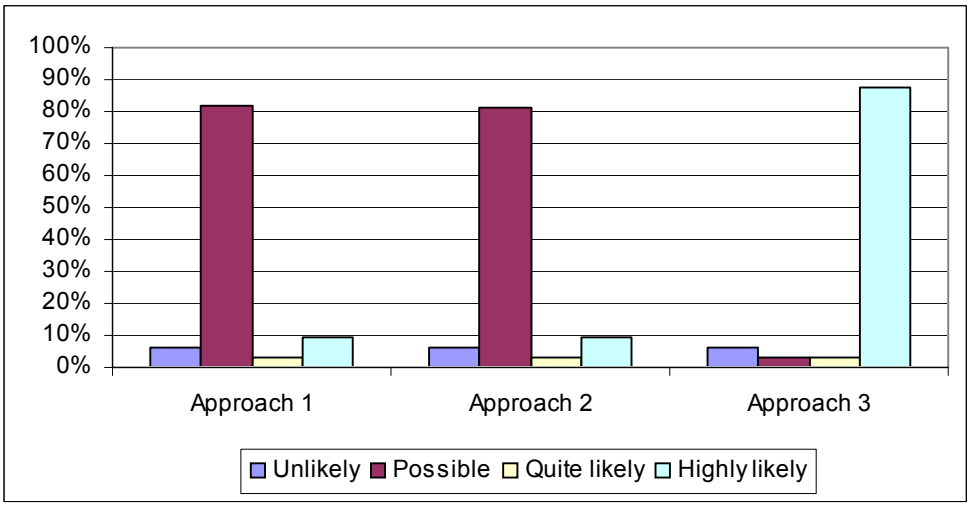
A7.14 Only approach 3 was expected to lead to changes in distribution of toys by importers and retailers.

Chart A7.15: Would your distributive procedures have to change?



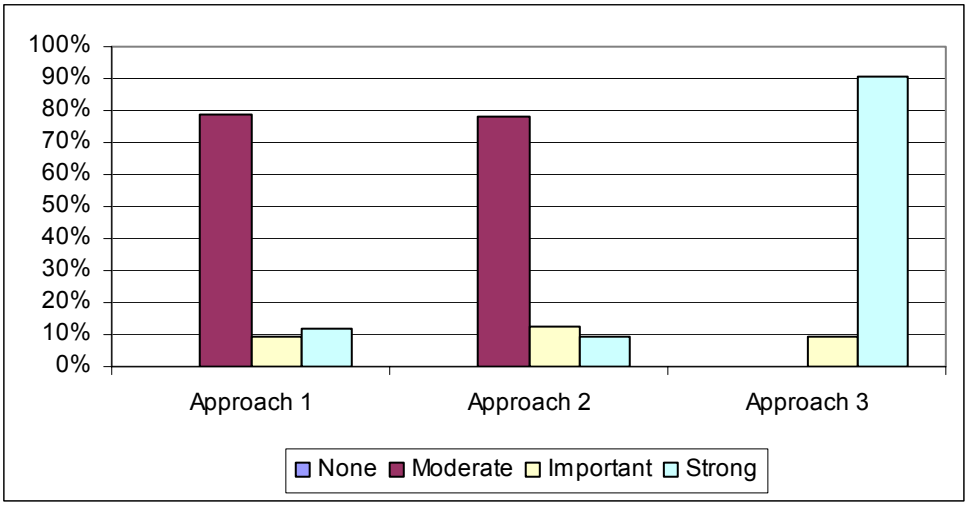
A7.15 Approach 3 was also believed to bring about significance capital expenditure — unlike in the case for manufacturers.

Chart A7.16: Would the change involve any significant capital expenditure?



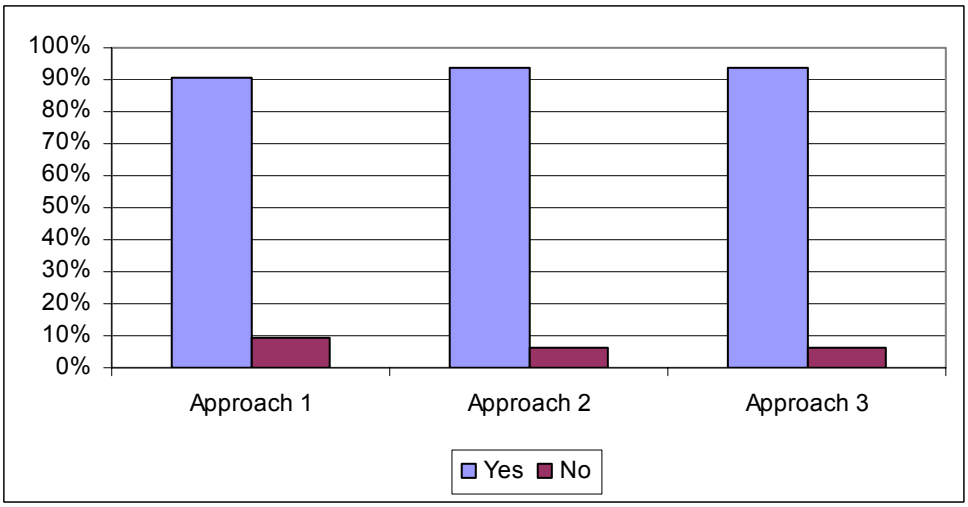
A7.16 The impact on prices, from the perspective of importers and retailers, is expected to be largely moderate for approaches 1 and 2 and strong for approach 3.

Chart A7.17: What impact would you expect on the price of your toy?



A7.17 As was the case for manufacturers, most importers and retailers would continue to deal with toys under all three approaches.

Chart A7.18: Would you continue to import and/or distribute the toy?



A7.18 The views and opinions of stakeholders from the categories of consumer and health groups were discussed in the previous section.

APPENDIX 8: CASE STUDIES

Introduction

A8.1 This section provides some examples of how the three approaches might impact on certain representative firms within the EU. We present four case studies of (i) a major toy manufacturer, (ii) an SME manufacturer, (iii) an importer, and (iv) an importer association. Each case study is anonymous at the request of the company in question.

Large manufacturer case study

Background

A8.2 Measured in terms of sales, this toy manufacturer is one of the five largest in the world. It is a well established firm of over 70 years and is involved in the production of creative construction toys that encourage learning through play. Its toys are not just by private users, but have also been used by a number of educational institutions. The company remains confident that it can remain successful and relevant to children as it responds to tastes and market trends.

A8.3 The manufacturer produces a broad product range for different age groups, producing its own brand toys based on various themes, as well as licensed toys. Unlike other large manufacturers, this manufacturer also has its own direct sales channel online and its own retail shops.

Manufacturing processes

A8.4 Product development takes place at the group's main headquarters in Europe. The Group also has "listening posts" elsewhere in Europe, North America and Asia to assist in monitoring of trends. The average length of time for product development is estimated to be 12 months — longer than of other toys.

A8.5 The bulk of toy manufacturer is done in Eastern Europe and Mexico by external suppliers. Only those toy products requiring specialised skills are manufactured in Europe — estimated at around 20 per cent.

A8.6 The main manufacturing process for this company's toys is moulding from plastic. The raw plastic material is heated and then injected in moulds at very high pressures (25-150 tonnes).

A8.7 The basic toy has remained unchanged for the last 50 years, although certain variations have been made due to new EU regulations.

Financial background

A8.8 After a period of losses at the turn of the century, the firm has returned to profitability in recent years. This return to profitability has coincided with a business-wide strategy which

aims to re-vitalise its brand. In terms of workforce, the firm has shed around 25 per cent of its work force since 2002.

Quality assurance and safety issues

A8.9 All raw materials that enter the manufacturer's products are tested in order to confirm with the TSD. Testing is undertaken both internally and externally.

A8.10 In fact, the company reports that it goes beyond the basic TSD and EN71 requirements by having internal quality assurance and safety standards which are comparable with those of EC Directive 2002/72/EC on plastic materials and articles intended to come into contact with foodstuffs.

A8.11 The firm itself does not add any additional chemicals in their manufacturing. Any chemicals that are added are added by raw materials suppliers (and are tested for at this stage). When the products are tested, it is the resins which are tested for the presence of residual content of monomers which have not been fully polymerized and are thus able to migrate to the surface of the plastic substance.

A8.12 The firm reports a very good safety record and has never received a complaint relating to chemicals in its products.

The three approaches

A8.13 The firm itself does not use any CMRs in its production processes. However, CMRs are added by its suppliers when producing the polymer raw material (in a chemical process where the monomers polymerizes to long chains polymers, which are not harmful). The raw material that is used in the moulding process does contain chemicals which can be classed as CMR level 1: these are acrylonitrile, butadiene, styrene (ABS), polycalonade and bisphenol A (for producing polycarbonates). Indeed, ABS is found in up to 80 per cent of all its toys, and is a common ingredient used in toys that are made from hard plastic. It is used for its properties of durability and robustness.

A8.14 However, these do not end up in the final product as they are "locked" in the chemical polymer which makes up the brick. The chemicals are only harmful if they separate from the main polymer. The toys are said to be "virtually pure" and safe for use by children and older users. Managers are confident enough to guarantee that any residual trace substances are harmless to users. The firm stressed that saying there are trace substances of CMRs in a product is not the same as saying a product contains CMRs.

A8.15 At present, since no testing is done for many of the new chemicals and the revised limits in the proposed three approaches, the firm is unaware whether it would automatically comply with any of the proposed revisions without a change to its manufacturing techniques. However, it does not regard it as particularly difficult to find out this information. Given that the firm already complies beyond the existing TSD, it did not regard any additional testing as excessive or infeasible.

A8.16 With regard to a preference between the proposed approaches for revising the TSD, the firm reports that as long as trace substances of known CMRs added in the manufacturing process are deemed technically unavoidable and are acceptable as part of good manufacturing processes, then approaches 2 and 3 would not be overly onerous. Of course, all approaches would entail further testing for chemicals (under approach 1 for the additional named chemicals), but the size of the company allows it to accommodate these costs and it would be the external labs who would be doing the testing.

A8.17 Indeed, given its size, the firm is confident that it could pass the costs of additional testing to its raw material suppliers; meaning that the final consumer would not see any additional increase in price.

A8.18 However, if trace substances of CMRs were not allowed (or defined differently, i.e. by saying trace substances are equivalent to no CMRs) than the viability of the firm would be called into question because so-called substitute chemicals are not regarded as meeting the product requirements. The example of banning bisphenol A in San Francisco was mentioned — this ban has meant the firm's products were banned from sale in that city.

SME manufacturer case study

Background

A8.19 This SME is one of the oldest toy manufacturers in the world, with a history of over 150 years. The SME produces a number of branded board games, interactive DVDs, and puzzles for children across a number of age groups. It sells it toys across the EU through third part retail outlets.

Manufacturing processes

A8.20 The majority of its toys are produced in Holland (estimated at 70 per cent), with the remaining toys produced in the Far East (mostly China). It is mostly components which are outsourced to the Far East.

A8.21 The main substances of its manufacturing process are moulding, finishing (the main process) and gluing.

A8.22 Copper and tin are used in its manufacturing processes to wire electronics and solder wiring and circuit boards.

Quality assurance and safety issues

A8.23 Product testing is done by using a toy sample as a reference for the whole process. The sample is tested by laboratories. On some occasions, the raw material is tested prior to its purchase.

A8.24 The company complies with the limits set by the EU, neither more nor less.

A8.25 The SME noted that testing toys has become increasingly time consuming than was previously the case, mainly due to an increasing number of bans on chemicals. It was noted that it now takes a number of weeks to test a toy, whereas previously it could be done in a matter of days.

The three approaches

A8.26 Although the SME has expressed a preference for approach 1, on the basis that it requires the least additional time, it does not have any objections to the other approaches, provided they are clearly defined. The SME noted that in the past they had had problems with EU legislation being ambiguous on definitions of what is and what is not safe to be used in toys. An example was given that a German lab might check its toy and say it is safe and complies with the EU Directive, but then a French lab may say the opposite.

A8.27 The SME did believe that the new Directive will increase its costs of compliance by up to 5 per cent for approach 1 and up to 20 per cent for approaches 2 and 3. This increase in costs would be passed on to the final consumer.

A8.28 The SME was concerned to that any new approach should ensure all participants in the toys industry are on a level playing field. In particular, if chemicals are to be substituted, then the Commission needs to make sure that it applies to everyone.

Importer case study

A8.29 The importer that we studied is a young company based in the UK that experienced constant growth since its inception in 1992. The company mainly imports and distributes licensed toys but has also a few proprietary brands.

A8.30 At the moment there are 70-80 employees based in the headquarters in the UK but a considerable part of the work is outsourced.

Import and distribution process

A8.31 The overall turnover in 2005 was about £125-130m, most of which came from importing toys produced in the Far East and selling them in the UK and Ireland. Their own products account for 30 per cent of their sales and 70 per cent of their sales come from toys of their clients.

A8.32 The vast majority of the products are licensed toys, from TV series, sporting events, films and cartoons. Most of the licensed products are owned by US based companies.

A8.33 While up to a few years ago the distribution of toys was mainly due to toys retailers over the last few years a growing share of sales is attributed to large supermarket chains that are currently attempting to expand their non food lines in the UK.

A8.34 The company has a number of showrooms in its headquarters where buyers of the various clients can see the products before ordering them; in addition the company

regularly presents the product at major international fairs in Hong Kong, London, Nuremberg and New York. The company also accompanies its buyers to Los Angeles to present the toys of some of its American clients.

Quality assurance and safety issues

A8.35 Quality control happens differently for products that are licensed and those that are owned by the company.

A8.36 For products that are designed by the company and are therefore intended for the UK and EU market, the company tests a sample of the products to make sure that it complies with EU legislation and with the various parts of the EN71 standard.

A8.37 Licensed products, on the other hand, are mainly designed for the US market. The company mainly distributes them in the UK and Ireland. Licensed products are "assessed" by the company and if they do not comply with EU standards, then they ask the owner of the product to modify it before distributing it. This is thought to be a problem in some cases, where American companies find it difficult to accept the idea that European requirements are stricter than those of the US.

The three approaches

A8.38 The company believes that irrespectively of the approach chosen the new requirements should be harmonised with REACH, otherwise they might end up testing the same product twice for the different provisions. According to the company, there is too much communality between the 3 approaches and REACH.

A8.39 Among the different approaches the company believes that the implementation of approaches 2 and 3 would be very difficult because of the very high number of chemical substances involved. Testing costs would increase exponentially and many small companies would probably be forced out of the business as they do not have the necessary skills and resources to comply with these requirements.

A8.40 According to them, it is nearly impossible to apply all the requirements of approaches 2 and 3 at once. If they were to implement such approaches then they should think of building it gradually.

A8.41 The company also does not understand where the different lists of chemicals/CMRs/etc have come from. Have they been added to the list because of some events/accidents, or just out of precaution? If the motivation was preventive, then they believe that it is not the right approach. Their preference is a more pragmatic approach in which scientific tests would be carried out.

A8.42 Approach 1 is the preferred one for the company although it stressed the fact that the zinc requirements could represent a problem for dyes. Having said that, they also mentioned that Zinc was not used heavily in the industry.

A8.43 The company believes that more efforts in monitoring and enforcement activities are needed irrespectively of the approach chosen and even if the "do-nothing" option is chosen.

Importer association case study

Background

A8.44 The membership of this toy association is involved in the sourcing, importation and distribution of all types of toy — from simply low value items through to mainstream advertised toys. Members import soft toys, board games, electronic toys, ride on toys, outdoor toys, puzzles, and so on. Members represent the majority of importers in this Member State.

A8.45 It should be noted for clarity that it is not unusual for there to be a large number of importers in any Member States, as there is little toy manufacturing in the EU in general, and even the larger toy companies (or manufacturers) import most of their toys from the Far East.

Quality assurance and safety issues

A8.46 The present safety standards adhered to are those outlined in the current toys safety directive and supported by the harmonised EU toy standard (EN71). All toys are tested to this standard by accredited laboratories (worldwide) and association members use the harmonised standard to assist in the self-certification module for CE marking purposes. In only a miniscule number of toys is EC-type examination either necessary or applied.

A8.47 Apart from the chemical requirements of the toy safety directive, other rules might also apply. In particular the EU Commission Decision on phthalate plasticisers is applicable and toy importers test their products when necessary to this requirement also. Since this particular rule does not form part of the requirements of the Directive for toys, it is not a pre-requisite for CE marking. However the decision is well known to distributors and retailers who commonly insist that some checking has been done.

A8.48 Association members were closely involved in the drafting of EN71-9-11 — the standard for organic chemicals in toys. Whilst this standard has not been harmonised for the purposes of CE marking, it is commonly applied to toys when necessary. In most cases when it is applied, companies will seek assurances from their foreign suppliers that no substances have been used which are banned by the standard. In some cases, testing is applied and the laboratory industry is working hard to set up the necessary competence for this. Members in general is very supportive of this new standard (EN71-9, 10, 11).

A8.49 Heavy (toxic) metals are reported to not be used knowingly in toys by the suppliers of toys to mainstream importers. Suppliers (mainly in the Far East) are now more than familiar with the need to avoid using toxic paints etc and it is a rare event that testing shows a toy not to comply with EN71-3 for example.

A8.50 With regard to CMRs, the association noted that the term encompasses many substances and it is not possible to state at present that none are knowingly used. Hoewever, whenever an issue has arisen about a particular substance (azo-dyes for example) and the substance has been regulated (usually within the chemicals regime rather than within the toys safety directive) the industry has reacted quickly to ensure that toys are checked when necessary. This has been done either by checking formulations at source or by testing finished products.

The three approaches

A8.51 The association notes that the list of CMRs changes over time. Specifying CMRs within a new Toys Safety Directive will inevitably mean on-going changes as the state of knowledge grows. It is the opinion of the association that EN71-9 is an excellent start of this process, dealing as it does, with many of the very toxic substances in "one hit". If the standard were harmonised like other parts of EN71 then the consumer would be protected from the risk from a great number of toxic substances immediately rather than waiting for individual additions to the list piecemeal. By way of example, the phthalate decision took many years to be agreed amongst the scientific community and all the while it was not applied diligently by the toy industry until the final decision was published as EU law.

A8.52 With regard to the three approaches, the following comments have been expressed.

(hhh) There is concern over the addition of the new substances to the list of those regulated. The association stated that there is no evidence that substances new to the list are of importance in the toy industry and some of them simply would not be used in any case (silver for example). Further, it notes that the eight currently regulated substances are themselves rarely found (through millions of tests over the years) and it would expect therefore that the list be shortened.

(iii) New proposals for incorporating cosmetic rules and other rules are achievable but are regarded as unnecessary since cosmetics have their own regime which apply equally to products which are both toys AND cosmetics.

A8.53 It was also noted that approach 4 will take the longest to apply properly. The association claims that this mimics the consultation approach taken by the Commission in the run up to phthalate rules. That process took an inordinate amount of time (for only a relatively few substances) and is argued to be inappropriate for the toy industry given the exposure risks compared with other categories of consumer products (e.g. food, cosmetics, food contact materials etc.)

A8.54 Further, the association noted that the wording of the requirement for Nickel is worrying. Whilst it would be sensible to limit the amount of Nickel in long term skin contact components of toys, there is no need to do this for all components of toys. The current wording does not make this distinction.

APPENDIX 9: HEALTH ADJUSTED LIFE YEARS

A9.1 This appendix provides a description of the concept of Health Adjusted Life Years and the related concepts of DALYs and QALYs and discusses the way in which they are interrelated.

A9.2 The term Health Adjusted Life Years (HALYs) is used to indicate health metrics that transform any type of morbidity or mortality into an equivalent number of life years.

A9.3 Two main concepts have been developed in the literature in this field: Quality Adjusted Life Years (QALYs) and Disability Adjusted Life Years (DALYs).

DALYs vs QALYs

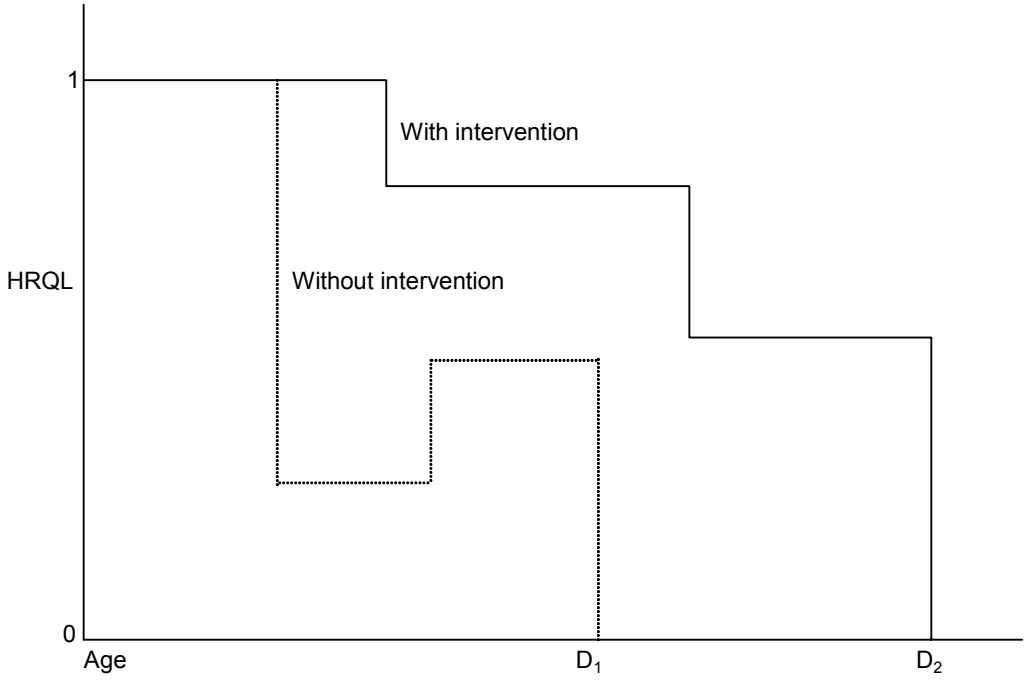
Quality Adjusted Life Years (QALYs)

A9.4 The QALY framework provides a way of measuring changes in health and mortality risks as a means of quantifying the benefits of a (medical) intervention. QALYs are based on the number of years that would be added by the intervention or by the medication. The framework provides a method for measuring the value of a health profile free from any health impairment. The number of QALYs in a specified health profile is calculated as the quality-weighted lifespan:

Equation 1: QALYs = $\sum$ qi Ti

A9.5 In the above equation (1), a person's lifespan is divided into M periods, each of which is indexed by i. The periods are defined such that in each period only one health state can be experienced. Ti is the duration of period I and the 'health related quality of life' (HRQL) that is associated with the period i is represented by weight qi. Measuring the difference between the health profiles obtained with and without intervention, as illustrated in Figure A9.1, gives an estimate of the value of that particular intervention.

Figure A9.1: Difference in health profiles



Source: Hammitt, James (2002) ' QALYs Versus DALYs'

A9.6 Quality of health is represented by the HRQL and is scaled such that a value of one corresponds to a state of perfect health and a value of zero represents to a state of health that is equivalent to death (in this case, an individual would be indifferent between living the rest of his/her lifespan in such a state or die immediately). [81]

Theoretical foundations of QALYs

A9.7 The theoretical foundations of QALYs are based on representing individual utility functions. Thus, QALYs assume that preferences over health and longevity are only a function of health consequences, and are therefore independent of other characteristics of the individual or the risk.[82] The conditions under which QALYs serves as a valid utility function for an individual is if his or her preferences satisfy the following conditions[83]:

(a) *Mutual utility independence* — This condition has two parts: (a) preferences between lotteries on health states, holding duration of life constant, do not depend on remaining lifespan; and (b) preferences between lotteries on lifespan, holding health state constant, do not depend on health state.

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81 Values of q less than zero would imply a state of health that is worse than death.

82 Technically, preferences over health quality and longevity must be 'utility dependent' of other characteristics of the individual and the risk.

83 James K. Hammitt (2002), 'QALYs Versus WTP'

(b) *Constant proportional trade-off longevity for health* —The fraction of the remaining lifespan the individual would be willing to sacrifice to improve his or her health form one state to another does not depend on his or her remaining lifespan**.**

(c) *Risk neutrality over lifespan* — Holding health constant, the individual prefers whichever lottery on longevity provides the greatest life expectancy.

(d) *Additive independence across periods* — The individual's preferences for lotteries on health in any subset of the periods do not depend on the health in other periods**.**

A9.8 When aggregating QALYs across individuals (in order to evaluate social policies), future QALYs are generally discounted at a rate equivalent to that used for discounting future monetary costs. The justification for the discounting of benefits across periods is to ensure no disparities of treatment between individuals when using costs-effectiveness ratios to allocate resources.

Methods of estimating values

A9.9 HRQL is associated with a period that corresponds to a weight qi. Typically, this weight is elicited directly or is calculated from a generic health utility scale. The latter are themselves calibrated using direct elicitation. The weight values between 0 and 1 are usually determined by methods such as;

(a) *Time trade off (TTO)* — With this, respondents are asked to choose between remaining in a state of ill health for a period of time, or being restored to perfect health but having a shorter life expectancy.

(b) *Standard gamble (SG)* — Using this method, respondents are asked to choose between remaining in a state of ill health for a period of time, or choosing a medical intervention which has a chance of either restoring them to perfect health, or killing them.

(c) *Visual analogue scale (VAS)* — In this method, respondents are asked to rate a state of ill health on a scale from 0 to 100, with 0 representing death and 100 representing perfect health.

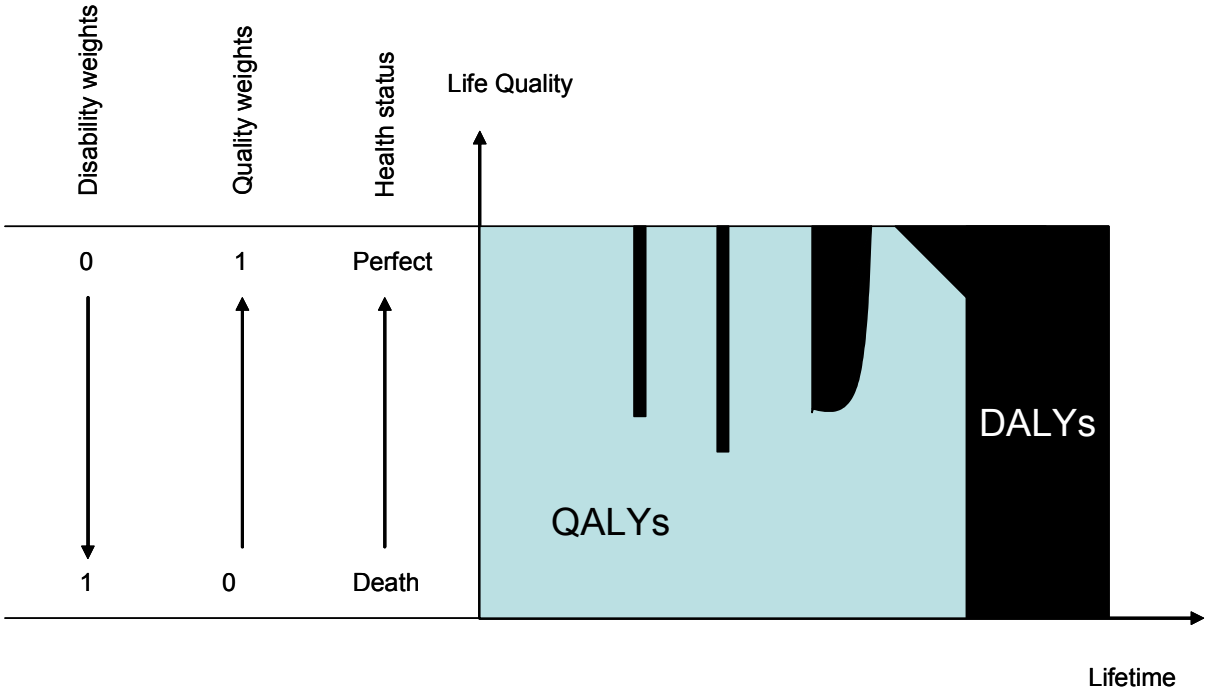
Disability Adjusted Life Years (DALYs)

A9.10 DALYs are similar to QALYs except that they incorporate a weighting factor that depends on age and measure the loss of longevity on and health from an idealized health profile. The age weighting factor present in this measure represents a judgement that years lived in young adulthood and middle age contribute more to society than years lived a s a child or in old age. Benefits accrued from a health intervention are thus discounted at a rate according to age (lower discount rates being applied to young adulthood ages and middle age and higher rates applied to child ages and old age).

DALYs and QALYs

A9.11 The DALY and QALY concepts are deeply interrelated. We illustrate the nature of the relationship with an hypothetical health profile of an individual described in Figure A9.2,

Figure A9.2: The relationship between DALYs and QALYs: an illustrative example



Source: adapted from Hosfetter and Hammitt (2002)

A9.12 The individual is in perfect health at birth then is injured in a car accident at the age of 20 and recovers fully. At 30 she has another (more serious) accident followed by a stroke at the age of 52. She recovers fully from both conditions. Finally, she gets breast cancer at the age of 60 and dies three years later because of it.

A9.13 The grey area in the figure represents the total number of QALYs lived by this hypothetical individual while the black area represents the total number of DALYs that she has lost due to injury and illness.

A9.14 Therefore it is clear that for each individual the share of DALYs and QALYs lived must sum to unity.[84] The QALY measures the total amount of quality years lived, the DALY is a measure of deprivation because of illness or injury.

[84] Under certain assumptions, e.g. that there are no health statuses that are worse than death.

A9.15 For the purposes of this study, we have chosen to use the DALYs measure in order to estimate the potential value of the interventions in question. This is mainly because the theoretical framework developed by Crettaz et al (2002) and by Bachmann (2005) deals with identifying the damages associated with the various chemicals and use the DALYs as their metric.

The value of a DALY

A9.16 Given the relationship between DALYs and QALYs it is not unreasonable to assume that for the society as a whole the value of one should not be very dissimilar for the value of the other. However the majority of the available literature focused on estimating the societal value of a QALY.

A9.17 In 2006 a study carried out by a team of researchers at the University of Birmingham[85] estimated the value of a QALY to be in the range between 45,000 and 63,000 British Pounds that at the current exchange rate are roughly 67,500 and 94,500 Euro. We have used these figures an approximate value of a DALY as well. However as a lower bound we have used the figure that the National Institute for Health and Clinical Excellence (NICE) in the UK uses to perform its health assessments, i.e. 30,000 British Pounds (roughly € 45,000).

[85] See Mason et al (2006).

APPENDIX 10: DATA SOURCES

Health effects

A10.1 Our data health effects came from the US Environmental Protection Agency. We drew from two links within the database: the Integrated Risk Information System (IRIS), and the Superfund Chemical Data Matrix (SCDM).

A10.2 The IRIS database is the source of bioassay information used by Crettaz et. al to estimate the ED_{10}-based measure, βED_{10}. It was developed originally for EPA internal purposes, in order to aid staff members to organise their information about both carcinogenic and non-carcinogenic chemicals commonly used in making risk assessments by providing standardised available statistics.[86,87] IRIS summaries are written using literature reviews and scientific studies, usually provided by EPA. It is regularly updated.

A10.3 In addition to qualitative summaries on each chemical, IRIS provides statistics in up to three areas:

(jjj) **Oral reference dose (RfD)**: an amount of daily oral exposure to the human population, given in mg per kg per day, that is "likely to be without an appreciable risk" over the course of a lifetime.

(kkk) **Inhalation reference concentration (RfC)**: a continuous inhalation exposure, given in mg per cubic metre, to the human population that is "likely to be without an appreciable risk" over the course of a lifetime.

(lll) **Carcinogenicity assessment**: this includes a quantitative estimate of carcinogenic risk from oral and/or inhalation exposure, and an EPA carcinogenicity assessment based on weighted evidence.

A10.4 While the EPA classification system for carcinogens differs from the EU CMR system nominally, the comparison is straightforward (see below) and therefore we use IRIS to ascertain the degree of carcinogenicity for each chemical substance in the EU toys industry.

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86 US Environmental Protection Agency (2007) "What is IRIS?" http://www.epa.gov/iris/intro.htm#ref.

87 IRIS chemicals are selected based on four criteria: (1) Agency statutory, regulatory, or program implementation need; (2) the availability of new scientific information or methodology that might significantly change current IRIS information; (3) interest to other levels of government or the public; (4) most of the scientific assessment work has been completed.

Table A10.1: Carcinogenicity Cross-Classifications

EPA	Definition	CMR	Definition
A	Human carcinogen	**1**	Known to be carcinogenic
B (1 and 2)	Probable human carcinogen	**2**	Should be regarded as carcinogenic
C	Possible human carcinogen	**3**	Possible carcinogenic effects
D	Not classifiable as to human carcinogenicity	**-**	N/A
E	Evidence of non-carcinogenicity to humans	**-**	N/A

Source: Greenfacts; School of Chemistry, University of Bristol

A10.5 In order to calculate RfD and RfC amounts, IRIS utilises up to several additional figures per each entry; namely Non-observable Adverse Effect Levels (NOAELs) and Low Observable Adverse Effect Levels (LOAELs), and variants thereof; Uncertainty Factor (UF) and Modifying Factor (MF).[88] Importantly, IRIS also occasionally provided information for Benchmark Doses and/or Concentrations (BMDs and BMCs), or the levels responsible for "a predetermined change in response rate of an adverse effect (called the benchmark response or BMR)" in comparison to the response rate which would occur in a

[88](Abbreviated) IRIS definitions:
No-Observed-Adverse-Effect Level (NOAEL): The highest exposure level at which there are no biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control.

No-Observed-Effect Level (NOEL): An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any effect between the exposed population and its appropriate control.

Lowest-Observed-Adverse-Effect Level (LOAEL): The lowest exposure level at which there are biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group.

Lowest-Observed-Effect Level (LOEL or LEL): In a study, the lowest dose or exposure level at which a statistically or biologically significant effect is observed in the exposed population compared with an appropriate unexposed control group.

Uncertainty/Variability Factor (UFs): One of several, generally 10-fold, default factors used in operationally deriving the RfD and RfC from experimental data. The factors are intended to account for (1) variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability); (2) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty); (3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and (5) uncertainty associated with extrapolation when the database is incomplete.

Modifying Factor (MF): A factor used in the derivation of a reference dose or reference concentration. The magnitude of the MF reflects the scientific uncertainties of the study and database not explicitly treated with standard uncertainty factors (e.g., the completeness of the overall database). A MF is greater than zero and less than or equal to 10, and the default value for the MF is 1. [Use of a modifying factor was discontinued in 2004.]

control group living in the natural or anthropogenic environment. Analogously, the BMDL and BMCL are lower statistical limits on their respective amounts.

A10.6 The SCDM also exists under the EPA umbrella. Similarly to IRIS, SCDM is used for toxicity assessment. In contrast to IRIS, it was initially created to be used as a public service tool.[89] It was built to be used for evaluating chemicals found in sites listed on the EPA's National Priorities List (NPL). The NPL is a compiled list of known US sites, usually locations or territories occupied by industrial firms, which release hazardous substances, pollutants or contaminants. Superfund is the name of a campaign engendered in 1980 to raise public awareness about contaminated properties throughout the US natural environment. (IRIS is also a Superfund database.)

A10.7 The SCDM is slightly more comprehensive in scope than IRIS, although it is exclusively quantitative. In addition to health-based bioassay dosages, SCDM considers equally the bioaccumulation potential and persistence of each substance on the natural environment and correspondingly provides a great number of statistics. We found the SCDM to provide valuable information; although it contributed to our collection of RfDs and RfCs, the SCDM was also the only of the two databases containing quotes on the Effective Dose Levels (ED_{10}). ED_{10} is "the dose corresponding to a 10 per cent increase in an adverse affect, relative to the control response". [90] Like the RfD/RfC it is internalised both orally and through inhalation.

A10.8 In following the Crettaz et. al model, possessing an estimate of the ED10 enables one to estimate βED10.

Other data

A10.9 Other data sources used in the modelling exercise are:

(mmm) The stakeholder questionnaire for the cost increases associated to each policy option;

(nnn) The EuroStat website for population projections;

(ooo) The RIVM/SIR Advisory Report for assumptions on the weight of children and on the amount of migration from toys;

(ppp) Papers by Crettaz et al (2002), Pennington et al (2002) and the book by Bachmann (2005) for the number of DALYs per incidence;

(qqq) The European Commission guidelines for the discount rate and;

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[89] US Environmental Protection Agency (2007) "National Priorities List: Superfund Chemicals Data Matrix" http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm.

(rrr) The study by Mason et al (2006) on the monetary value of a QALY.

[90] US Environmental Protection Agency (2007) "National Priorities List: Superfund Chemicals Data Matrix" http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm.

APPENDIX 11: STAKEHOLDER QUESTIONNAIRE

Introduction and respondent details

Europe Economics is currently carrying out a study for the European Commission Directorate General for Enterprise, investigating the impact of revising Council Directive 88/378/EEC on the Safety of Toys, in particular with regard to the provisions for chemicals. As part of this study, we are seeking the views and opinions of stakeholders across the European Union.

Technological developments in the toys market have raised new issues with respect to the safety of toys, and allied with the experience of the existing Directive on toy safety, a conclusion has been reached to update the safety requirements in Directive 88/378/EEC.

A general impact assessment was carried out on the proposed revision in 2003 and can be found at http://ec.europa.eu.enterprise/toys/index_en.htm.

In addition a specific study on certain chemicals used in toys was carried out in 2006 which investigated the limits of bioavailability in the Annex of the Directive. The results can be found at http://ec.europa.eu/enterprise/toys/index_en.htm.

This current study, launched in March 2007, will explore the impacts of the revision of chemical requirements in the Directive; in particular the three different possible approaches to regulate chemicals in toys in the Directive.

Your answers to this questionnaire will be important for decision makers when deciding which directive on chemical requirements in toys to apply. For an explanation of the policy context please refer to the website of the European Commission Directorate General for Enterprise, http://ec.europa.eu/enterprise/toys/index_en.htm.

Please make sure you answer the questions as accurately as possible. Your answers will be treated in the strictest confidence and individual responses will not be made available to the European Commission.

Question A1

Please complete the following details.

Name	Position	Address	Email	Telephone

Question A2

May we contact you for a follow up interview?

Question A3

What is the nature of your business/organisation? (Please choose from below)

Toy manufacturer	Toy importer/Toy retailer	Consumer and health group	Other

When respondent clicks one of them, they are automatically directed to the relevant section.

Toy manufacturer

Question S3.1

What is the size of your company?

Micro – employing less than 25 people	Small/medium: employing between 25 and 250 people	Large: employing more than 250 people

Question S3.2

In which country is your company headquarters located in?

[Choose country]

Question S3.3

For the toy you manufacture, approximately how many units do you sell in annually?

[Type in number]

Question S3.4

For the type of toy you manufacture, approximately what is your market share?

0-5%	6-10%	11-25%	26-50%	50%+

Question S3.5

Do toys represent the majority of your income revenue?

Yes/No

Question S3.6

In which Member States do you sell your toy?

[Choose Member State]

Question S3.7

In which EU Member State are the toys manufactured?

[Choose Member State]

Question S3.8

If the toys are not manufactured in the EU, where are they manufactured?

Other EEA	China	Other Asia	USA	Rest of the world	Don't know

Please specify for the rest of the world and other Asia

Question S3.9a

For the toy that you manufacture, please tick the manufacturing processes that are used.

Moulding	Stabilising	Finishing	Sewing	Gluing	Other

If other, please specify.

Where: moulding refers to the moulding of the toy from plastic or other materials; stabilising refers to ensuring the toy's integrity during use; finishing refers to fabrication and assembly processes such as painting; sewing is for textile toys; and gluing refers to gluing together of toys.

Question S3.9b

What percentage of your total operating costs are allocated to the following manufacturing processes

Moulding				Stabilising				Sewing			
0-5%	0-5%	6-10%	11-20%	>20%	6-10%	11-20%	>20%	0-5%	6-10%	11-20%	>20%
Gluing				Other *(please specify)*				Finishing			
0-5%	6-10%	11-20%	>20%	0-5%	6-10%	11-20%	>20%	0-5%	6-10%	11-20%	>20%

Question S3.10

Do the toys you manufacture contain any of these chemicals, or are of these used in the manufacturing process?

	Chemicals contained in toy	Chemicals deliberately added
Aluminium		
Antimony		
Arsenic		
Barium		
Boron		
Cadmium		
Chromium		
Chromium (VI)		
Cobalt		
Copper		
Lead		
Manganese		
Mercury		
Nickel		
Selenium		
Silver		
Strontium		
Tin		
Organic tin		
Zinc		

Tick those that apply.

Question S3.11

If you use any of the above chemicals, what is their purpose?

Question S3.12

Do the toys you manufacture contain any carcinogens, mutagens and reproductive toxicants CMRs?

Tick those that apply.

CMR1	
CMR2	
CMR3	

If you do use CMRs, which ones?

Question S3.13

If you explicitly purchase any of the named chemicals above, or deliberately include materials containing them within your production processes, what is your approximate annual expenditure on it in €? Please answer for all chemicals.

Question S3.14

How might a user of your toy come into contact with the chemical?

Direct ingestion	Mouthing (sucking/licking)	Inhalation via evaporation	Inhalation via dust/spray	Skin contact	Breaking it	Other

A11.1 If other, please specify.

Question S3.15

Have you had any safety or quality issues with the chemicals in your toys in the last 5 years that has resulted in a patient safety issue?

Ask by chemical.

Question S3.16

Are you aware of any of the following impacts associated with these chemicals?

List chemicals against impacts.

Skin irritation	Allergy	Respiratory effects (wheezing)	Cardiovascular (circulation/heart) effects	Neurological effects (eg dizziness, blurred vision, muscle weakness)	Vomiting

Question S3.17

Are you aware of any of these chemicals having significant environmental impacts, which may occur during the manufacturing process?

List chemicals. If yes, please explain.

Question S3.17b

In addition to any environmental impacts, are you aware of any impacts involved in the disposal of the toy?

Impact assessment questions

Describe the three options.

Question SI1.1

Would any of these approaches entail a change in your manufacturing processes?

Approach 1	Yes/No
Approach 2	Yes/No
Approach 3	Yes/No

Question SI1.2

If there were to be a change in the overall manufacturing process, how large would this change be?

Approach 1	Minor/Moderate/Major
Approach 2	Minor/Moderate/Major
Approach 3	Minor/Moderate/Major

Question SI1.3

Would the change involve any significant capital expenditure?

Approach 1	Unlikely/Possible/Quite likely/Highly likely
Approach 2	Unlikely/Possible/Quite likely/Highly likely
Approach 3	Unlikely/Possible/Quite likely/Highly likely

Question SI1.4

Please estimate the one-off costs for your company that would result from instituting each approach in each manufacturing process, as a percentage of annual operating costs.

Give same option for the different stages of manufacturing.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI1.5

Please estimate the ongoing annual costs for your company that would result from instituting each approach in each manufacturing process, as a percentage of annual operating costs.

Give same option for the different stages of manufacturing.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI1.6

If there were to be a change in the overall administrative process, how large would this change be?

Approach 1	Minor/Moderate/Major
Approach 2	Minor/Moderate/Major
Approach 3	Minor/Moderate/Major

Question SI1.6b

Please estimate the one-off costs for your company that would result from instituting each approach in the administrative process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI1.6c

Please estimate the ongoing annual costs for your company that would result from instituting each approach in the administrative process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SIi.7

What would be the change in the amount of time needed for quality control?

Approach 1	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None
Approach 2	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None
Approach 3	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None

Question SI1.8a

Would your distributive procedures have to change?

Approach 1	Yes/No
Approach 2	Yes/No
Approach 3	Yes/No

Question SI1.8b

Please estimate the one-off costs for your company that would result from instituting each approach in the distributive process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI1.8c

Please estimate the ongoing annual costs for your company that would result from instituting each approach in the distributive process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI1.9

What impact would you expect on the price of your toy?

Approach 1	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None
Approach 2	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None
Approach 3	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None

Question SI1.10

Would you continue to manufacture and/or distribute the toy?

Approach 1	Yes/No
Approach 2	Yes/No
Approach 3	Yes/No

Question SI1.11

In your opinion, which of the three proposed options is the most appropriate one?

Approach 1	
Approach 2	
Approach 3	

Question SI1.12

Are there any further comments you wish to add?

Toy importer/Toy retailer

Question S4.1

What is the size of your company?

Micro – employing less than 25 people	Small/medium: employing between 25 and 250 people	Large: employing more than 250 people

Question S4.2

In which country is your company headquarters located in?

[Type in country]

Question S4.3

What proportion of your business is conducted online?

Question S4.4

Apart from toys, what else do you retail/import?

Question S4.5

For the type of toy you import/retail, what is your approximate market share?

0-5%	6-10%	11-25%	26-50%	+50%

Question S4.6

If you are an importer, from which countries do you import your toys?

Other EEA	China	Other Asia	USA	Rest of the world

Please specify for the rest of the world and other Asia

Question S4.7

For the toy you import/retail, approximately how many units do you sell in annually?

[Type in number]

Question S4.8

Do toys represent the majority of your income revenue?

Question S4.9

In which EU Member States do you sell your toy?

[Choose Member State]

Question S4.10

Have you had and/or are you aware of any safety or quality issues with or caused by the chemical(s) in your toy(s) that resulted in a patient safety issue in the last 5 years?

Yes/No

Impact assessment questions

Describe the three options.

Question SI2.1

Would any of these approaches entail a change in your importing or retailing processes?

Approach 1	Yes/No
Approach 2	Yes/No
Approach 3	Yes/No

Question SI2.2

If there were to be a change in the retailing/importing processes, how large would this change be?

Approach 1	Minor/Moderate/Major
Approach 2	Minor/Moderate/Major
Approach 3	Minor/Moderate/Major

Question SI2.3a

Please estimate the one-off costs for your company that would result from instituting each approach, as a percentage of annual operating costs

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI2.3b

Please estimate the ongoing annual costs for your company that would result from instituting each approach, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI2.4a

Would there be any change in your administrative processes, and if so, how large would it be?

Approach 1	Minor/Moderate/Major
Approach 2	Minor/Moderate/Major
Approach 3	Minor/Moderate/Major

Question SI2.4b

Please estimate the one-off costs for your company that would result from instituting each approach in the administrative process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI2.4c

Please estimate the ongoing annual costs for your company that would result from instituting each approach in the administrative process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI2.5a

Would your distribution procedures have to change?

Approach 1	Yes/No
Approach 2	Yes/No
Approach 3	Yes/No

Question SI2.5b

Please estimate the one-off costs for your company that would result from instituting each approach in the distributive process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI2.5c

Please estimate the ongoing annual costs for your company that would result from instituting each approach in the distributive process, as a percentage of annual operating costs.

Approach 1	0-5%/6-10%/11-20%/+20%
Approach 2	0-5%/6-10%/11-20%/+20%
Approach 3	0-5%/6-10%/11-20%/+20%

Question SI2.6

Would the change involve any significant capital expenditure?

Approach 1	Unlikely/Possible/Quite likely/Highly likely
Approach 2	Unlikely/Possible/Quite likely/Highly likely
Approach 3	Unlikely/Possible/Quite likely/Highly likely

Question SI2.7

What impact would you expect on the price of your toy?

Approach 1	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None
Approach 2	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None
Approach 3	Strong (+20%)/Important (10-20%)/Moderate (0-10%)/None

Question SI2.8

Would you continue to import or retail the toy?

Approach 1	Yes/No
Approach 2	Yes/No
Approach 3	Yes/No

Question SI2.9

In your opinion, which of the three proposed options is the most appropriate one?

Approach 1	
Approach 2	
Approach 3	

Question SI2.10

Are there any further comments you wish to add?

Consumer and health groups

Question S6.1

Are you aware of any toy products containing ingredients that are likely to trigger allergies, diseases or any other sort of reaction(s)?

Yes/No

If yes, please explain how long it would take for the impact to take effect and which chemicals/ingredients are involved.

Question S6.2

For the identified chemicals, please explain how long it would take for the impact to take effect and which chemicals/ingredients are involved.

Question S6.3

Are you aware of any health conditions associated with exposure to the following chemicals?

List chemicals.

Question S6.4

For each chemical identified, please outline the condition associated with it.

Question S6.5

With reference to the health conditions identified in the previous question, in your view are the amounts listed below more or less than what is needed to trigger the health conditions you describe? (amounts given are in mg/kg toy material).

List chemicals alongside chemical amounts from options, giving the choices or more/less/equal.

Question S6.6

By which method is exposure to these chemicals harmful in toys?

Direct ingestion	Mouthing (sucking/licking)	Inhalation via evaporation	Inhalation via dust/spray	Skin contact	Breaking it	Other

A11.2 If other, please specify.

Question S6.7

For the chemicals and conditions identified, what is the estimated probability that these conditions will occur after exposure (and how long is the necessary exposure)? Please answer in percentage terms.

Question S6.8

Are you aware of any of the above chemicals having significant environmental impacts, which may occur during the manufacturing process?

Question S6.9

In addition to any environmental impacts, are you aware of any impacts involved in the disposal of the toy?

Impact assessment questions

Describe the three options.

Question SI3.1

Would there be any change in the likelihood of adverse health impacts identified previously resulting from the policy change?

List three options.

Question SI3.2

If we choose approach 1 (fully-risk based approach) what is the estimated probability that the health impacts will appear after such exposure, with regard to the chemicals and conditions identified above?

Question SI3.3

If we choose approach 2 (combined hazard/risk based approach) what is the estimated probability that the health impacts will appear after such exposure, with regard to the chemicals and conditions identified above?

Question SI3.4

If we choose approach 3 (hazard/risk based approach) what is the estimated probability that the health impacts will appear after such exposure, with regard to the chemicals and conditions identified above?

Question SI3.5

Are you aware of any of the identified chemicals as having significant environmental impacts, which may occur during the manufacturing process? If yes, please explain.

Question SI3.6

In your opinion, which of the three proposed options is the most appropriate one?

Approach 1	
Approach 2	
Approach 3	

Question SI3.7

Are there any further comments you wish to add?

Other

Question O1

What challenges, in general, do you see in the toys industry?

[Type in comments]

Question O2

Please describe your business/institution's relationship to the toy industry

[Type in comments]

Question O3

Are you aware of any health conditions associated with exposure to the following chemicals?

Choose from list.

Skin irritation	Allergy	Respiratory effects (wheezing)	Cardiovascular (circulation/heart) effects	Neurological effects (eg dizziness, blurred vision, muscle weakness)	Vomiting

If yes, please explain.

Question O4

Are you aware of any of the following chemicals being found in toys?

Choose from list of chemicals.

If yes, please explain by what method is exposure harmful from toys?

A11.3 If other, please specify.

Question O5

For the chemicals and conditions identified, please estimate the probability that these health impacts will occur after exposure.

Approaches summary

The following questions seek responses to three possible options for revising the Toy Safety Directive.

The options are (1) Risk-based approach, (2) Combined hazard / risk-based approach, and (3) Hazard / risk-based approach.

Within the three options, there are some common features. These are summarised as follows:

(sss) Manufacturers shall ensure that toys are so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed of or which they contain, when the toys are used as specified in Article 5 (2) of the Toy Safety Directive.

(ttt) Toys shall in all cases comply with relevant Community legislation relating to certain categories of products or to the prohibition of use of certain dangerous substances and preparations. Toys that are themselves substances or preparations must comply also with Directives 67/548/EEC and 1999/45/EC relating to the classification, packaging and labelling of dangerous substances and dangerous preparations.

(uuu) Cosmetic toys, such as play cosmetics for dolls, shall also comply with directive 76/768/EEC.

(vvv) For the protection of children's health, the following migration limits, from toys of components of typos that are accessible to children during use, shall not be exceeded (all units in mg/kg toy material): aluminium (5625 mg/kg), antimony (45 mg/kg), arsenic (7.5 mg/kg), barium (4500 mg/kg), boron (1200 mg/kg), cadmium (3.8 mg/kg), chromium (37.5 mg/kg), chromium (VI) (0.04 mg/kg), cobalt (10.5 mg/kg), copper (622.5 mg/kg), lead (27 mg/kg), manganese (1200 mg/kg), mercury (15 mg/kg), nickel (75 mg/kg), selenium (37.5 mg/kg), silver (37.5 mg/kg), strontium (4500 mg/kg), tin (15000 mg/kg), organic tin (1.9), zinc (3750 mg/kg).

The differences are as follows

Approach 1: Risk-based approach

Toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children when toys

are used as specified in Article 5 (1) shall not contain allergenic fragrances that appear on the list of substances in Annex II of Directive 76/768/EEC. In addition, toys that are themselves substances or preparations that are intended to be released from toys or components of toys, and toys or components of toys that are accessible to children during use as specified in Article 5 (2) shall list if added, as such, at concentrations exceeding 0.01 % by weight, the allergenic fragrances that appear on the list of substances in Annex III, Part 1 of Directive 76/768/EEC.

The risk-based approach will also require a detailed description of the design and manufacture, including the safety data sheets on chemicals used to be obtained from chemical suppliers.

Approach 2: Combined hazard / risk-based approach

Toys shall not contain substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2 (CMR) according to Directive 67/548/EEC unless the incorporation of that substance has been authorised in accordance with the procedure foreseen in Article [57 to 61] of Regulation […..] (REACH). However, the presence of traces of those substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and it conforms to paragraph 1.

The combined hazard/risk-based approach will also require a detailed description of the design and manufacture, including a list of components and materials used in toys as well as the safety data sheets on chemicals used to be obtained from chemical suppliers.

Approach 3: Hazard / risk-based approach

The use in toys of the following substances shall be prohibited: a) substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1, 2 and 3 (CMR) according to Directive 67/548/EEC, (b) substances such as those having endocrine disrupting properties or and which are identified as causing serious and irreversible effects to humans which are equivalent to those of substances listed in point (a). However, the substances referred to in the first subparagraph can be used under the following conditions: (a) the substance is essential to the functioning of the toy; (b) there are no alternative substances available with intrinsic hazard properties of a lower order of toxicity than the referred to in the first subparagraph; (c) the manufacturer has demonstrated that the substance is not released in amounts that are detectable by a validated method when the toy is used as specified in Article 5 (2); and (d) the substance has been evaluated by the Scientific Committee on Health and Environmental Risks found acceptable to be used in toys by a decision taken by the Commission in accordance with the procedure laid down in Article X [Comitology procedure]. The presence of traces of substances referred to in subparagraph 1 shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and it conforms to paragraph 1.

Hazard/risk-based approach will also include a detailed description of the design and manufacture, including substances contained in the toy as well as the amount of the individual substances and the relevant Safety data sheets on chemicals to be obtained from chemical suppliers.

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