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DG Enterprise and Industry

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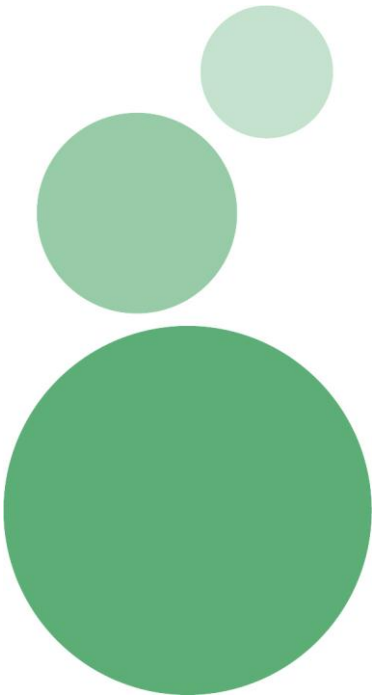
Impact assessment study on the health costs due to children's exposure to lead via toys and on the benefits resulting from reducing such exposure

23 May 2012

FINAL REPORT



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1.0 Executive Summary

Methodology

The study undertaken by Matrix Insight between January and April 2012 draws upon **stakeholder interviews, a literature review and economic modelling.**

Context

Lead is a toxic metal for which there is no 'safe' threshold. Lead exposure has particularly damaging effects on children. Children may absorb lead through dietary or non-dietary exposure including via exposure to toys.

In the European Union, **the Toy Safety Directive (TSD, Directive 2009/48/EC)** regulates the amount of a chemical that can be released from toy material when ingested, namely the migration limit[1]. The TSD was introduced in June 2009, but the newly established migration limits will only be enforceable as from July 2013, after a transition period of four years.[2]

Health Impacts

Lead absorption can cause a number of health related and non-health related impacts. The most widespread health impacts include: **kidney damage**, **hearing problems**; **behaviour and attention problems**; and **slowed body growth**. This study has focussed on behaviour/attention problems (ADHD) and reduced IQ being the areas where there was sufficient evidence of impact.

Policy Options

A study by EFSA has concluded that exposure to lead, from both dietary and non-dietary sources (including toys), should be reduced. The European Commission is considering two policy options.[3] Each option sets a proposed new minimum migration level with Policy Option 1 covering all toys and Policy Option 2 retaining current levels for toys containing clay, kaolin and/or pigments, but reduced levels for all other toys.

[1] Migration limits report how much of the element migrates from (e.g.) the toy to the human body, or in other words the amount of element actually released from the toy and to which the body is exposed.

[2] During this transition period, the bioavailability levels established by the previous Directive 88/378/EEC apply. Thus, any toy placed on the market before 20 July 2013 will have to comply with a lead bioavailability level of 0.7 µg, corresponding to a migration limit of 90 mg/kg, as established by EN 71-3.

[3] During the scoping interviews carried out so far, stakeholders have stressed that reducing the migration level might have substantial impacts on the industry and on the internal market.

Table 1 – Proposed Policy Options

Toy Material	Migration Limits (mg/kg)			
	Policy Option 0 (Status Quo)	Policy Option 1	Policy Option 2	
			Clay, Kaolin, Pigments	Others
Dry, brittle, powder-like, pliable toy material	13.5	4	13.5	4
Liquid or sticky toy material	3.4	1	3.4	1
Scraped-off toy material	160	47	160	47

Impact

Even if toys contribute to a maximum of 10% of the TDI of lead in children, there are long-term economic costs of exposure to lead in toys that relate to: a reduction in health related quality of life (QALYs)[4]; an increase in health cost due to treatment; and a reduction in productivity. The health benefits of a reduction of the limits generated by the different policy option are summarised in Table 2. These savings are based on a total population of nearly 16 million children aged 0-3, which will benefit from the reduction of lead in toys. On a per child basis **Policy Option 1 represents a 9.1% reduction in costs from baseline for ADHD and 18% for IQ**. The figures for **Policy Option 2 are 8.6% and 17.1% respectively. In terms of health benefits Policy Option 1 is the preferred option.**

Table 2 – Health Benefits following the Introduction of the Policy Options

Benefits	PO0 (Baseline scenario)		PO1		PO2	
	ADHD	IQ	ADHD	IQ	ADHD	IQ
Health cost benefits						
Lifetime treatment cost of ADHD	€ 3,383	-	€ 3,077	-	€ 3,092	-
Lifetime treatment cost of mother caring for a child with ADHD	€ 634	-	€ 577	-	€ 579	-
Quality of life benefits (QALY)						
Lifetime health related quality of life quality of life	€ 2,543	-	€ 2,313	-	€ 2,325	-
Productivity benefits						
Productivity cost associated with mother caring for a child with ADHD	€ 1,472	-	€ 1,339	-	€ 1,346	-
Productivity cost associated with child	€ 841	€ 6,271	€ 764	€ 5,141	€ 768	€ 5,198

[4] The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.

Benefits	PO0 (Baseline scenario)		PO1		PO2	
	ADHD	IQ	ADHD	IQ	ADHD	IQ
Unit cost per child	€ 8,873	€ 6,271	€ 8,070	€ 5,141	€ 8,110	€ 5,198
Total cost (€m)	€142,066	€100,406	€129,209	€82,313	€129,852	€83,226
Incremental benefit per child			€ 803	€ 1,130	€ 763	€ 1,073
Total Incremental benefit (€m)			€ 12,857	€18,091	€12,214	€17,187

2.0 Introduction

This document contains the **final report** for a "Study on the health costs due to children's exposure to lead via toys and on the benefits resulting from reducing such exposure". The objective of this report is to:

1. Present the results of our research, with respect to
    - Children's level of exposure to lead via toys;
    - The effects of the policy options; and
    - Health related and non-health related impacts of the policy options.
2. Present a sound analysis of findings and factually based conclusions and recommendations.

This section illustrates our understanding of the study objectives and key issues and challenges associated with this study and how we tackled them.

2.1 Study Objectives

The **purpose of this study** is to support the European Commission impact assessment on the health costs of children's exposure to lead via toys and on the benefits resulting from reducing such exposure. The study is designed to answer the following questions:

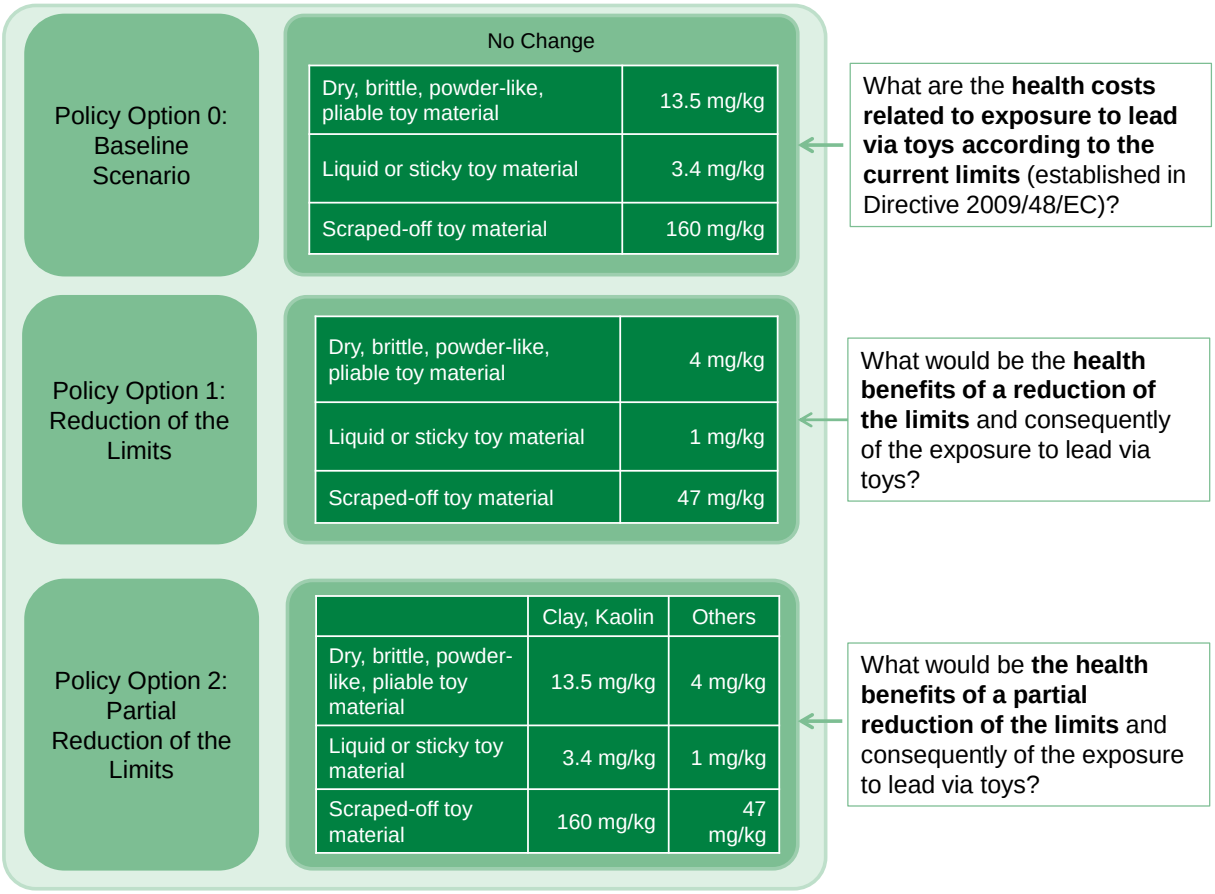
- What are the **health costs related to exposure to lead via toys according to the current limits** (established in Directive 2009/48/EC)?
- What would be the **health benefits of a reduction of the limits** and consequently of the exposure to lead via toys?
- What would be **the health benefits of a partial reduction of the limits** and consequently of the exposure to lead via toys?

The **aim of this study** is to estimate the health costs and benefits related to the introduction of specific policy options. The study covers the following three scenarios:

1. **Policy Option 0 (Status Quo):** this will involve an analysis of the health costs for children if the migration limits are maintained at the levels set by Toy Safety Directive (TSD, 2009/48/EC).
2. **Policy Option 1:** we will evaluate the health benefits resulting from a reduction in the limit values, expected to lead to a decrease in children's exposure and absorption of lead.
3. **Policy Option 2:** our modelling exercise will estimate the health benefits resulting from a reduction in the lead migration limits, which also envisages an exoneration of some materials from such reduction.

Figure 1 summarises the research questions and the corresponding policy options proposed by the Commission.

Figure 1 - Relation Research Question and Policy Options



This report is the **final output of the study**. It contains a comparison table showing the health costs of children's exposure to lead via toys and the benefit of the options proposed by the European Commission.

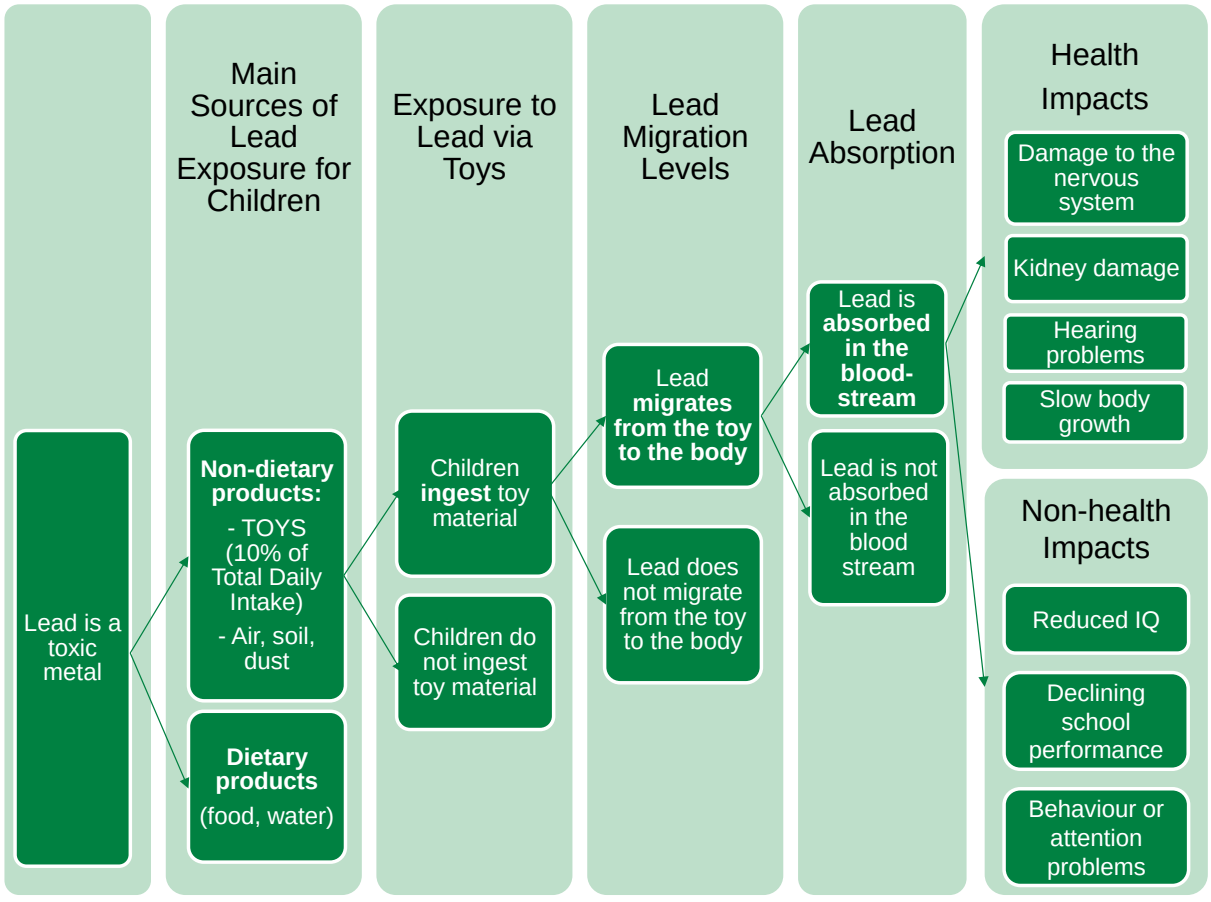
The report covers all points of the work plan and includes sound analysis of findings and fact-based conclusions and recommendations. It is also accompanied by an executive summary.

3.0 Problem Definition

This chapter outlines the problem related to children's exposure to lead via toys and the consequences of this exposure on their health. Section 1 (Nature of the problem) provides the background related to lead and children's exposure to it. Section 2 (Problem drivers) outlines the different channels of exposure to lead in children, with toys being one of these channels. Section 3 (Magnitude of the problem) discusses how much lead children are exposed to via toys and how much of these lead is likely to migrate to their body and bloodstream. Finally, Section 4 (Consequences of the problem) outlines the health consequences of this exposure.

The key problem, its causes and its impacts are also outlined in the figure below.

Figure 2 – Problem Tree



3.1 Nature of the Problem: Children's Exposure to Lead

Lead is a heavy metal which takes both organic and inorganic form. As it naturally occurs in the earth crust, it is contained in many natural resources such as zinc ore, silver and (most abundantly) copper. Lead is also found in the air, soil, water and food (EFSA, 2010), as the result of human activities and due to its extensive use in industrial processes.

Lead is a toxic metal and there is no threshold below which exposure to lead has no critical health effects (EFSA, 2010). The International Agency for Research on Cancer has classified lead as being "probably carcinogenic to humans" (EFSA, 2010b). This is confirmed by a recent European Food Safety Authority (EFSA) article, which concluded that there is "no evidence for a threshold for critical lead-induced effects". In non-human primate models, even low-level exposure to lead has caused neurotoxicity (i.e. damage to the nervous system and/or brain), in particular learning deficits (EFSA, 2010b). In adults, lead exposure has been found to detrimentally affect central information processing, particularly spatial organisation and short-term verbal memory (EFSA, 2010b).

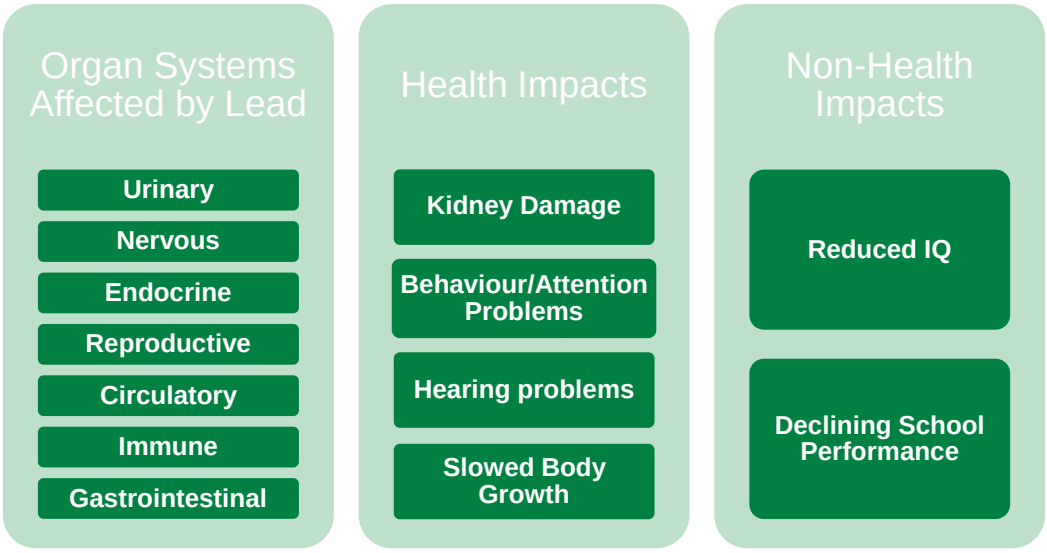
Lead exposure has particularly damaging effects on children. Children are in fact more susceptible to lead than adults (UNEP, 2012) for two main reasons:

- **A developing brain is more susceptible to neurotoxicity of lead than a fully-developed adult brain** (Lidsky and Schneider, 2002). One reason for this being that the so-called 'blood brain barrier' protecting the adult brain from toxic agent (to some extent) is not fully developed in children. Moreover, as the nervous system undergoes tremendous development in children, any interference by a toxic agent at this stage would have consequences on the ultimate functioning of the system. Thus, small quantities of lead might influence the intellectual and behavioural development of children.
- Children, especially under the age of six, absorb greater amounts of lead than adults do, even when the absolute exposure to lead is identical.[5] Several factors increase lead absorption rate in children as opposed to adults (WHO, 2002):
    - The **overall intake of lead per unit of body weight** is higher for children than for adults;
    - **Physiological uptake rates** of lead in children are higher than in adults especially given their hand-to-mouth activities, resulting in the ingestion of dust and soil and, possibly, increased intake of lead.

The figure below summarises the effects and impacts of lead exposure in children.

[5] It has been estimated that for a given oral dose of lead, children absorb three times the quantity that adults absorb, and retain six times as much. Goyer, RA (1991): Toxic effects of metals. In Amdur Mo, Doull J. & Klaassen CD (Eds.), Casarett and Doull's Toxicology: the Basis Science of Poison, Fourth Edition. New York, NY, Pergamon Press.

Figure 3 – Effects and Impacts of Lead Exposure in Children



3.2 Problem Drivers: Channels of Lead Exposure

As mentioned in the paragraphs above, lead is present in a wide range of materials in the environment, in both organic and inorganic form. Consequently, children may absorb lead through **dietary** or **non-dietary exposure** (EFSA, 2010).

Table 3 – Lead Exposure Channels

Dietary exposure	
Food	• Source of lead in food primarily as a consequence of air pollution. • Largest contributors to overall food lead exposure across the EU are vegetables, nuts and pulses (between 14% - 19%), as well as cereals and cereal products (13% - 14%) (EFSA, 2010). • Major source of lead exposure in children. For young children, this particularly includes some calcium supplements, infant formulae and breast milk (Gould, 2009).
Water	• Primarily from steel and iron industries, as well as from lead production and processing operations. • Lead exposure via water, which is generally higher for those living near hazardous waste sites (EFSA, 2010).
Total Diet	• For children between 0 and 7 years old, estimates of reported dietary exposure range from 0.21 to 3.10 µg/kg b.w. per day (EFSA, 2010).
Non-dietary exposure	
Air	• Primarily from anthropogenic sources, i.e. metal production, manufacturing industries, electricity and heat production. • In the USA, household lead paint and related dust and chips are a particularly large source of high lead levels in children, though less so in the EU (MACCHE, 2012). • Bioavailability of atmospheric lead has decreased rapidly over the past forty years, because of regulations banning the usage of lead in petrol (EFSA, 2010). • For children, air exposure is split into outdoor air and environmental tobacco smoke (EFSA, 2010). • Daily outdoor air lead exposure is estimated to be between 0.001 and 0.003 µg/kg b.w. per day in children. • Daily environmental tobacco smoke lead exposure between 0.012 and 0.052 µg/kg b.w. per day in children (EFSA, 2010).
Soil & Dust	• Important source of lead exposure for children. • This includes, e.g. lead dust in carpets and dust near waste sites (Committee on Environmental Health 2005; MACCHE 2012). • It is estimated that children are exposed to between 0.18 and 0.80 µg/kg b.w. on a daily basis (EFSA 2010).

3.2.1 Lead in Toys

Toys represent one of many channels of children's exposure to lead. Whilst it is difficult to assess how much of the daily quantity of lead children are exposed to actually comes from toys, an extensive review of the relevant scientific literature on exposure channels indicates **that the proportion of children's lead exposure that is due to toys is small**. In particular, this proportion must be regarded in the context of several other more significant lead channels, as depicted above.

Throughout this study we follow the assumption that toys contribute to a maximum of 10% of the total lead intake by children. This is in line with the recommendations of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE). In 2004, the Committee recommended that

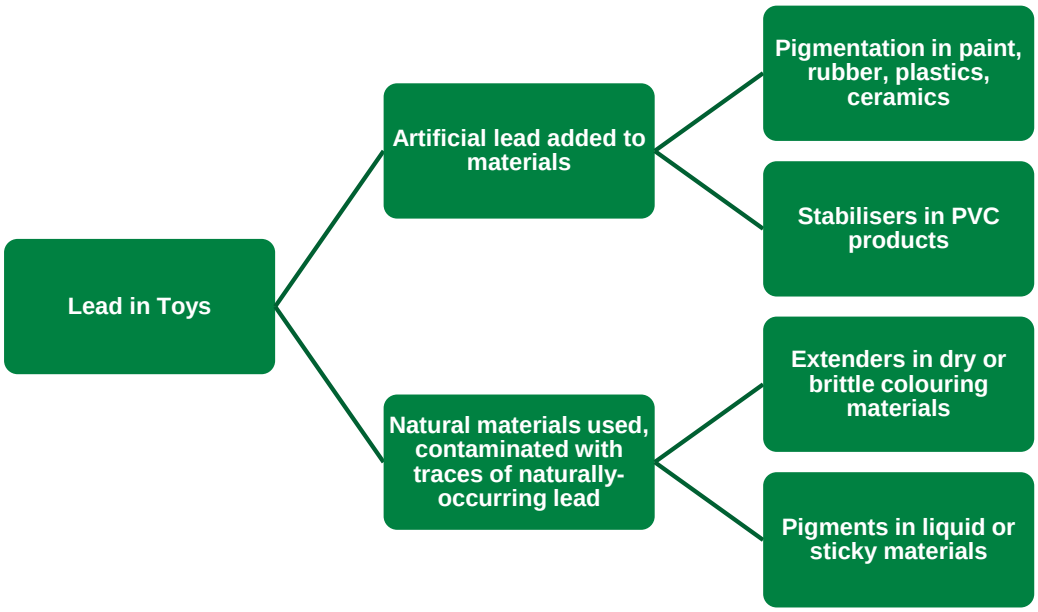
maximum of **10% of the 'Tolerable Daily Intake (TDI) of lead in children should come from toys**. The TDI is an estimate of the amount of a substance that can be taken-in daily over a lifetime without appreciable health risk. It is calculated on the basis of laboratory toxicity data to which uncertainty factors are applied. JECFA (1986) concluded that a provisional tolerable weekly intake (PTWI) for lead was 25 µg/kg b.w. for children, which corresponds to a TDI of 3.6 µg/kg b.w. The EFSA (2010) report concluded that this is no longer appropriate and recommended reducing the TDI. The proportional TDI allocation to toys (10%, as recommended by CSTEE 2004) was also questioned by RIVM (2008), which calculated alternative migration limits based on proportional allocations of 5%, 10% and 20%. The proportion of the TDI allocated to lead in toys affects the migration limits applied: the lower the allowed toys' contribution to the TDI, the lower the toys' migration limits.

Lead can be present in toys either because:

- **Artificial lead** is added to non-contaminated materials; or
- **Natural materials**, which are contaminated with traces of naturally-occurring lead, have to be used to produce the toy.

The figure below summarises the different sources of lead in toys.

Figure 4 – Sources of Lead in Toys



The two most common ways in which toy manufacturers use **artificial lead** are:

- **For pigmentation in paint, rubber, plastics and ceramics**. Examples of toys that *could* contain artificial lead for pigmentation include painted blocks, metal cars, tea sets, baby's cribs, etc.
- **As a stabiliser in PVC[6] products** – for softening plastic to make it more malleable. When lead is used to soften plastic in toys, it makes the plastic degrade to lead dust on overexposure to heat, which is toxic for anyone who comes in contact with it. Examples of

[6] Polyvinyl chloride (PVC) is the third most widely produced plastic.

toys that *could* contain artificial lead as a stabiliser include lunchboxes, changing bags, toy balls, toys from vending machines, etc.

The two most common ways in which toy manufacturers **use natural materials that are contaminated with traces of naturally-occurring lead** are:

- **As extenders** (e.g. kaolin, chalkstone, clay, talc or other grinded rock materials), in dry or brittle colouring materials to maintain stability, breaking resistances and smoothing abrasion without scraping. Examples of toys that *could* contain natural materials contaminated with traces of naturally-occurring lead include chalks, pencils, pens, crayons (WECF, 2009) – i.e. primarily in the arts and crafts industry.
- **As pigments** (e.g. iron oxides, titanium dioxide, bariumsulfate), in liquid or sticky materials to render them opaque – Examples of toys that *could* contain natural materials contaminated with traces of naturally-occurring lead include paints (EWIMA, 2011) – i.e. primarily in the arts and crafts industry.

Toys that contain traces of naturally-occurring lead include (EWIMA, 2012):

- Chalks
- Coloured pencils
- Fibre pens
- Finger paints
- Drawing games (spiro games)
- Modelling materials
- Water colours
- Wax crayons
- Window colour
- Fancy products

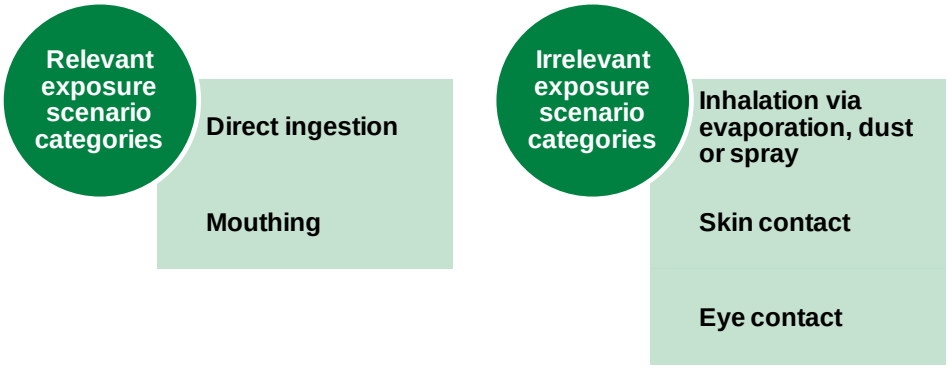
These toys are generally produced by writing instrument manufacturers and are part of the arts and craft sales sector. According to the European Writing Instruments Manufacturers Associations (EWIMA, 2011), alternative materials without natural lead content are not easily, if at all, available to produce this particular group of toys.

Based on the results of the scoping interviews with stakeholders conducted as part of this study and on a thorough review of the evidence; the writing instrument segment of the toy industry appears to be the only sector which uses natural materials that could be contaminated with traces of naturally-occurring lead.

3.2.2 Exposure Scenario Categories

There are several ways in which children can generally be exposed to lead, though some of these are deemed not particularly significant in the context of toys (RIVM, 2008).

Figure 5 – Exposure Scenario Categories



The scenarios of direct ingestion and mouthing[7] are relevant for elements in toys. Oral exploration behaviour in children below 3 years of age implies that all sorts of toys could be both mouthed and ingested by them. Children above 3 could also mouth toys intended to be placed in the mouth, as well as ingest scraped-off material from them.

Due to the nature of the vast majority of toys, **inhalation, skin contact and eye contact are unlikely to be significant channels of children's lead exposure**, for two primary reasons:

- **Toy characteristics:** Inhalation via evaporation would imply extremely volatile chemicals, whilst inhalation via dust or spray would imply significant amounts of dust being released or chemicals being released via a spraying system. There are only very rare examples of toys fulfilling these criteria, though if they do, they are subject to the toy migration limits.
- **Nature of exposure:** Skin contact is not a significant channel, because dermal uptake of lead is very low. Eye contact effects, such as eye irritancy, are of a mild and transient nature.

The ways in which, and the extent to which, children are exposed to lead through toys has been a key issue of interest in the scientific and policymaking communities. RIVM (2008) estimates that 8 mg of scraped-off, 100 mg of brittle and 400 mg of liquid or sticky toy material are ingested by children every day.[8] This implies that if such toys contain traces of lead, a small amount of lead will be ingested by children (RIVM, 2008). As children of a young age are constantly exposed to toys; **toys partially manufactured with lead are a problem driver for lead exposure in children and its resulting neurotoxic effects.** This is true even if, as mentioned above, we assume that toys contribute to a maximum of 10% of the TDI of lead in children.

3.3 Magnitude of the Problem: Amount of Lead Absorbed by Children from Toys

From this section onward, we discuss and analyse the consequence of lead absorbed by children from toy sources only.

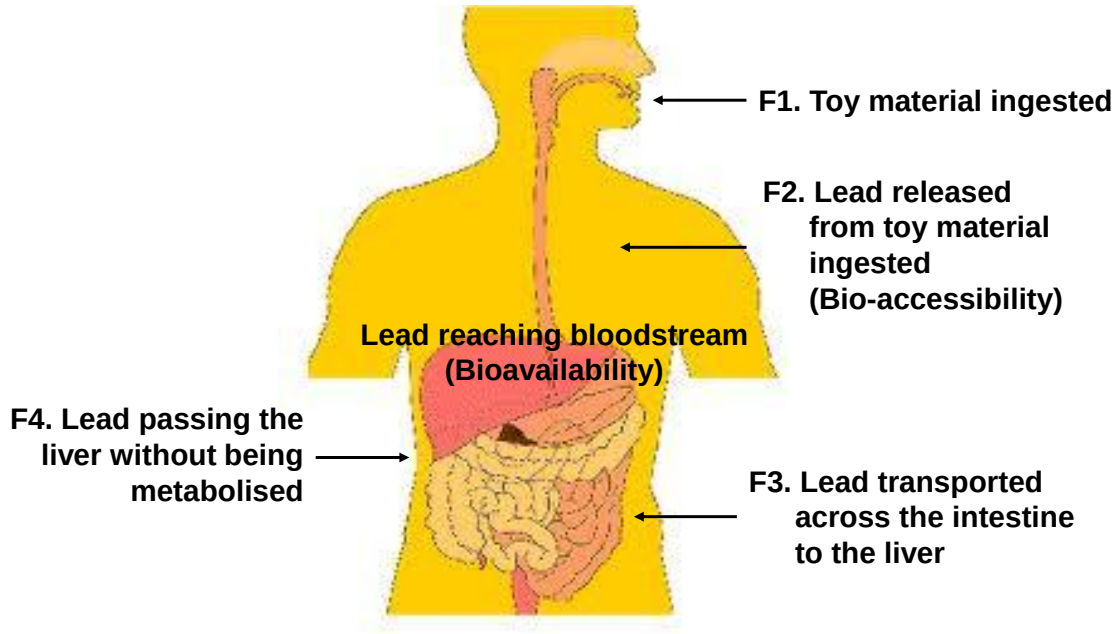
Lead poisoning and other consequences of exposure to lead manifest only once the chemical is absorbed in the blood stream and accumulates in organs and tissues. Thus, **the health impacts of children's exposure to toxic metals, including lead, via toys can only be measured through the bioavailability of the material in the blood stream.** Bioavailability is defined as 'the amount of each

[8] Industry stakeholders, and in particular EWIMA, have criticised these estimates of the level of ingestion of toy materials, arguing that they are implausible, even as worst case scenarios (EWIMA, 2011)

element in the toy which could be absorbed into the systemic circulation of a child' (Scientific Committee on toxicity, 2004).

Estimates of the amount of lead that can be absorbed into the blood circulation of a child can be measured taking into consideration the various steps of the digestive process. There are five main determinants of the amount of lead that is absorbed in children's bloodstream, thus affecting his or her health. These processes are outlined in the figure below and are described in the following paragraphs.

Figure 6 – Process of Bioavailability



The bioavailable fraction (F) is the amount of the toxic metal (in this case lead) that can be absorbed in the systemic circulation. This fraction will be transported throughout the body and will be distributed to three main compartments: blood, soft tissue (kidney, bone marrow, liver and brain) and mineralized tissue (bones and teeth). Lead may exert toxicity in these organs and tissues. Most of the harm produced will be due to lead's ability to mimic and inhibit the actions of calcium. The amount of lead reaching the bloodstream, following children's ingestion of the toy material is the result of the four steps outlined below:

1. **Toy Material Ingested (F_1):** As outlined in the section above, children are exposed to lead in toys primarily through direct ingestion and mouthing. On this basis, RIVM (2008) estimates that, in the worst case scenario, children ingest 100 mg/day of dry, brittle, powder-like or pliable toy material; 400 mg/day of liquid or sticky toy material; and 8mg of scraped off toy material.[9]

[9] These estimates are based on the worst case assumption that children play with one toy for 3 hours/day consecutively. It is important to highlight that the industry, and in particular EWIMA, has argued that, even in the worst case scenario, such levels of ingestions are implausible (EWIMA, 2011).

Figure 7 – Quantity of Toy Material Ingested

Toy Material	Quantity of Toy Ingested (per day)
Dry, brittle, powder-like, pliable toy material	100mg
Liquid or sticky toy material	400mg
Scraped off toy material	8mg

2. **Lead released from toy material ingested (Bio-accessibility) (F_2):** During digestion in the gastro-intestinal tract, lead might be partially or totally released from the toy material ingested. The fraction of the chemical that migrates from the toy into the body does not necessarily correspond to the lead content of the toy. Most of the chemical elements will remain in the matrix, even after mouthing or swallowing (SCHER, 2010). In the European Union, the Toy Safety Directive (TSD, Directive 2009/48/EC) regulates the amount of a chemical that can be released from toy material when ingested, namely the migration limit[10]. Thus, if the toy is built in compliance with the TSD, the amount of lead that migrates to the children's body (i.e. bio-accessible fraction) should not exceed the new migration limit. The TSD was introduced in June 2009, but the newly established migration limits will only be enforceable as from July 2013, after a transition period of 4 years. Until then, toy manufacturers must comply with the bioavailability levels established in the previous Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys. Lead bioavailability[11] resulting from the use of toys must not exceed 0.7 µg per day.

Figure 8 – Lead Migration Limits (Bio-accessibility), Applicable as from 20 July 2013

Toy Material	Lead Migration Limit
Dry, brittle, powder-like, pliable toy material	13.5 mg/kg
Liquid or sticky toy material	3.4 mg/kg
Scraped off toy material	160 mg/kg

3. **Lead transported across the intestine to the liver (F_3):** the bio-accessible fraction of lead released from the toy material ingested is potentially available for transport across the intestine. However, only a fraction of the bio-accessible lead is transported from the lumen through the intestinal epithelium, the small intestine and portal vein and to the liver. In order to

[10] Migration limits report how much of the element migrates from (e.g.) the toy to the human body, or in other words the amount of element actually released from the toy and to which the body is exposed.
[11] Bioavailability of lead, as defined in Directive 88/378/EEC, means the soluble extract having toxicological significance

calculate systemic bioavailability as a daily body burden, a gut **absorption value for lead of 50%** (RIVM, 2008; ATSDR, 2005) has been applied to intake levels. This is equivalent to saying that half of lead intake (F_1 x F_2) becomes systematically bioavailable. This is a conservative absorption value based upon data in infants and children and assumes lead is in its elemental form.

4. **Lead passing the liver without being metabolised (F_4):** Part of the lead absorbed through the intestine will be metabolised by the liver. Only a fraction of the lead absorbed will not be metabolised (i.e. eliminated from the body via urine and faeces) and it will hence reach the systemic circulation and be transported across the body. The non-metabolised fraction will thus exert toxicity in the organs and tissues. The complex biokinetic model (IEUBK)[12] used in this impact assessment takes into account the elimination rates in calculating blood lead levels.

Thus, the amount of lead in toys absorbed by children depends on four main determinants: the amount of toys ingested, the amount of lead released from the ingested toy (migration limit), the amount of lead absorbed in the intestine, the amount of lead not metabolised in the liver. The bioavailable amount can be calculated through the following formula:

$$F = F_1 * F_2 * F_3 * F_4$$

The amount of toy material ingested (F_1), the fraction of lead released from toy material ingested (Bio-accessible lead fraction, F_2) and fraction of lead absorbed by the intestine (F_3) determine the **systemic body burden** of lead in children's body. In other words, it refers to the amount of lead within the body within a certain period of time. Results on the systemic body burden of lead in children's body via toys, related to the migration limits set in the Toy Safety Directive (2009/48/EC)[13] are presented in the table below.

Table 4 – Bioavailability of Lead via Toys at the Migration Limits Set by the Toy Safety Directive

	F_1	F_2	F_1*F_2	F_3	$F_1*F_2*F_3$	F
Material	**Amount of Toy Ingested (mg/day)**	**Bio-accessible lead[14] (mg/kg)**	**Total Lead Intake[15] (µg/day)**	**Lead in the intestine (proportion of bio-accessible lead)**	**Systematic body burden (µg/day)**	**Bioavailable lead (µg lead/dL blood)**
Dry, brittle, powder-like, pliable toy material	100	13.5	1.35	0.5	0.7	0.333
Liquid or sticky toy material	400	3.4	1.36	0.5	0.7	0.333
Scraped-off toy material	8	160	1.28	0.5	0.7	0.333

More details on the calculation are provided in Section 6.1, where the limit values for toys as established in the new Toy Safety Directive (2009/48/EC) are discussed in the context of Policy Option 0.

[12] More details on the model are provided in Appendix 8.2
[13] More details on the Directive are presented in the next chapter.
[14] Which corresponds to the migration limit if we assume full-compliance.
[15] This corresponds to (F1 * F2 / 1000) to convert mg/day into µg/day.

3.4 Consequences of the Problem: Health Impacts

Lead absorption can cause a number of health related and non-health related impacts. The effects of lead poisoning on human health depend on the amount of lead absorbed and the time over which this amount is absorbed. In the case of large quantities of lead absorbed over a short time period, the effects can manifest immediately. The immediate symptoms of lead poisoning, often easily overlooked (Marcus, 2011), may include abdominal pain and cramping, aggressive behaviour, anaemia, constipation, difficulty sleeping, loss of developmental skills, low appetite and energy, reduced sensations and headaches (MedlinePlus, 2011).

Lead has also toxic effects if absorbed in small quantities over a longer period of time. Effects of lead exposure on health have been thoroughly studied and research demonstrates that lead is toxic to a number of organ systems including the urinary, nervous, endocrine, reproductive, circulatory, immune and gastrointestinal systems (UNEP, 2012). The most widespread health impacts include:

- **kidney damage**, which manifests as loss of function and decreased reabsorption (UNEP, 2012);
- **hearing problems** caused by slowed nerve conduction in the auditory pathway (Schwartz, 1991);
- **behaviour and attention problems** (MedlinePlus, 2011), which can manifest in ADHD (Attention Deficit Hyperactivity Disorder); and
- **slowed body growth** (MedlinePlus, 2011).

Moreover, lead absorption might also have impacts on the individual's quality of life, which are not necessarily health related. For instance, lead might reduce IQ and productivity (EFSA, 2010b), as a result of its effect on the nervous system, or it might affect fertility rate, through its effects on the reproductive system. Both the health related and non-health related impacts of lead absorption might imply a reduction in individual quality of life, increase treatment costs for society and generate a reduction in productivity. More evidence on these impacts is presented in Section 6.2.

4.0 Baseline Analysis

The European toy market is the largest in the world in revenue terms. It comprises over 25% of the world toy market, exporting €1.05 billion worth of traditional toys to non-EU countries in 2010[16] and importing €6.96 billion of traditional toys from non-EU countries in 2010.[17] Toys are therefore a highly significant industry within the EU and EU policy has a large impact on this market.

There exists a number of approaches to risk assess and set safety standards for heavy metals, and other organic substances, in consumer products. In the United States, safety limits are based on content requirements. In other words, toys, and other consumer products must not contain lead in excess of pre-determined levels. The United States Consumer Product Safety Commission (CPSC)[18] has gradually reduced the lead content in products designed or intended primarily for children aged 12 and younger from 600ppm (before February 2009) to 300ppm (August 2009) and to 100ppm in August 2011[19].

In 1988, the European Union introduced Directive 88/378/EEC[20] on the "approximation of the laws of the Member States concerning the safety of toys".[21] The aim of the directive was to harmonise toy safety requirements across Member States and establish the 'CE mark' of safety[22]. Directive 88/378/EEC also established bioavailability limits for chemicals in toys, where bioavailability means the soluble extract having toxicology significance. The use of bioavailability levels as safety standards is based on the fact that the total amount of chemical elements present in a toy *per se* does not necessarily represent a risk for children, as most of the chemical elements will remain in the toy even after mouthing or swallowing parts of it (SCHER, 2010).

On this basis, Directive 88/378/EEC established that lead bioavailability resulting from the use of toys must not exceed 0.7 μg. The European Standard on safety of toys – Part 3: Migration of certain elements (EN 71-3) has translated this into an upper limit of migration of toy material, corresponding to **90 mg/kg for lead**. This transposition has been based on the hypothesis that average intake for toy material is 8 mg/day, being aware that in certain individual cases this figure might be exceeded (British Standards, 1995).

Whilst Directive 88/378/EEC was transposed by all Member States and served its purpose well for a number of years, technological developments in the toys market made it necessary to update the safety requirements, particularly in relation to noise and chemicals in toys. **To address these problems, the Toys Safety Directive (2009/48/EC, TSD) was introduced in 2009.** The TSD sets essential safety requirements that toys placed on the EU market must fulfil, whilst it leaves the technical specifications of products up to standardisation organisations**.** In line with this, and in order to guarantee the enforcement of these safety requirements, the Directive also specifies the need to strengthen national market surveillance systems.[23]

[16] The production of toys is mainly concentrated in Germany, Italy, France and Spain.
[17] http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/448&type=HTML
[18] http://www.cpsc.gov/about/cpsia/sect101.html
[19] In the US, the surface of the tested consumers' product is screened through the XRF. XRF is an X-Ray Fluorescent screening apparatus used for qualitative and quantitative elemental analysis of environmental, geological, biological, industrial and other samples. Products which fail the contents limits are immediately removed from the market. Source: Interview with Noel Toledo (PROSAFE), 13/01/2012.
[20] OJ No L 187/1 of 16.7.88
[21] http://ec.europa.eu/enterprise/sectors/toys/documents/directives/index_en.htm
[22] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1988L0378:20090112:en:PDF
[23] http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/448&type=HTML

The TSD established that risk assessment of toys should be based on examining migration levels of chemical elements, rather than bioavailability levels. Migration limits take into consideration the fact that exposure to a chemical element from a toy can only occur when it is released from the toy matrix and when it becomes bio-accessible (RIVM, 2008). **It is the total concentration of lead in the toy that is absorbed, rather than merely its presence, which is the crucial factor in determining whether adverse effects may occur or not** (RIVM, 2008).

Along with limits for heavy metals such as nickel or mercury, the TSD established very strict migration limits for lead in toys[24]. These limits are based on:

- estimations around the maximum percentages of the tolerable daily intake (TDI) of lead derived from the Tolerable Weekly Intake of 25 µg /kg of bodyweight established by the FAO/WHO Joint Expert Committee on Food Additives (JECFA);
- the recommended percentage of daily intake of lead that may be allocated to toys (5%); and
- the estimated daily quantity of toy material ingested by children (8 mg of scraped-off material, 100 mg of brittle toy material and 400 mg of liquid or sticky toy material).

The table below presents the current migration limits for lead from toys or components of toys, established by EN 71-3, and the new migration limits established by the TSD and which will enter into force in July 2013.

Table 5 - Migration Limits in the European Union

Toy Material	EN 71-3	TSD (applicable as from 20 July 2013)
Dry, brittle, powder-like, pliable toy material	90 mg/kg	13.5 mg/kg
Liquid or sticky toy material	90 mg/kg	3.4 mg/kg
Scraped off toy material	90 mg/kg	160 mg/kg

Even though the TSD was introduced in June 2009, the newly established migration limits will only be enforceable after 20 July 2013. During this transition period, the bioavailability levels established by the previous Directive 88/378/EEC apply. Thus, any toy placed on the market before 20 July 2013 will have to comply with a lead bioavailability level of 0.7 µg, corresponding to a migration limit of 90 mg/kg, as established by EN 71-3. Consequently, conformity assessments[25] carried out so far by market safety authorities, laboratories and toys manufacturers do not test compliance with the new migration limits, but instead with the old bioavailability limits.

Consequently, there is no data available on the level of compliance with the current TSD as the new migration limits are not enforceable yet. For this reason, this impact assessment will be informed on the basis of the level of compliance with the EN 71-3 migration limits, established by Directive 88/378/EEC. However, evidence suggests that the rate of compliance with the new TSD migration limit will not be different from the rate of compliance with the previous EN 71-3 migration limits. Tests carried out so far in fact suggest that only a very small percentage of toys do not comply with lead migration limits and, if they do, their lead content is much higher than the migration limit. In

[24] The new requirements for chemicals will be applicable from 20 July 2013.
[25] In Europe XRF is used as a preliminary screening test. Source: Interview with Noel Toledo (PROSAFE) and Jan van Leent (JWA), 13/01/2012.

the last 4 years, RAPEX[26] has only reported 64 toys infringing the migration limits set by Directive 88/378/EEC and whose lead content was usually at least twice the migration limit. On the basis of this evidence, we assume that only the toys that already violated EN 71-3 standards are likely to also violate the new TSD migration limits.

[26] RAPEX is the EU rapid alert system for all dangerous consumer products, with the exception of food, pharmaceutical and medical devices. It allows for the rapid exchange of information between Member States via central contact points (the National Contact Points) and the Commission of measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.

5.0 Policy Objectives and Policy Options

In this section we discuss policy objectives and present the policy options. We also discuss the rationale for EU action in this area.

5.1 Policy Objectives and Rationale for EU Action

Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys[27] was adopted in the context of establishing the internal market. Its purpose was to harmonise the safety requirements of toys throughout the Member States and to remove obstacles to trade in toys between Member States.

Technological developments in the toys market subsequent to the Directive have raised new issues with respect to the safety of toys which gave rise to increased consumer concerns. In order to address those challenges Directive 88/378/EEC was revised and replaced by Directive 2009/48/EC, which introduced very strict migration limits in toys. Those limits were based on the recommendations of the 2008 report by the Dutch National Institute for Public Health and the Environment (RIVM, 2008). However, the latest EFSA (2010) study on "lead in food", called for further reducing lead exposure from both food and non-foods products.

The new scientific evidence shows that the level of protection of children against exposure to lead, as established in 2009, is no longer appropriate. Therefore, in order to reduce children's exposure to lead, the European Community believes that it becomes necessary to act and amend the current values for lead and align them with the latest scientific data.

On this basis, the policy objectives of this initiative are:

- to **ensure a higher level of safety for children** by reducing the exposure of children to a particularly toxic substance; and
- to **ensure a proper functioning of the internal market** for toys.

5.2 Policy Options

A study by EFSA has concluded that exposure to lead, from both dietary and non-dietary sources (including toys), should be reduced (EFSA, 2010). New scientific evidence has in fact suggested that there is no threshold below which lead in the bloodstream has no impacts on individuals' health (EFSA, 2010). The European Commission is thus considering **three policy options, in order to achieve the goal of reducing lead exposure in children, whilst considering the internal market dimension.**[28]

The three policy options are presented in the table below and discussed in the following paragraphs.

[27] OJ L 187, 16.7.1988, p. 1.
[28] During the scoping interviews carried out so far, stakeholders have stressed that reducing the migration level might have substantial impacts on the industry and on the internal market.

Table 6 – Proposed Policy Options

Toy Material	Migration Limits (mg/kg)			
	Policy Option 0 (Status Quo)	Policy Option 1	Policy Option 2	
			Clay, Kaolin, Pigments	Others
Dry, brittle, powder-like, pliable toy material	13.5	4	13.5	4
Liquid or sticky toy material	3.4	1	3.4	1
Scraped-off toy material	160	47	160	47

- **Policy Option 0** (Status Quo) proposes that the migration limits remain as established in the Toys Safety Directive 2009/48/EC.

- As **Policy Option 1**, it is considered that, in the absence of a TDI for calculating migration limits and based on the Expert Group on toy safety recommendations (0.50 µg/kg of bodyweight per day and 10% of lead TDI allocated to toys), the limit values for toys could be: 4 mg/kg in dry, brittle, powder-like or pliable toy material, 1 mg/kg in liquid or sticky toy material and 47 mg/kg in scraped-off toy material.

- **Policy Option 2** seeks to exonerate from the reduction of the limits certain materials, which naturally contain lead and which are used to produce toys. Lead naturally occurs in the earth crust; hence, it can be found as a 'natural' contamination in the environment (e.g. soil, rock, water). Thus, a certain natural content of lead cannot be removed from materials from natural sources, used in many different industries.

Discussion of Policy Option 2

There are certain materials for which reducing the lead content below the current limits might not be possible, as they contain lead in a natural form. For this reason, if the migration limits are further reduced, certain categories of toys will be driven out of the market completely, imposing high costs on the industry. The European Commission is thus considering creating an exemption for those materials where lead can be found naturally. However, introducing such exoneration would inevitably reduce the size of the health benefits of containing children's exposure to lead via toys. Moreover, the exoneration might favour certain sections of the industry with respect to others.

Lead is a heavy metal which takes both organic and inorganic form. As it naturally occurs in the earth crust, it is contained in many natural resources such as ore with zinc, silver and (most abundantly) copper. Extenders (such as kaolin, chalkstone, clay, talc or other grinded rock materials) and pigments (such as iron oxides, titanium dioxide, bariumsulfate) are materials from natural sources that are used in writing instruments. Extenders are used to maintain stability, breaking resistance and smooth abrasion without scrapping in dry or brittle colouring materials. Pigments are used in opaque paints.

Extenders and pigments are required in the production of certain toys. As mentioned in Section 3.2, many arts and craft industry's products (including chalk, wax crayons, pastels, water paint tablets and finger paints. A full list is provided in Section 3.2 above) require the use of kaolin as an extender in order to leave a trace. According to information provided by the European Writing Instruments Manufacturers' Association (EWIMA), depending on the quality of the kaolin used in toys,

the lead content of kaolin can be up to 50 mg/kg. The lead migration from kaolin can range from between 2 mg/kg to 16 mg/kg (i.e. there is no one-to-one relationship between content and migration), making compliance with a 4 mg/kg limit on dry and brittle materials and a 1 mg/kg limit on liquid or sticky materials extremely difficult for manufacturers of products using these materials. Alternative materials (such as titanium oxide or iron oxide) also naturally contain lead and thus cannot be used to replace kaolin and reduce the lead content in the product.

Most writing instruments classified as toys contain natural sources of lead, such as clay, kaolin and pigments, which have traces of lead. Inevitably, the fact that lead is naturally contained in materials used to produce toys and that this lead content cannot be reduced implies that certain toys could be driven out of the market. Multiple industry stakeholders[29] have argued that the arts and craft industry in particular would have difficulties in complying with the revised migration limits (proposed in Policy Option 1). According to Toy Industries of Europe (TIE), **6.5% of all toys sales in the EU consists of arts and crafts sales.** As such, it is likely that a reduction in the limits would have a large impact on colouring products currently classified as toys, which are established in the market since decades. As the proposed limits could not be matched for the foreseeable future, these products could not be marketed as toys any longer.

In order to avoid the exclusion from the market of certain toys, the Commission is considering allowing exoneration from the reduction of the migration limits (proposed in Policy Option 1) for certain materials, such as clay, kaolin or pigments. Thus, the migration limits proposed under Policy Option 2 are the following:

Table 7 – Policy Option 2

Toy Material	Migration Limits (mg/kg)	
	Clay, Kaolin, Pigments	Others
Dry, brittle, powder-like, pliable toy material	13.5	4
Liquid or sticky toy material	3.4	1
Scraped-off toy material	160	47

There are however a number of factors to account for when considering applying exonerations for clay, kaolin and pigments, as in Policy Option 2:

- The purpose of reducing lead migration limits in toys and toy material is to prevent negative impacts on children's health. The reduction of migration limit might lead to certain health benefits. The exoneration of certain materials from the proposed limits would inevitably reduce the size of these health benefits.
- Natural sources of lead and artificial sources of lead bear the same negative impacts on individuals' health. Thus, from a health perspective, material containing natural traces of lead should be treated equally to material containing artificial traces of lead.
- Reducing the migration limits for toys imposes compliance costs on the industry, which has to reduce lead content in toys. An exemption for certain materials could end up favouring certain sections of the industry with respect to others.

[29] Including TIE (Toy Industries of Europe), the European Writing Instruments Manufacturers' Association (EWIMA), PROSAFE, etc.

- Exoneration criteria need to be very well defined. The exoneration would create the incentive for manufacturers to particularly emphasise their usage of specific materials from natural sources, or for them to start using such materials, in order to avoid having to comply with lower limits. Monitoring of compliance would be extremely important in this sense.
- Exonerations for certain materials imply an additional dimension to national market surveillance. This could create an additional governmental administrative burden and associated increased budgetary consequences.

The European Writing Instrument Manufacturers Association has also made suggestions with respect to the minimum migration limits for certain materials, such as clay, kaolin or pigments that would prevent the exclusion from the market of certain toys. These suggestions are presented in Section 9.2.

6.0 Impact Assessment

This chapter presents the health impacts of the policy options. Section 1 outlines the methodology to calculate lead exposure and absorption related to the different migration levels proposed in the policy options. The lead bioavailability levels calculated through the methodology outlined in Section 1 feed into the model to calculate the health impacts of the policy options. This methodology is outlined in Section 2.

6.1 Effects of Lead Absorption

The proposed policy options aim to reduce the migration limits of lead in toys or components of toys, with respect to the (not yet enforced)[30] migration limits established in the TSD (Policy Option 0)**.** As the maximum limit changes, following the proposed introduction of Policy Option 1 and Policy Option 2, the level of exposure and absorption of lead in children will vary accordingly. The migration limit in fact regulates the amount of lead that can be released from the matrix (i.e. toy material ingested by the child) into the oesophagus, stomach and small intestine, also known as the bio-accessible fraction.

A reduction in the bio-accessible fraction would ultimately lead to a reduction in the bioavailable fraction, namely the amount of lead in the toy which can be absorbed into the systemic circulation of the child, exerting toxicity in the organs and tissues. Health benefits will result from a reduction in the amount of lead entering the bloodstream and thus being transported throughout the body to organs and tissues (lead bioavailability).

The formula to calculate lead bioavailability is reported below.

$$F = F_1 * F_2 * F_3 * F_4$$

where:

F = Bioavailable lead fraction
F_1 = Amount of Toy Material Ingested
F_2 = Fraction of lead released from toy material ingested (Bio-accessible lead fraction)
F_3 = Fraction of lead absorbed by the intestine
F_4 = Fraction of lead passing the liver without being metabolised

F_2 is regulated by the migration limit set at the EU level. Toys manufacturers have to comply with EU legislation by ensuring that the fraction of lead released from the toy material ingested by children does not exceed certain migration limits. Currently, F_2 is regulated by the limits set in EN 71-3, following Directive 88/378/EEC. Once the TSD will enter into force (July 2013), F_2 will be regulated by the migration limits set in the TSD.

If full compliance with EU law is assumed, F_2 corresponds to the migration limits set at EU level. The models used in this study to estimate the health impacts of EU policy options assume full compliance with EU legislation. This assumption is based on available data on the level of compliance with the EN 71-3 standards, which are still in force. As discussed in Section 4.0, the compliance rate

[30] As discussed in Section 4.0, the migration limits set down in the TSD will be enforced only after 20 July 2013. Until then, the bioavailability level of 0.7 ug, established in Directive 88/378/EEC, will be applied.

with the new TSD migration limits is likely to correspond to the compliance rate with the EN 71-3 standards.

The rationale for assuming full compliance with the migration limits set in the TSD and proposed in the policy options is based on evidence that suggests that **a very small percentage of toys tested before entering the EU market violate the migration limits.** Market safety authorities, laboratories and toy manufacturers test compliance with the migration limits set in EN 71-3 (as the migration limits set in the TSD are not enforced yet).[31] In the last 4 years, RAPEX has only reported 64 toys infringing the migration limits set by Directive 88/378/EEC. In the UK, less than 0.05% of toys components tested[32] fail migration limits.[33] Finally, EN71-3 tests[34] conducted as part of the Joint Action on Toys[35] on a sample of 227 toys,[36] found that 15 (6.6%) failed the lead test and thus exceeded the currently allowed migration limit of 90 mg/kg for all toy material. The sample used in the Joint Action on Toys tests however included toys at risk of non-compliance and thus the sample is not representative of the population.

It is also important to stress that the Joint Action on Toys[37] concluded that there are **limits in the current measurements of lead content in toys and tests often come to different conclusions**. Safety test are usually carried out on very small samples of toys, which are considered at risk of having a lead content above the migration limits.

On the basis of the bioavailability formula presented below and in line with the above assumptions, the next section presents estimates of the amount of lead that reaches children's blood stream (i.e. bioavailability level), resulting from exposure to lead in toys that comply with the various migration limits (i.e. bio-accessibility level) set in the policy options.

6.1.1 Measuring the Effects of the Policy Options

This section presents estimates on the **amount of bioavailable lead related to each policy option**. The effects of Policy Option 1 and 2 are represented by the difference between the bioavailable amount corresponding to Policy Option 0 and the bioavailable amount corresponding to Policy Option 1 and 2 respectively.

For the purpose of this impact assessment, bioavailability is only calculated for children between 0 and 3 years old. As discussed in Section 3.2.2, relevant exposure scenarios for lead in toys are direct ingestion and mouthing[38]. These scenarios refer to children below 3 years of age who mouth or ingest all sort of toys. The health impact of this exposure (see Section 6.2) will however be calculated for the entire lifetime of the child.

Assuming full-compliance with the migration limits set in the TSD and proposed in the policy options, it is possible to measure the effects of the policy options on the bioavailability of lead in the blood stream of children due to exposure via toys. In order to obtain an estimate of the amount of lead in the

[31] As explained in Section 4.0
[32] These figures refer to toys tested in the UK and refer to one testing company alone.
[33] This figure is against a migration limit of 90mg/Kg.
[34] EN71-3 standards set migration limits of certain elements, including lead, based on the previous Directive 88/378/EEC
[35] The Joint Market Surveillance Action on Toys, seeks to ensure that toys that are placed on the European Market for children under 3 years old respect, among other things, migration of heavy metals in toys: http://www.prosafe.org/
[36] Originally, a total of 23,000 toys were XRF screened.
[37] Joint Market Surveillance Action on TOYS was awarded to PROSAFE in 2006. Its primary purpose was to ensure that toys for children under 3 years old with respect to the investigated aspects placed within the Single Market are safe.
[38] Mouthing can be defined as encompassing licking/lip touching, sucking/trying to bite, biting or chewing. (Norris, B., Smith, S. (2002). 'Research into the mouthing behaviour of children up to 5 years old.' Available at: http://webarchive.nationalarchives.gov.uk/+/http://www.berr.gov.uk/files/file21800.pdf)

blood stream related to the migration limits in each policy option, the following calculations need to be performed:

- Firstly, the general **systemic body burden of lead** needs to be estimated. The systemic body burden refers to the amount of lead within the body within a certain period of time. The systemic body burden of lead depends on the amount of toy material ingested (F_1), the fraction of lead released from toy material ingested (Bio-accessible lead fraction, F_2) and fraction of lead absorbed by the intestine (F_3).
- Secondly, the **mean weight of children of different ages** needs to be taken into account. As body weight affects overall blood levels of children, bioavailability depends on the weight of children.
- Thirdly, specific **calculation algorithms** need to be used to estimate the bioavailability levels. In this case, the IEUBK model, a complex biokinetic model, has been used to calculate blood lead levels due to children's exposure via toys.

Below we present each of these steps separately, in order to arrive to the calculation of the effects of each policy option on lead bioavailability levels in children.

Systemic Body Burden

The systemic body burden is measured as the amount of lead that is released (F_2) from the toy material ingested (F_1) and that is absorbed in the body (F_3). Hence, it results from the multiplication of the amount of toy ingested (F_1), times the bio-accessible lead fraction (F_2), times the fraction of lead absorbed by the intestine (F_3).

The tables below outline the calculation parameters and steps leading to the estimation of the systemic body burden resulting from the three toy categories, under Policy Options 0, 1 and 2.

Table 8 - Systemic Body Burden for Policy Option 0

	F_1	F_2	F_1*F_2	F_3	F_1*F_2*F_3
Material	**Amount of Toy Ingested (mg/day)**	**Bio-accessible lead[39] (mg/kg)**	**Total Lead Intake (µg/day)**	**Lead in the intestine[40] (proportion of bio-accessible lead)**	**Systemic body burden (µg/day)**
Dry, brittle, powder-like, pliable toy material	100	13.5	1.35	0.5	0.7
Liquid or sticky toy material	400	3.4	1.36	0.5	0.7
Scraped-off toy material	8	160	1.28	0.5	0.7

The reduction in the migration limits proposed under Policy Option 1 would result in a reduction of the daily systemic body burden (lead absorbed into the body) from 0.7µg/day to 0.2µg/day, for all toy categories.

[39] Which corresponds to the migration limit if we assume full-compliance.
[40] According to RIVM (2008), the most appropriate definition of bioavailability within this context is the pharmacology definition – "the fraction of a substance present in toy material that reaches the systematic circulation (of a child)." An intestinal absorption percentage of 50% is thus applied to lead intake, based on RIVM (2008) and ATSDR (2005). This is equivalent to saying that half of all lead intake (F_1 x F_2) becomes uptake, i.e. systematically bioavailable.

Table 9 - Systemic Body Burden for Policy Option 1

	F_1	F_2	F_1*F_2	F_3	F_1*F_2*F_3
Material	**Amount of Toy Ingested (mg/day)**	**Bio-accessible lead[41] (mg/kg)**	**Total Lead Intake (µg/day)**	**Lead in the intestine (proportion of bio-accesible lead)**	**Systemic body burden (µg/day)**
Dry, brittle, powder-like, pliable toy material	100	4	0.4	0.5	0.2
Liquid or sticky toy material	400	1	0.4	0.5	0.2
Scraped-off toy material	8	47	0.4	0.5	0.2

As discussed in Section 5.2, Policy Option 2 seeks to exonerate from the reduction of the limits certain materials, which naturally contain lead and which are used to produce toys. It does not propose the introduction of migration limits that are different from those discussed for Policy Option 0 and Policy Option 1 respectively. More precisely, if Policy Option 2 is introduced, the migration limits would be reduced to the level proposed in Policy Option 1 for all materials but for clay, kaolin and pigments. For these materials, the migration limits would remain at the levels established by the TSD.

On this basis, the reduction in the migration limits proposed under Policy Option 2 would result in a reduction of the daily systemic body burden from 0.7µg to 0.2µg, only for the toy categories that are not excluded. For toys containing clay, kaolin and pigments, the daily body burden will remain at 0.7 µg.

Table 10 - Systemic Body Burden for Policy Option 2

	Clay, Kaolin and Pigments				Other Elements			
Materials	F_1	F_2	F_3	F_1*F_2*F_3	F_1	F_2	F_3	F_1*F_2*F_3
Dry, brittle, powder-like, pliable toy material	100	13.5	0.5	0.7	100	4	0.5	0.2
Liquid or sticky toy material	400	3.4	0.5	0.7	400	1	0.5	0.2
Scraped-off toy material	8	160	0.5	0.7	8	47	0.5	0.2

Accounting for Body Weight

In order to convert the systematic body burden into the amount of lead absorbed into the systemic circulation of the child (bioavailable fraction), it is necessary to account for the body weight of the child. For this reason, values on mean body weight of children at different ages are divided by the systematic body burden calculated above, so as to obtain data in µg/kg bodyweight/day. As is outlined in Appendix 9.4, accounting for bodyweight yields a range of body burden levels, depending on the age and weight of the child. Lead body burdens accounting for body weight for Policy Options 0, 1 and 2, for the age range between 0 and 3 are presented below.

The IEUBK model used in this impact assessment is based on US bodyweight data. In order to ensure that data from US sources are not dissimilar in range and magnitude from data from European sources, data on mean bodyweight data from RIVM (2006) have been compared to US bodyweight

[41] Which corresponds to the migration limit if we assume full-compliance

data (see Appendix 9.4). This comparison has confirmed that there are no meaningful differences between the two.

Table 11 - Lead Body Burden Accounting for Bodyweight

		Lead Body Burden
Policy Option 0		0.14 – 0.04 µg/kg bw/day (females) 0.14 – 0.04 µg/kg bw/day (males)
Policy Option 1		0.04 – 0.01 µg/kg bw/day (females) 0.04 – 0.01 µg/kg bw/day (males)
Policy Option 2	Clay, Kaolin and Pigments	0.14 – 0.04 µg/kg bw/day (females) 0.14 – 0.04 µg/kg bw/day (males)
	Others	0.04 – 0.01 µg/kg bw/day (females) 0.04 – 0.01 µg/kg bw/day (males)

Bioavailability of Lead

The US EPA Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK)[42] is broadly accepted as the best currently available model for estimating blood levels of lead in children. The results on the systemic body burden of lead, accounting for bodyweight, presented above have been fed into the model in order to estimate the amount of lead that children of different ages absorb in their blood stream through toys.

The starting point for the model is the **default bioavailability of lead in children of different ages resulting from exposure through multiple channels**, including both dietary and non-dietary sources. As discussed in Section 3.2, children absorb lead via dietary and non-dietary channels, which include food, water, air, land, etc. Exposure to lead via toys is only one of the many channels through which children absorb lead in their bloodstream and, according to the literature, the proportion of children's lead exposure that is due to toys is small. This proportion ultimately depends on the migration limits for lead on toys; thus, it varies across the policy options.

The tables below provide estimates on both the default bioavailability of lead from all sources excluding toys and on the bioavailability of lead from toys only. The difference between the first column (default bioavailability from all sources excluding toys) and the second column (bioavailability from all sources including toys) represents the amount of lead absorbed in children's blood stream via toys only. The detailed calculations and algorithms involved in taking the intake values to lead blood levels are outlined in the Appendix 9.4.

Policy Option 0

Using the calculation model, lead bioavailability in blood *excluding toys* ranges from 3.0 µg lead/dL blood (0.5 - 1 year olds) to 3.5 µg lead/dL blood (1-2 year olds). Once the bioavailability of lead from toys is included, overall estimates of bioavailability range from 3.4 – 3.7 µg lead/dL blood.[43]

[42] **Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Windows® 32-bit** [EPA 9285.7-42] (Updated May 2007) Version 1.1 for windows (latest version as of 5 April 2012) has been used for the calculations.

[43] Note that the first and third columns are added to result in the second column. Any disparities in addition result from rounding.

Table 12 – Bioavailability of Lead in Policy Option 0

Age range	Bioavailability from All Sources (excluding toys) (µg Lead/dL blood)	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	Bioavailability of Lead from Toys only (µg lead/dL blood)
0.5-1	3.0	3.4	0.4
1-2	3.5	3.7	0.3
2-3	3.2	3.4	0.3

Policy Option 1

Under the scenario of Policy Option 1 the migration limits are reduced. Hence, the bioavailability of lead from all sources *including toys* (second column below) is lower than in the case of Policy Option 0 above. More precisely, bioavailability of lead from all sources, including toys, decreases by 0.3 µg lead/dL for children between 0.5 and 1 years old; by 0.2 3 µg lead/dL for children between 1 and 2 years old; and by 0.1 3 µg lead/dL for children between 2 and 3 years old. As this bioavailability falls by 0.2-0.3 µg lead/dL for all age groups (from 0.3 – 0.4 to 0.1 in all age groups), overall bioavailability is also reduced by 0.2-0.3 µg lead/dL for all age groups (from 3.4 – 3.7 to 3.1 – 3.5).

Table 13 – Bioavailability of Lead in Policy Option 1

Age range	Bioavailability from All Sources (excluding toys) (µg Lead/dL blood)	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	Bioavailability of Lead from Toys only (µg lead/dL blood)	Difference in Bioavailability between PO0 and PO1 (µg lead/dL blood)
0.5-1	3.0	3.1	0.1	0.3
1-2	3.5	3.5	0.1	0.2
2-3	3.2	3.3	0.1	0.1

Policy Option 2

As discussed above, Policy Option 2 does not propose the introduction of migration limits different from those discussed for Policy Option 0 ad Policy Option 1. The main difference between Policy Option 2 and Policy Option 1 is the fact that the new proposed limits would only apply to a reduced share of the market. More precisely, the migration limits would be reduced to the level proposed in Policy Option 1 for all materials but for clay, kaolin and pigments. For these materials, the migration limits would remain at the levels established by the TSD.

Based on consultation with stakeholders and desk research, and as discussed in Section 5.2, it appears that, under Policy Option 2, **6.5% of the toys** would be excluded from the application of the migration limits proposed in Policy Option 1. This corresponds to the share of the toys market which is likely to contain traces of naturally-occurring lead, because clay, kaolin and pigments are used during the production.

The table below presents the results on lead bioavailability related to the Policy Option 2.

Table 14 - Bioavailability of Lead in Policy Option 2

	Clay, kaolin, pigments		All other toys	
Age range	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	Bioavailability of Lead from Toys only (µg lead/dL blood)	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	Bioavailability of Lead from Toys only (µg lead/dL blood)
0.5-1	3.4	0.4	3.1	0.1
1-2	3.7	0.3	3.5	0.1
2-3	3.4	0.3	3.3	0.1

These bioavailability levels are used to calculate the health effects in the below section. The difference in bioavailability levels between Policy Option 0 and Policy Option 1 and 2 are also used to calculate the health benefits of the policy options, with respect to the (not yet enforced)[44] migration limits established in the TSD (Policy Option 0).

The tables below summarises the effects of Policy Option 1 and 2, in terms of a reduction of lead bioavailability, with respect to Policy Option 0, which represents the baseline.

Table 15 – Effects on Bioavailability of Policy Option 1

Age range	Policy Option 0 (Baseline)	Policy Option 1	Difference in Bioavailability between PO0 and PO1 (µg lead/dL blood)
	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	
0-1 years old	3.4	3.1	0.3
1 to 2 years old	3.7	3.5	0.2
2 to 3 years old	3.4	3.3	0.1
Average	3.5	3.3	0.2

Average = weighted average calculated on the basis of the number of children in the EU 27 in the different age ranges

Table 16 – Effects on Bioavailability of Policy Option 2

Age range	Policy Option 0	Policy Option 2	Difference in Bioavailability between PO0 and PO1 (µg lead/dL blood)
	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	Bioavailability from All Sources (including toys) (µg Lead/dL blood)	
0-1 years old	3.4	3.1	0.3
1 to 2 years old	3.7	3.5	0.2
2 to 3 years old	3.4	3.3	0.1
Average	3.5	3.31	0.187

Average = weighted average calculated on the basis of the number of children in the EU 27 in the different age ranges

[44] As discussed in Section 4.0, the migration limits set down in the TSD will be enforced only after 20 July 2013. Until then, the bioavailability level of 0.7 ug, established in Directive 88/378/EEC, will be applied.

6.2 Health Related and Non-Health Related Impacts

In order to estimate the impacts and long term economic value of lead absorption, the following steps will be undertaken:

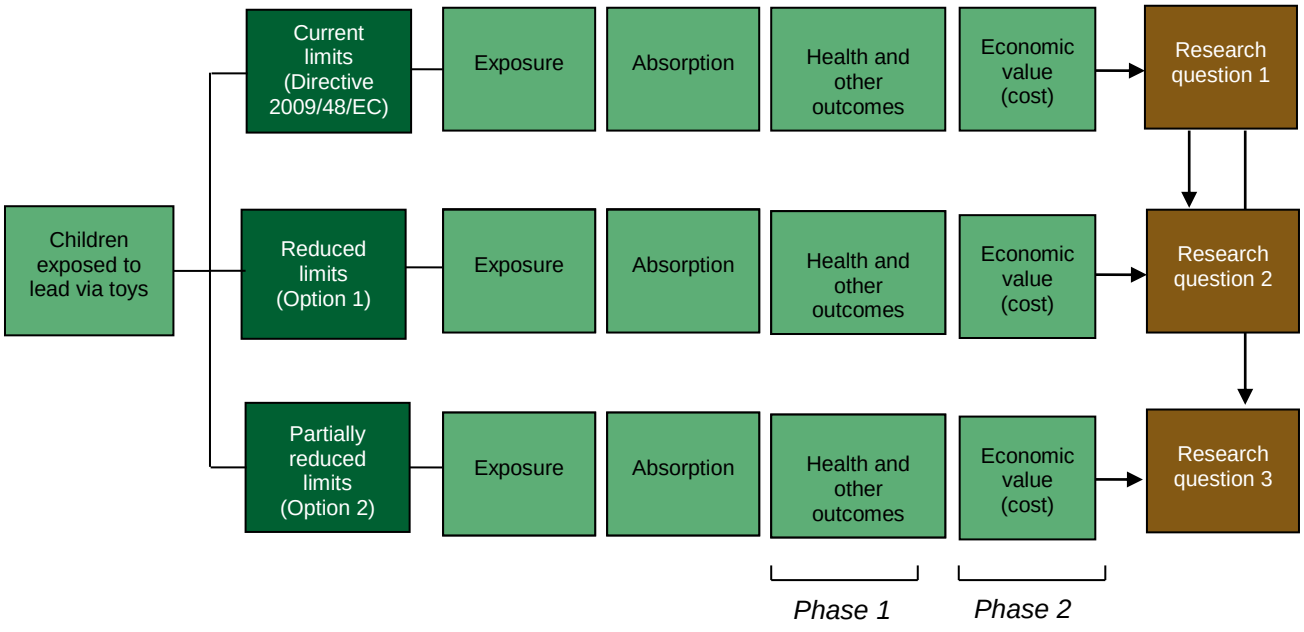
1. **Conceptual modelling**. Conceptualising the model required to estimate the economic impacts of each policy option. This requires an understanding of the likely data requirements.
2. **Reviewing the existing data**. Identifying the data available in the existing literature in order to populate the model.
3. **Supplementing the existing data with expert opinion**. Interviews will be undertaken with key stakeholders and experts to fill gaps in the data.
4. **Data extraction and modelling**. Data will be extracted into Excel-based models to estimate the health and economic impacts due to different policy options.

Figure 9 provides a summary of the conceptual model. It illustrates how the economic models will break down the relationship between policy options and economic value in order to facilitate the measurement of these values. Specifically, it specifies the following data requirements:

- Lead absorptions: the relationship between policy options and the amount of lead in the blood (bioavailability).
- Health and other impacts: the relationship between the amount of lead in the blood and health and other impacts.
- Economic value: the relationship between health and other impacts and economic value.

Only the former of these three estimates will be determined specifically for the policy options. The other two estimates will draw on more general evidence.

Figure 9 - Modelling the Impacts of Exposure to Lead in Toys



In order to populate the model two phases of a brief literature review were undertaken:

- **Phase 1**: Based on the preliminary list of health and other impacts associated with lead identified in the proposal, a review was undertaken to identify data on the relationship between lead absorption and the likely health and other impacts. The review focused on identifying robust studies which estimate the effect of lead absorption measured through:
    - Health related conditions, such as
        - Hearing problems
        - Kidney damage
        - Slowed body growth
        - Behaviour/attention problems
    - Non-health related conditions, such as
        - Declining school performance
        - Reduced IQ

- **Phase 2**: Reviewed the existing literature for evidence on the relationship between the health and other impacts identified above and long term economic consequences. Specifically:
    - **Health related quality of life**, measured as Quality Adjusted Life Years (QALYs).[45]
    - **Health cost due to treatment**, such as drug cost, hospital treatment cost, GP treatment cost, etc.
    - **Productivity,** measured as work days loss due to the health condition, multiplied by the average wage.

Section 6.2.2 summaries the results of the first phase of the literature review. Section 6.2.2 summaries the results of the second phase of the literature review. Lastly, Section 6.2.3 summarises the results of the analysis of the health costs due to children's exposure to lead via toys and on the benefits resulting from reducing such exposure.

6.2.1 Relationship between Lead Bioavailability and Health Impacts

Table 17 summarises the key studies identified from the first phase of the review on health and other impacts associated with lead.

It is evident from Table 17 that there is sufficient evidence on the effects of lead across several impacts to consider building models. Our ability to include these impacts within the economic analysis will depend on two factors:

- **The availability of literature measuring the long term economic consequences of each impact.** For example with regards to kidney damage, the second phase of the review will determine the availability of literature measuring the health costs associated with renal

[45] The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.

tubular failure, which is the consequence of kidney damage and the way in which kidney damage is usually diagnosed and measured.

- **The translation of the unit in which the impacts are measured to EU-27-relevant metrics.** For example, declining school performance is measured in terms of specific education attainment exams outside the EU. Through our literature review we will need to be able to identify a method in which this data can be translated to be EU-27.

Table 17 – Key Findings from Phase 1 Literature Review

Impact	Key studies	Measure of impact	Relationship between lead and impact identified (Y/N)	Type of model used	Study done within EU	Type of relationship measured in study	Age Group
Behaviour/Attention problems	Chiodo et al (2004)	Positive diagnosis for ADHD	Y	Regression analysis	No	Continuous	7.5 years old
	Froehlich et al (2009)	Positive diagnosis for ADHD	Y	Regression analysis	No	Not Continuous	8 to 15 years old
Declining school performance	Bellinger et al (1991)[46]	McCarthy subscale and General Cognitive Index	Y	Regression analysis	No	Continuous	2 to 5 years old
	Nelson et al (2009)	Spatial Reversal Cognitive Test	Y	Regression analysis	No	Continuous	2 to 6 years old
Hearing problems	Buchanan et al (1999)	Audiometric examination which measures distortion product oto-acoustic emissions	N	Regression analysis	No	Continuous	5 to 14 years old
	Shargorodsky et al (2011)	Audiometric examination measuring low and high frequency hearing loss	Y	Regression analysis	No	Continuous	12 to 19 years old
Kidney damage	Loghman-Adham (1998)	Incidence of renal tubular dysfunction in	Y	Retrospective study	No	Not continuous	9 to18 years

[46] This paper researches health conditions in children. As health conditions tend not to change over time, the fact that these papers are relatively old does not affect the results.

Impact	Key studies	Measure of impact	Relationship between lead and impact identified (Y/N)	Type of model used	Study done within EU	Type of relationship measured in study	Age Group
		children with lead poisoning					
	Verberk et al (1996)	Presences of N-acetyl-beta-D-glucosaminidase(NAG) in urine (indicator of renal tubular failure)	Y	Regression analysis	Yes	Continuous	3 to 6 years old
Reduced IQ	Lanphear et al (2005)	IQ scores	Y	Regression analysis	No	Continuous	0 to 5 or 10 years old
	Canfield et al (2003)	IQ scores	Y	Regression analysis	No	Continuous	0 to 5 years old
Slowed body growth	Kafourou et al (1997)	Head circumference, height, and chest circumference	Y	Generalized Additive Model	Yes	Continuous	6 to 9 years old
	Ballew (1999)	Stature and head circumference	Y	Regression analysis	No	Continuous	1 to 7 years old
	Ignasiak et al (2006)	Height and weight	Y	Regression analysis	Yes	Continuous	7-14 years old

6.2.2 Relationship Between Health Impacts and Long Term Economic Consequences

Table 18 summarizes the key studies identified from the second phase of the review. The second phase of the review focused on identifying both:

(a) a relationship between the short term childhood impact of lead; and

(b) the long term adulthood impact and the valuing the long term adulthood impact.

Within the table, the source and type of model used to estimate the relationship between the short term and long term outcome is outlined. In addition, a check mark indicates where the value of the impact is identified and the corresponding source.

It is evident from Table 18 that there is sufficient data to estimate the long term economic consequences of only some of the above listed impacts, namely **behaviour/attention problems, reduced IQ, and slowed body growth.**

In fact, the first phase literature review identified an impact of lead on declining school performance, hearing and kidney damage, while the second phase of the review was unable to identify studies with which to estimate the long term economic value of these impacts. This was due to:

- For **hearing problems** the short-term impact was measured in terms of specific hearing frequencies (Hz). However, the health related quality of life and treatment costs associated with hearing problems is measured in terms of the decibels (db). The hearing literature does not provide a standard relationship between Hz and db. Therefore, in order to incorporate this data, the model would need to assume a relationship between hearing frequency and decibels.
- For **declining school performance**, the cognitive tests used within the short term studies were US specific. The literature review could not identify studies which estimated the relationship between the US exams and EU specific equivalents. However, within the impacts identified there is significant overlap between behaviour/attention problems, declining school performance, and reduced IQ. For example, studies which measure reduced IQ could also be accounting for declining school performance as the two outcomes are likely to be related. Therefore, even if declining school performance is excluded from the analysis, the expected economic value can be accounted for within behaviour attention problems and reduced IQ.
- For **kidney damage**, it is possible to estimate the short term treatment costs associated with kidney damage. However, Loghman-Adham (1998) focus on children who have experienced lead poisoning, not for children that have been continuously exposed to small fractions of lead, as discussed in the problem definition. Furthermore, the second phase review was unable to identify a relationship between the predictor of renal tubular failure estimated by Verberk et al (1996) and actual incidence of renal tubular failure. The second phase review was also unable to identify a relationship between renal tubular failure in childhood and long term kidney damage.

Based on the results of the literature review, the **economic analysis only focuses on the long term value associated with behaviour/attention problems, reduced IQ and slowed body growth.** In the next section, we present the impact of a reduction in the bioavailability of lead in the blood stream, generated by the policy options, with respect to:

- **Health related quality of life**, measured as Quality Adjusted Life Years (QALYs).[47]
- **Health cost due to treatment**, such as drug cost, hospital treatment cost, GP treatment cost, etc.
- **Productivity,** measured as work days loss due to the health condition, multiplied by the average wage.

[47] The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.

Table 18 - Key Findings from Phase 2 Literature Review

Impact	Measure of impact	Short term economic value			Relationship between short-term and long-term effect	Type of model used	Long term economic value		
		Health related quality of life	Health cost due to treatment	Productivity costs			Health related quality of life	Health cost due to treatment	Productivity costs
Behaviour/attention problems	ADHD	✓ *Denchev et al (2010)*	✓ *Hakkaart-van Roijen et al (2007)*	✓[48] *Hakkaart-van Roijen et al (2007)*	Faraone (2005)	Meta-analysis	✓ *Denchev et al (2010)*	✓ *Hakkaart-van Roijen et al (2007)*	✓ *Graaf et al (2007)*
Declining school performance	Performance on cognitive tests	-	-	-	-	-	-	-	-
Hearing problems	Hearing frequency	-	-	-	-	-	-	-	-
Kidney damage	Renal tubular failure	-	✓ *Loghman-Adham (1998)*	-	-	-	-	-	-`
Reduced IQ	IQ test	-	-	-	Grosse et al (2002)	Mathematical computation of the impact of IQ on wages	-	-	✓ *Grosse et al (2002)*
Slowed body growth	Height	-	-	-	Christensen et al (2007)	Regression Analysis	✓ *Christensen et al (2007)*	-	✓ *Christensen et al (2007)*

[48] Productivity costs in the short term for ADHD are associated with the parents of children with ADHD,

6.2.3 Health Impacts of the Policy Options

Table 19 summarises the findings from the economic analysis for the cohort of 16,011,195 million children aged 0-3 across Europe. The table outlines the lifetime costs of lead exposure related to the different scenarios: migration limits as set in the TSD (PO0), reduction in the lead limits (PO1) and a partial reduction in lead limits (PO2):

- The results presented under **Policy Option 0** represent the lifetime costs of lead exposure if the migration limits remain at the levels established in the TSD. Thus, Policy Option 0 represents the baseline scenario, where nothing is changed.
- The difference between Policy Option 0 and Policy Option 1 represents the incremental benefit attributable to **Policy Option 1**. The savings are associated with a reduction in the migration limits, which corresponds to a decrease in the blood lead level from 3.50 ug/dl to 3.30 ug/dl (refer to Table 15 in Section 5.1.1).
- The difference between Policy Option 0 and Policy Option 2 represents the incremental benefit attributable to **Policy Option 2**. The savings are associated with a reduction in the migration limits, which corresponds to a decrease in the blood lead level from 3.5 ug/dl to 3.31 for PO2 (refer to Table 16 in Section 5.1.1).

It is evident from Table 19 that **even if toys contribute to a maximum of 10% of the TDI of lead**; decreasing the migration limits of lead in toys can generate considerable savings. Within the benefits specific to behavioural/attention problems nearly 45 per cent of the benefit is due to reduction in treatment costs associated with ADHD. In comparison, nearly 26 per cent and 29 per cent of the benefits are associated with reduced productivity loss and improvement in health related quality of life respectively. Within the benefits specific to IQ, 100 per cent of the benefit is due to reduced productivity loss.

Table 19 - Summary of Costs and Benefits Associated with a Reduction in Lead in Toys (€, 2011 prices)[1,2]

Benefits	PO0		PO1		PO2	
	ADHD	IQ	ADHD	IQ	ADHD	IQ
Blood lead level	3.5 0 ug/dl		3.30 ug/dl		3.31 ug/dl	
Health cost benefits						
Lifetime treatment cost of ADHD	€ 3,383	-	€ 3,077	-	€ 3,092	-
Lifetime treatment cost of mother caring for a child with ADHD	€ 634	-	€ 577	-	€ 579	-
Quality of life s (QALY)						
Lifetime health related quality of life quality of life	€ 2,543	-	€ 2,313	-	€ 2,325	-
Productivity benefits						
Productivity cost associated with mother caring for a child with ADHD	€ 1,472	-	€ 1,339	-	€ 1,346	-
Productivity cost associated with child	€ 841	€ 6,271	€ 764	€ 5,141	€ 768	€ 5,198
Unit cost per child	€ 8,873		€ 8,070		€ 8,110	
Total cost (€m)	€ 142,066	€ 100,407	€ 129,209	€ 82,315	€ 129,852	€ 83,220
Benefits of a Reduction in the Migration Limits						
Incremental benefit per child	**-**	**-**	**€ 803**	**€ 1,130**	**€ 763**	**€ 1,073**
Total Incremental benefit (€m)	**-**	**-**	**€ 12,857**	**€ 18,091**	**€ 12,214**	**€ 17,187**

1 For the IQ model the average annual earnings across EU-27 provided by Eurostat were used to calculate the benefits

2 For the ADHD model the healthcare costs and productivity benefits were based on Hakkaart-van Roijen et al (2007) which present all figures in Euros. The QALY gains were monetised using the UK threshold of £20,000 per QALY; the threshold was converted to Euro's using the GBP to Euro conversion rate provided by DG Budget.

Detailed calculation on how the numbers presented above are generated can be found in Appendix 9.6. However, some of the key data sources used to estimate the values are outlined below.

The key considerations around the **behavioural/attention (ADHD) model** include:

- The relationship between blood lead levels and ADHD is taken from Froehlich et al (2009). Froehlich et al. estimate the increased likelihood of ADHD associated with three specific levels of lead which are: (i) 0.2 ug/dl to 0.8 ug/dl, (ii) 0.8 ug/dl to 1.3 ug/dl, (iii) > 1.3 ug/dl. As the lead level estimates for PO0 and PO1 are greater than 1.3 ug/dl, the prevalence of ADHD associated with > 1.3 ug/dl was used. Based on the data provided a continuous relationship between lead and ADHD was assumed. Details of these calculations can be found in Appendix 9.6.1.
- The health costs associated with ADHD are derived from Hakkaart-van Roijen et al (2007). Hakkaart-van Roijen et al. estimate the annual treatment costs associated with both a child with ADHD and the mother of a child with ADHD. Based on the annual cost data, the lifetime health costs associated with ADHD were calculated.
- The relationship between childhood ADHD and adulthood ADHD is derived from Faraone (2005) which provided a systematic review of the literature on the probability children with ADHD continue to experience symptoms as adults.
- The quality of life values are based on Denchev et al. (2010). Denchev et al estimate the QALY loss associated with ADHD both in childhood and adulthood.
- The productivity loss associated with ADHD is derived from two papers. Hakkaart-van Roijen et al (2007) estimate the number of work days lost due mothers caring for children with ADHD. In addition, Graaf et al. (2007) estimate the number of work days lost associated with adult ADHD patients.

The key considerations around the **IQ model** include:

- The relationship between blood lead levels and IQ is taken from Lanphear et al. (2005). Lanphear et al. estimate the decrease in IQ associated with three specific levels of lead which are: (i) 2.4 ug/dl to 10 ug/dl, (ii) 10 ug/dl to 20 ug/dl, (iii) 20 ug/dl to 30 ug/dl. As the lead level estimates for PO0 and PO1 are within the lower ranges, the decrease in IQ associated with 2.4 ug/dl to 10 ug/dl was used. Based on the data provided a continuous relationship between lead and IQ was assumed. Details of these calculations can be found in Appendix 9.6.2.
- The effect of IQ on productivity was estimated using Grosse et al (2002). Grosse et al. provide a regression analysis estimating the effect of a 1 unit change in IQ on lifetime earnings.
- Lifetime earnings are estimated using the average annual wage provided by Eurostat. Based on the annual wage, the lifetime earnings were calculated.

As stated in section 5.2.2 the literature did identify studies which estimated the economic value of lead on slowed body growth. However, the measurable impact of lead on growth is only for high levels of lead absorption. For example, a minimum of a 6.5 cm change in height for women and 7.0 cm change in height for men would be required in order to measure any loss or gain in health related quality of life or productivity. A change in height of that level would require an increase or decrease of blood lead levels of nearly 40 ug/dl. As a change of this magnitude is not likely to occur due to the change in migration limits proposed in the policy options, the results of this analysis were excluded.

7.0 Comparison of the Policy Options and Conclusions

The **purpose of this study** was to support the European Commission impact assessment on the health costs of children's exposure to lead via toys and on the benefits resulting from reducing such exposure. The study was designed to answer the following questions:

- What are the **health costs related to exposure to lead via toys according to the current limits** (established in Directive 2009/48/EC)?
- What would be the **health benefits of a reduction of the limits** and consequently of the exposure to lead via toys?
- What would be **the health benefits of a partial reduction of the limits** and consequently of the exposure to lead via toys?

Children are exposed to lead via multiple channels, including both dietary and non-dietary sources. The evidence suggests that toys are only one of many channels of lead exposure in children and, in general, **the proportion of children's lead exposure that is due to toys is small**. In particular, this proportion must be regarded in the context of several other more significant lead channels, as depicted above.

Children between 0 and 3 are exposed to lead via toys primarily because they might ingest or mouth toy material. If the toy contains lead, during digestion in the gastro-intestinal tract, lead might be partially or totally released from the toy material ingested (bio-accessible fraction of toy material). The fraction of the chemical that migrates from the toy into the body does not necessarily correspond to the lead content of the toy: most of the chemical elements will remain in the matrix, even after mouthing or swallowing (SCHER, 2010).

In the European Union, the Toy Safety Directive (TSD, Directive 2009/48/EC) regulates the amount of a chemical that can be released from toy material when ingested, namely the migration limit[49]. Thus, if the toy is built in compliance with the TSD, the amount of lead that migrates to the children's body (i.e. bio-accessible fraction) should not exceed the new migration limit. The TSD was introduced in June 2009, but the newly established migration limits will only be enforceable as from July 2013, after a transition period of 4 years.

The bio-accessible fraction of lead released from the toy material ingested is potentially available for transport across the intestine. Part of the lead absorbed through the intestine will be metabolised by the liver. Only a fraction of the lead absorbed will not be metabolised (i.e. eliminated from the body via urine and faeces) and it will hence reach the systemic circulation and be transported across the body. The non-metabolised fraction that reaches the bloodstream of the child (bioavailable amount) can exert toxicity in the organs and tissues, with consequences for the child's health.

[49] Migration limits report how much of the element migrates from (e.g.) the toy to the human body, or in other words the amount of element actually released from the toy and to which the body is exposed.

Lead bioavailability in children's bloodstream can cause primarily:

- **kidney damage**, which manifests as loss of function and decreased reabsorption (UNEP, 2012);
- **hearing problems,** caused by slowed nerve conduction in the auditory pathway (Schwartz, 1991);
- **behaviour and attention problems** (MedlinePlus, 2011), which can manifest in ADHD (Attention Deficit Hyperactivity Disorder); and
- **slowed body growth** (MedlinePlus, 2011).

Based on the results of the literature review, the economic analysis has focused on the long term value associated with **behaviour/attention problems (ADHD), reduced IQ and slowed body growth.** As a consequence of these health impacts, children's exposure to lead via toys can give raise to long-term economic costs related to:

- **a reduction in health related quality of life**, measured as Quality Adjusted Life Years (QALYs)[50]
- **an increase in health cost due to treatment**, such as drug cost, hospital treatment cost, GP treatment cost, etc.
- **a reduction in productivity,** measured as work days loss due to the health condition, multiplied by the average wage.

The health costs related to exposure to lead via toys according to the current migration limits (established in Directive 2009/48/EC) are summarised in the table below. Although the impact of lead on slowed body growth is estimated in the literature, the current levels of lead in children are below the levels required to estimate a change in body growth. Therefore, the health costs related to slowed body growth could not be estimated.

Table 20 – Health Costs Related to Exposure to Lead via Toys, at the Migration Limits Set by the TSD (Policy Option 0)

	ADHD	IQ
Health cost benefits		
Lifetime treatment cost of ADHD	€ 3,383	-
Lifetime treatment cost of mother caring for a child with ADHD	€ 634	-
Quality of life s (QALY)		
Lifetime health related quality of life quality of life	€ 2,543	-
Productivity benefits		
Productivity cost associated with mother caring for a child with	€ 1,472	-

[50] The quality-adjusted life year (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.

	ADHD	IQ
ADHD		
Productivity cost associated with child	€ 841	€ 6,271
Unit cost per child	**€ 8,873**	**€ 6,271**
Total cost (€m)	**€ 142,066**	**€ 100,407**

The policy options discussed in this impact assessment propose a reduction in the migration limits for lead in toys, which would ultimately lead to a reduction in the amount of lead that reaches children's systemic circulation (bioavailable fraction).

- As **Policy Option 1**, it is considered that, in the absence of a TDI for calculating migration limits and based on the Expert Group on toy safety recommendations (0.50 µg/kg of bodyweight per day and 10% of lead TDI allocated to toys), the limit values for toys could be: 4 mg/kg in dry, brittle, powder-like or pliable toy material, 1 mg/kg in liquid or sticky toy material and 47 mg/kg in scraped-off toy material.

- **Policy Option 2** seeks to exonerate from the reduction of the limits certain materials, which naturally contain lead and which are used to produce toys. Lead naturally occurs in the earth crust; hence, it can be found as a 'natural' contamination in the environment (e.g. soil, rock, water). Thus, a certain natural content of lead cannot be removed from materials from natural sources, used in many different industries.

The new migration limits proposed by the policy options are summarised in the table below.

Table 21 – New Migration Limits Proposed in Policy Option 1 and Policy Option 2

Toy Material	Migration Limits (mg/kg)			
	Policy Option 0 (Status Quo)	Policy Option 1	Policy Option 2	
			Clay, Kaolin, Pigments	Others
Dry, brittle, powder-like pliable	13.5	4	13.5	4
Liquid or sticky	3.4	1	3.4	1
Scraped-off	160	47	160	47

A reduction in the migration limits would ultimately lead to a lower level of bioavailable lead into children's systemic circulation. This would imply that the health costs related to children's exposure to lead via toys, presented above, would be reduced. The reduction would generate health benefits for children, throughout their lifetime.

The health benefits of a reduction of the limits generated by the different policy option are summarised below and presented in Table 22.

- Through introducing **Policy Option 1**, the decrease in lead levels in toys could generate an estimated €9.2 billion in cost savings due to reduced incidence of behavioural/attention problems (ADHD). Another €18 billion in cost savings could be generated due to improvements in IQ. In addition, another €3.7 billion could be generated due to improvements in quality of life associated with reduced incidence of ADHD.
- Through introducing **Policy Option 2**, the decrease in lead levels in toys could generate an estimated €8.7 billion in cost savings due to reduced incidence of behavioural/attention problems (ADHD). Another €17.2 billion in cost savings could be generated due to improvements in IQ. In addition, another €3.5 billion could be generated due to improvements in quality of life associated with reduced incidence of ADHD.

These savings are based on a total population of nearly 16 million children aged 0-3 which will benefit from the reduction of lead in toys. It is important to stress that **it is not possible to aggregate these savings as the relationship between lead and health and non-health impacts is not mutually exclusive**. For example, the effect of lead on ADHD could affect IQ which has an impact on productivity. Alternatively, a child can experience an IQ impact with no experience of ADHD which also impacts productivity. The relationship between ADHD and IQ is not considered, therefore, aggregating these figures could lead to double counting of benefits.

Table 22 – Health Benefits following the Introduction of the Policy Options

Benefits	PO0 (Baseline scenario)		PO1		PO2	
	ADHD	IQ	ADHD	IQ	ADHD	IQ
Health cost benefits						
Lifetime treatment cost of ADHD	€ 3,383	-	€ 3,077	-	€ 3,092	-
Lifetime treatment cost of mother caring for a child with ADHD	€ 634	-	€ 577	-	€ 579	-
Quality of life s (QALY)						
Lifetime health related quality of life quality of life	€ 2,543	-	€ 2,313	-	€ 2,325	-
Productivity benefits						
Productivity cost associated with mother caring for a child with ADHD	€ 1,472	-	€ 1,339	-	€ 1,346	-
Productivity cost associated with child	€ 841	€ 6,271	€ 764	€ 5,141	€ 768	€ 5,198
Unit cost per child	**€ 8,873**	**€ 6,271**	**€ 8,070**	**€ 5,141**	**€ 8,110**	**€ 5,198**
Total cost (€m)	**€142,066**	**€100,406**	**€129,209**	**€82,313**	**€129,852**	**€83,226**
Incremental benefit per child			**€ 803**	**€ 1,130**	**€ 763**	**€ 1,073**
Total Incremental benefit			**€ 12,857**	**€18,091**	**€12,214**	**€17,187**

(€m)						

Preferred Policy Option: Policy Option 1

In conclusion, our analysis suggests that if the migration levels set by the Toys Safety Directive (2009/48/EC) are not revised (Policy Option 0) children would incur a unit health cost over their lifetime of €8,873 due to behavioural and attention problems (**which represents a 9.1% reduction from baseline)** and a unit health cost over their lifetime of € 6,271 due to reduced IQ (**which represents an 18% reduction from baseline)**.

The introduction of Policy Option 1 would generate higher benefits than Policy Option 2 and it is therefore the preferred policy option in terms of health benefits. Under Policy Option 2, the migration limits would be reduced to 4 mg/kg in dry, brittle, powder-like or pliable toy material, 1 mg/kg in liquid or sticky toy material and 47 mg/kg in scraped-off toy material. This would generate an overall **lifetime benefit of €803 per child (which represents an 8.6% reduction from baseline)**, in terms of reduced behavioural and attention problems, and an overall **lifetime benefit of €1,130 per child**, in terms of increased IQ (**which represents a 17.1% reduction from baseline**).

It is not possible to aggregate these benefits as the relationship between lead and health and non-health impacts is not mutually exclusive. For example, the effect of lead on ADHD and IQ are both measured through productivity gains. Therefore, aggregating these figures would lead to double counting of benefits.

8.0 Work Plan

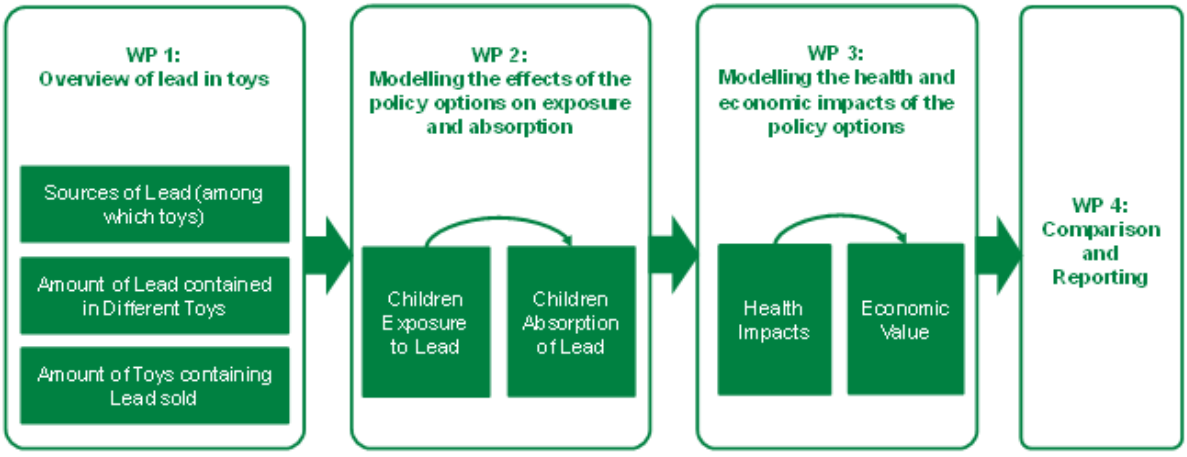
In this section we present the detailed work programme and discuss the research tools we use for carrying out the assignment. A detailed timeline is provided at the end of the section.

Our revised methodology is structure around four main work packages:

1. **Work Package 1:** Overview to establish how many toys would be affected by new limits.
2. **Work Package 2:** Effects of the policy options in terms of reducing exposure to and absorption of lead.
3. **Work Package 3:** Health Impacts of the policy options to provide monetary values for each of the proposed amendments.
4. **Work Package 4:** Comparison and Reporting.

The work packages are presented in the figure below.

Figure 10 - Work Packages



Each of the work packages is instrumental to answer the research questions. The work-packages build on each other and for this reason we launched them at different stages of the project, to ensure that results and evidence obtained from different phases is integrated and used to inform the subsequent work package.

8.1 Overview of the Work Programme

The work programme for this assignment can be divided into three phases:

- Phase 1: Inception & Preparatory Tasks
- Phase 2: Research and Analysis

- Phase 3: Analysis & Reporting

Before describing each phase in detail, an overview is presented in the table below.

Table 23 - Overview of work plan

	Phase 1 Inception	Phase 2 Data Collection and Literature Review	Phase 3 Analysis and reporting
Tasks/Activities	• Internal Start-up Meeting • Consultation with expert panel • Scoping literature review • Scoping Interviews • Develop conceptual model	• Incorporate feedback • Data on lead in toys (WP1) • Targeted Literature Review (WP2) • Targeted Literature Review (WP3) • Identifying data gaps	• Incorporate feedback • Desk-based modelling (WP2 and WP3) • Comparison and Reporting (WP4)
Deliverables	• Inception Report (M1)	• Progress Report (M2)	• Draft final report (M4) • Final report (M4)
Meetings	• Kick-off meeting (M1)	• Progress report meeting (M2)	• Draft final report meeting (M4)

8.2 Phase 1: Inception and Preparatory Tasks

The inception phase is now completed and it was concluded with the kick-off meeting. The key objective of this phase was to work closely with DG ENTR to set out and agree management processes and work plans for the duration of the project, as well as conduct scoping data collection in order to refine the methodology and guide the next phases of the study.

Internal Start-up Meeting

As a first step upon award of the contract, we held an internal meeting with the core team to clarify roles and responsibilities. The outcome of this meeting has been a revised and more detailed work-plan and methodological approach.

Scoping literature review

We have conducted a review focusing on key literature concerning children's exposure to lead through toys. The aim of this literature review has been to develop a good understanding of:

- Lead presence in toys;
- Children's exposure to lead via toys;
- Children absorption of lead via toys;

- Health impacts of lead exposure in children; and
- Economic value of health impacts.

This broad scoping of the literature has allowed us to identify academic papers, policy documents and reviews that would be relevant for each of the subsequent work packages. Moreover, the scoping of the literature has informed the conceptual understanding of the effects and impacts of existing and proposed lead limits. We have also used the literature to extract relevant secondary data, which fed into and supplement the secondary data analysis conducted in the next phase of the study.

Consultation with Expert Panel

In order to inform and extend the scoping of the literature, we have also engaged with our expert panel. The chemical, toxicology and risk assessment experts included in our team have been able to identify and point us to relevant papers and documents, which were included in the literature review. In addition, experts' inputs have been relevant to review our methodological approach.

Scoping Interviews

Concurrently with the literature review, we have carried out interviews with relevant European stakeholders. We had envisaged carrying out up to a total of 10 interviews; however, after consultation with some experts we have decided to go beyond the 10 interviews to ensure that we get access to the most relevant data and evidence. We have then scheduled and conducted more interviews with stakeholders identified by other interviews.

The interview questionnaire had been submitted to the Commission for feedback prior to interviews being carried out. The main objective of the interviews was to:

- refine our understanding of main issues related to children's exposure to lead;
- identify data sources for consequent phases of the study; and
- obtain information and data relevant for work package 1 (overview of lead presence in toys).

The stakeholder groups contacted as part of the scoping interviews are presented in the table below.

Table 24 - Scoping Interviews

Name	Organisation	Interview Date
Jan van Leent	VWA Netherlands	13/01/2012
Noel Toledo	Prosafe	13/01/2012
Albert Vallejo	Toy Industries of Europe	17/01/2012
Derek Markie	Toy Retailers Association	13/01/2012
Joanne Vincenten	European Child Safety Alliance	15/02/2012
Dr Franz Fiala	ANEC	20/01/2012

Dr Bertram Reindl	CEN	20/02/2012
Gijs Manneveld	Mattel / TIE	26/01/2012
Daryl Scrivens	Hasbro	26/01/2012
Line Ehlert Thomsen	Lego	07/02/2012
Jerry Burnie	IQS, British Toy Association	02/02/2012
Philip Bullock	Intertek Laboratories	20/01/2012
Dr Christoph Lutermann	EU Directives Consultancy	08/02/2012
Dr Heidrun Pfeffer	European Writing Instruments Manufacturers Association	25/01/2012
Janice Robinson	European Council of the Paint, Painting Ink and Artists' Colours Industry (Brussels)	27/01/2012
Shima Dobel	Danish Ministry of the Environment	13/02/2012

Kick-off meeting

The kick-off meeting with the Commission took place on 1 February 2012, after the submission of the inception report. During the kick-off meeting, we presented to the Commission our revised methodology and we discussed possible risks arising during the project and available solutions. The Commission has also provided, in that occasion, comments on the inception report, which have been taken into consideration for the drafting of this progress report.

8.3 Phase 2: Secondary Data Collection and Literature Review

The objective of this phase of the study is to collate and analyse existing secondary information concerning children's exposure to lead via toys. The focus has been on academic research, national and international literature reviews, international and EU-level databases and grey literature. This phase of the study informed the modelling carried out in the second and third work package.

Meeting with Ecorys

We attended a meeting with the contractors on the parallel study on the competitiveness of the toy industry. During the meeting, we discussed the respective projects in order to ensure that all activities carried out as part of the two studies are fully coordinated and that data exchange takes place where this is beneficial to either study.

Due to the timeline of the parallel study, it was be difficult to obtain relevant information and results on the impact of the policy options on the competitiveness of the industry, before the submission of our final report. This has been flagged to the Commission as a potential problem, during the kick-off meeting.

Targeted Literature Review

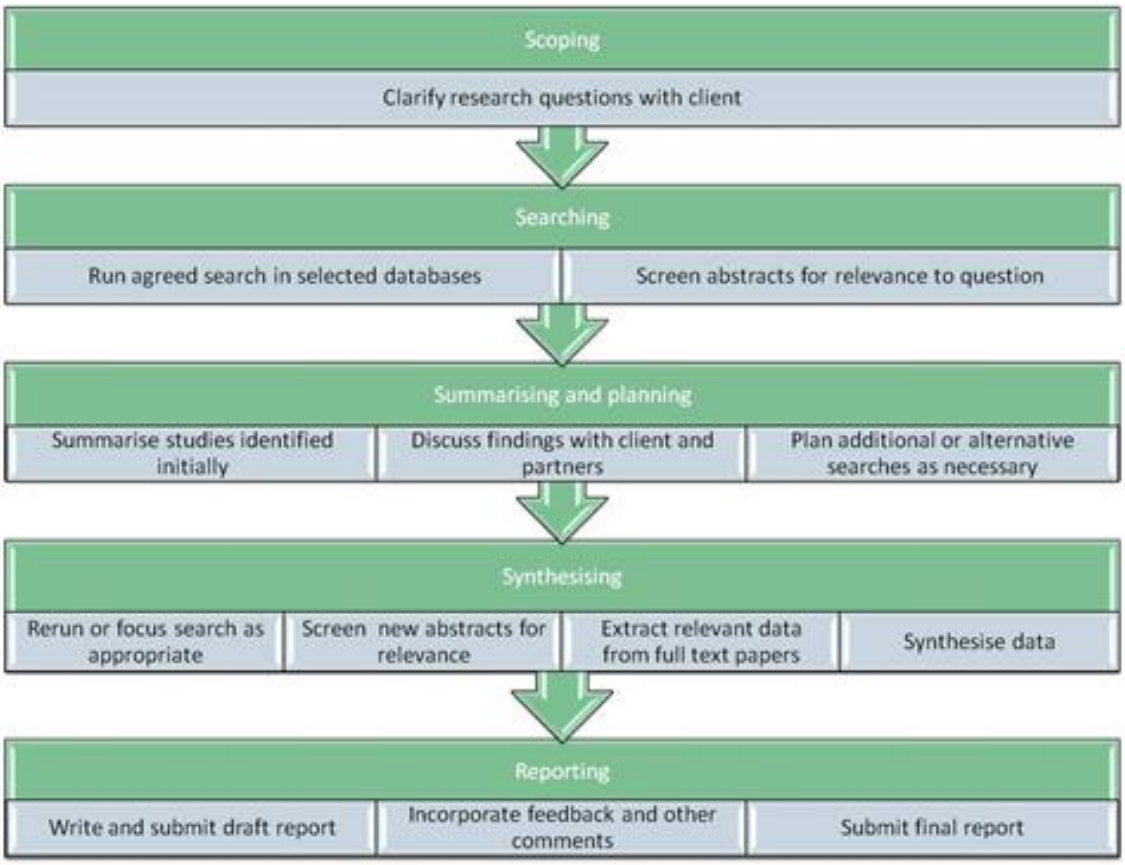
Alongside the above data collection activities, we carried out two targeted reviews of the literature. The aim of this literature reviews was to collect data and inform the modelling for the second and third work package.

The literature review informed the following aspects of the study:

a) Quantifying children's exposure and absorption of lead through toys; and
b) Information on the health and economic impacts of children's exposure to lead.

The review provided relevant evidence and data to build an economic model. The phases of the literature review are summarised in the figure below.

Figure 11 - Summary of Evidence Review Phases



The reviews used a systematic and robust search and appraisal methodology to identify and synthesise relevant studies from a range of databases and other sources. Our tools and methods ensure that a full audit trail is generated at each stage of the review process, ensuring transparency and reproducibility. The key features of the rapid evidence review methodology are summarised below:

- **Searching:** We develop targeted, focussed strategies to locate evidence that might be relevant to the review questions.
- **Screening**: We use clearly defined inclusion criteria as we screen abstracts to determine which of the located studies are relevant to the review questions.

- **Data Extraction:** We use comprehensive data extraction tools to capture all necessary data, including study context, population, intervention content, and effectiveness and cost-effectiveness findings.
- **Write-Up:** We summarise our findings in the final report and we are experienced at meeting a variety of specific data presentation needs.

Progress Report (M2)

The progress report has been submitted to the Commission on February 20th, 2012. It provided DG ENTR with an operational overview of study progress including the findings to date, namely the analysis undertaken as part of the first work package and early findings from the second and third work packages.

The report has been used primarily by our in-house team to guide further activities and by DG ENTR to provide feedback on progress. On the basis of the comments received from the Commission, we have revised the progress report and submitted a new version on 9 March 2012. This version has been approved by the Commission.

8.4 Phase 3: Analysis and Reporting

The objective of this phase of the project was to extract the analytical and presentational value added that our team brings to this study. The output of this phase is this final report, together with a comparison table and an executive summary.

Modelling the effects of the policy options

Based on the conceptual model presented in Section 6.1 and the targeted literature review, we refined our conceptualisation of the exposure and absorption of lead in children through toys.

In order to model the changes in exposure and absorption following the introduction of the policy options, we used the approach developed in previous studies (such as RIVM, 2008). This approach was tested with our expert panel.

Modelling health and economic impacts

This included a phase 1 review of the existing literature to determine the availability of data on each of the outcomes identified in the proposal which included:

- Behaviour/attention problems
- Declining school performance
- Hearing problems
- Kidney damage
- Reduced IQ
- Slowed body growth

Based on the results from the phase 1 review data across the impacts was identified. The phase 2 of the review focused on identifying data measuring the long term economic value of each of the outcomes, specifically in terms of:

- Health related quality of life
- Health costs due to treatment
- Productivity costs

Based on the second phase literature review, it is recommended the economic analysis focus on: **behaviour/attention problems, reduced IQ, and slowed body growth**.

On this basis, we have generated Excel based models which estimate the economic impact of the policy options.

Draft final report (M4)

This report is the **draft final report** for the study. It includes a synthesis of the data collection and analysis pertaining to the three work packages, namely:

1. Overview of lead presence in toys;
2. Effects of the policy options; and
3. Economic impacts of the policy options.

The synthesis of tasks is supplemented by a comparison table, answering the key research questions.

Final report (M4)

Matrix prides itself on producing accessible reports and studies that provide our public sector clients with the best possible evidence base to inform their decisions. As a result, we have developed a reporting approach (based on the 1:3:25 model) that facilitates both dissemination of the main study results across a broad range of interested stakeholders and, at the same time provides a rigorous description of methods and data for readers interested in the technical/methodological approach or in testing the validity and robustness of findings.

All our reports are also accompanied by a full deck of presentation slides, ready for dissemination among interested stakeholders within the Commission, at European and national levels. We will discuss the appropriate focus of the presentation slides with the Commission at the kick-off meeting and throughout the project. The table below has an outline of the draft final report.

Outline of the Draft Final Report
1. Executive Summary 2. Introduction 3. Definition of key terms 4. Overview of lead presence in toys

5. Effects of the policy options
6. Impacts of the policy options
7. Comparison and conclusion

Appendices
- Methodological approach
- Data collection tools
- References
- Contact list

The table below includes a detailed timeline for the study based on the list of tasks in this section including identification of the main deliverables.

Table 25 – Detailed Work Plan

	Month																			
	1				2				3				4				5			
Internal Kick Off Meeting																				
Consultation with expert panel																				
Scoping literature review																				
Scoping interviews																				
Review conceptual model																				
Inception report																				
Kick-off meeting																				
Analysis of existing databases																				
Targeted literature review (WP2)																				
Targeted literature review (WP3)																				
Identifying data gaps																				
Progress report																				
Progress report review meeting																				
Modelling of the Effects of the Policy Options																				
Modelling health and economic impacts																				
Comparison and reporting																				
Draft final report																				
Draft final report meeting																				
Final report																				
Project close-down																				

Tasks Deliverables Meeting

9.0 Appendices

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9.2 Summary Outcomes Initial Interviews

This Annex summarises the outcomes of the Initial Interviews, which involved European level stakeholders and experts in the field of toxicology and toys safety. Due to the technical nature of some questions, not all interviewees could provide an answer. Respondents recommended relevant existing studies and relevant background information. They also suggested additional EU level and national stakeholders that we might want to talk to. We have taken these suggestions into account in our research.

- In your view, what are the **main health impacts** associated with exposure to and absorption of lead, particularly in children?

According to stakeholders in the field of toxicology, assessing harm costs from exposure to chemical elements, such as lead, is difficult. The risks associated with certain limits and ensuing acceptable doses of chemical elements can be calculated, but the direct harm costs associated with these doses cannot.

- What is your view regarding **current migration limits for lead in toys** established by the Toy Safety Directive (TSD) (2009/48/EC)?

Interviewees have welcomed the EFSA report which suggests that lead uptake has to be reduced and triggered the new limits. The new limits derived within the study are deemed convincing.

- Do you have access to or do you know of any **data source on the amount of lead contained in toys**?

It is difficult to make assessments in relation to the amount of lead contained in toys.
UK toys safety experts reported that they test between 3,000-4,000 toys per year, which contain in excess of 15,000 components. Detectable traces of lead were found in only 5% of these components.

- According to your experience, are there still **toys on the European market with a lead content above the migration limits** established by the TSD?

As mentioned above, it is difficult to gauge the level of lead contained in toys. Likewise, information on compliance with migration limits is as difficult to assess. UK toys safety experts reported that around 0.25% of the 15,000 components they annually test fail lead migration limits set by the TSD.
Stakeholders also pointed to the fact that the migration limits set by the TSD call for advanced technical requirements. Existing instruments employed to risk assess elements in toys; can detect levels as low as 5mg/kg. However some of the new limits are below this threshold. This will, therefore, require new machines which can detect such small values.

- Do you know of any **countries (within and outside the EU)** where the migration limit for lead in toys has already been reduced? Are you aware of any study carried out to measure the effectiveness and impact of such legislation?

All countries which use migration limits as a risk assessment methodology rely on the values set by the EN7-3 standards. Once the TSD limits will be in force in July 2013, EU countries will be the only ones where the limits have been reduced.

9.3 Industry Position on Policy Option 2

An alternative to Policy Option 2, which would entail fewer administrative and competitiveness problems, would be to **introduce a smaller reduction in migration limits than in Policy Option 1**. This smaller reduction would be one which the arts and crafts industry would be able to comply with, without having to exclude certain toys from the market.

The European Writing Industry Manufacturers' Association (EWIMA), has stated that the lowest lead migration limits its members could still comply with are lower than the current limits, but higher than the proposed revised limits. It has suggested the following migration limits:

Material	Migration Limits (mg/kg)
Dry, brittle, powder-like pliable toy material	9[51]
Liquid or sticky toy material	3.4[52]
Scraped-off toy material	50[53]

The writing instruments industry thus finds a reduction of the liquid or sticky toy material migration limit most problematic (suggesting that this remain unchanged from the status quo) and the dry, brittle, powder-like pliable toy material migration limit also relatively problematic (suggesting this be reduced less than proposed in Policy Option 1). The similarity of the suggested scraped-off toy material migration limit to the proposed new migration limit implies that this is not an area of concern for the industry.

Conversely, TIE has stated that it is in agreement with the proposed migration limits because they are based on scientific evidence provided in the EFSA report. It does acknowledge that they would mean that certain toys would fail the lead tests due to naturally-occurring kaolin and titanium dioxide, however (e.g. liquid paints, poster paints, finger paints and crayons).[54]

[51] 4.5 mg/kg lower than the status quo, 5 mg/kg higher than the new revised limits.
[52] No change from the status quo, 2.4 mg/kg higher than the new revised limits.
[53] 110 mg/kg lower than the status quo, 3 mg/kg higher than the new revised limits.
[54] Information provided by TIE.

9.4 Calculation of Bioavailability of Lead

This appendix includes the technical work and calculations leading to the estimations of blood levels outlined in Section 5.1 in this Report. These estimates of bioavailability are repeated below, for ease of reference.

Toy Material	Migration Limits (mg/kg)	Bioavailability (lead in blood) (µg/dL)
Policy Option 0		
Dry, brittle, powder-like, pliable toy material	13.5	0.2-0.4 *
Liquid or sticky toy material	3.4	0.2-0.4 *
Scraped-off toy material	160	0.2-0.4 *
Policy Option 1		
Dry, brittle, powder-like, pliable toy material	4	0.1
Liquid or sticky toy material	1	0.1
Scraped-off toy material	47	0.1

** Age dependent. For an average 15kg child, age 1-3 years, the blood lead level is 0.3µg/dL.*

9.4.1 Introduction

Section 2.0 of the main section summarises the research questions for the impact assessment and the corresponding policy options proposed by the Commission, in relation to setting the migration limits of lead in toys. The calculations in this Appendix estimate the blood levels (systemic bioavailability) of lead in children, were they to be exposed to levels of lead in toys at different migration limits. The blood levels are calculated for Policy Options 0 and 1, indicated below.

9.4.2 General Approach and Assumptions used in Calculation of Blood Lead Levels

The general approach is to first calculate intake values (in mg/day) for children who may play daily with lead-containing toys at the various migration limits defined in Policy Options 0 and 1. Migration limits are derived on the basis of migration tests (see Chapter 4 RIVM 2008), which can be performed to quantify how much lead can migrate out of different toy materials, and an acceptable level of intake and bioavailability. Uptakes (in mg/kg/day) have been calculated for children of different ages to provide an indication of the level of systemic bioavailability (body burden) from ingesting lead in toys. Intakes (in mg/day) have also been translated into mg lead/dL blood, using an exposure modelling tool.

The following assumptions have been made:

- **Children ingest the toy material.** The only exposure route considered is oral ingestion. Inhalation, dermal absorption and eye contact are not considered, as exposure by these routes is expected to be negligible (see Section 2.2).
- Data from RIVM (2008) have been drawn upon to estimate the amount of toy material per day a child may ingest i.e.:
    - 8mg/day of scraped-off toy material
    - 100mg/day of brittle toy material
    - 400mg/day liquid/sticky toy material
- These estimates are based upon a child playing with one toy for 3 hours/day consecutively.
- The proposed lead migration limits for inclusion to be considered in this study, as outlined above.
- Intakes (in mg/day) (see Step 1 of the calculations) have been used to estimate uptake (see Step 2 of the calculations) i.e. systemic bioavailability (in mg/kg/day) from exposure to lead in toys alone (i.e. assuming no other contribution). Taken from the RIVM 2008 report: 'The pharmacology definition of bioavailability is considered to be the most appropriate within the present context, i.e. *the fraction of a substance present in toy material that reaches the systemic circulation (of a child)*.' In order to calculate systemic bioavailability as a daily body burden, a gut absorption value for lead of 50% (RIVM, 2008; ATSDR, 2005) has been applied to intake levels. This is a conservative absorption value based upon data in infants and children reported within ATSDR 2005, and assumes lead is in its elemental form. The body weight of children of different ages has an impact on body burden and therefore has also been taken into account in the calculations.
- It has been assumed that **all lead ingested is 100% bioaccessible**, as the migratability of the lead out of the toy material has already been taken into account in the context of setting 'migration' limits.
- To translate intakes (mg/day) to uptakes as blood lead levels, the US EPA Integrated Exposure Uptake BioKinetic (IEUBK) model has been used. This is considered to provide the most appropriate exposure model available for this purpose (see Step 3 below). The model considers children's exposure to all sources of environmental lead, and the comparative output in Step 4 illustrates the proportion of blood lead which comes from lead in toys, as relevant to each of the migration limits. **There is no direct relationship between intake and blood lead levels and the relationship is not always linear**.
- Lead is an element and is therefore not metabolised *per se* by the liver, and it should be noted that no aspects of lead elimination from the body (in urine and faeces) have specifically been accounted for in the simple body burden calculations in mg/kg/day.

The IEUBK model is a complex biokinetic model and absorption & elimination rates have been taken into account in calculating blood Lead levels.

9.4.3 Exposure Calculations: Step 1 - Calculation of 'intake' into the child's stomach, and body burden into the systemic circulation

Policy Option 0

Dry, brittle, powder-like toy material
The migration limit means that when a toy is analysed, no more than 13.5 mg of migratable lead[55] is allowed per kg of toy material. If a child ingests 100 mg/day of this material, then 13.5mg lead/kg toy material is equivalent to 13.5 microgram lead/g toy material, which equals **1.35 microgram lead/day ingested in 100mg toy material.** (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.7 microgram/day)
Liquid, sticky material
The migration limit means that when a toy is analysed, no more than 3.4 mg of migratable lead is allowed per kg of toy material. If a child ingests 400 mg/day of this material, then 3.4 mg lead/kg toy material is equivalent to 3.4 microgram lead/g toy material, which equals **1.36 microgram lead/day ingested in 400mg toy material.** (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.7 microgram/day)
Scraped-off toy material
The migration limit means that when a toy is analysed, no more than 160 mg of migratable lead is allowed per kg of toy material. If a child ingests 8 mg/day of this material, then 160 mg lead/kg toy material is equivalent to 160 microgram lead/g toy material, which equals **1.28 microgram lead/day ingested in 8 mg toy material.** (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.7 microgram/day)

Hence, all of the above three Policy Option 0 scenarios yield one maximal 'intake' level of approximately **1.35 microgram lead/day** and one maximal systemic body burden level of **0.7 microgram lead/day**. However, there is no account of the age or body weight of the child at this point and **body weight/blood volume will impact on blood concentration**.

Policy Option 1

Dry, brittle, powder-like toy material

[55] Migratable lead - analytical chemistry methods (described in Chapter 4 of RIVM 2008) are used to assess the quantity of how much lead can migrate out of a toy material to become bioaccessible.

The migration limit means that when a toy is analysed, no more than 4 mg of migratable lead is allowed per kg of toy material. If a child ingests 100 mg/day of this material, then 4 mg lead/kg toy material is equivalent to 4 microgram lead/g toy material, which equals 0**.4 microgram lead/day ingested in 100mg toy material**. (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.2 microgram/day)
Liquid, sticky material
The migration limit means that when a toy is analysed, no more than 1 mg of migratable lead is allowed per kg of toy material. If a child ingests 400 mg/day of this material, then 1 mg lead/kg toy material is equivalent to 1 microgram lead/g toy material, which equals **0.4 microgram lead/day ingested in 400mg toy material.** (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.2 microgram/day)
Scraped-off toy material
The migration limit means that when a toy is analysed, no more than 47 mg of migratable lead is allowed per kg of toy material. If a child ingests 8 mg/day of this material, then 47 mg lead/kg toy material is equivalent to 47 microgram lead/g toy material, which equals **0.4 microgram Lead/day ingested in 8 mg toy material**. (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.2 microgram/day)

Hence, all of the above three Policy Option 1 scenarios yield one maximal 'intake' level of approximately **0.4 microgram lead/day** and one maximal systemic body burden level of **0.2 microgram lead/day**. However, there is no account of the age or body weight of the child at this point and **body weight/blood volume will impact on blood concentration**.

EWIMA Suggestion Migration Limits

Dry, brittle, powder-like toy material
The migration limit means that when a toy is analysed, no more than 9 mg of migratable lead is allowed per kg of toy material. If a child ingests 100 mg/day of this material, then 9 mg lead/kg toy material is equivalent to 9 microgram lead/g toy material, which equals **0.9 microgram lead/day ingested in 100mg toy material**. (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.45 microgram/day. A reduction from the previous 0.7 microgram/day EU acceptable systemic bioavailability level but not in agreement with Policy Option 1).
Liquid, sticky material

The migration limit means that when a toy is analysed, no more than 3.4 mg of migratable lead is allowed per kg of toy material. If a child ingests 400 mg/day of this material, then 3.4 mg lead/kg toy material is equivalent to 3.4 microgram lead/g toy material, which equals **1.36 microgram Lead/day ingested in 400mg toy material.** (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.7 microgram/day. Equivalent to current bioavailable limit set by the EU – i.e. no change)
Scraped-off toy material
The migration limit means that when a toy is analysed, no more than 50 mg of migratable lead is allowed per kg of toy material. If a child ingests 8 mg/day of this material, then 50 mg lead/kg toy material is equivalent to 50 microgram lead/g toy material, which equals **0.4 microgram lead/day ingested in 8 mg toy material.** (Of this ingested intake, 50% is estimated to be absorbed across the gut into the systemic circulation = 0.2 microgram/day. Meets the new proposed reduced criteria as in Policy Option 1)

The above options proposed by industry lead to different maximal intake values and different systemic body burdens per scenario, and will yield different maximal blood concentrations. There is no account of the age or body weight of the child at this point and body weight/blood volume will impact on blood concentration.

9.4.4 Exposure Calculations: Step 2 – Estimating the intakes and body burdens accounting for body weight (in microgram/kg body weight/day)

A simple calculation can be done to convert the 'intakes' (Table 26) and 'systemic body burdens' (uptake) (Table 27) from Step 1 above, to values that account for mean body weight of children at different ages. Intakes and body burdens in µg/day from Step 1 above have been divided by mean body weight as per age to yield data in µg/kg bw/day. An analysis has been performed using two sources of available body weight data for children, to assess the impacts and differences body weight makes to the overall calculation of blood Lead level. Table 26 and Table 27 use data from a Dutch analysis (RIVM 2006), as relevant to a European population. For comparison and assurance that the biokinetic model used in Section 6.1.1 from the US EPA is relevant to a European population, a set of USA data has also been analysed.

Table 26 Intake Data in mg/kg bw/day, Using Average Dutch Body Weight Data (for both males and females)

				Policy option 0 1.35 µg lead/day	Policy option 1 0.4 µg lead/day
Age	**Mean weight in kg**	**SD**	**25th %ile**	**µg lead/kg bw/day intake**	**µg lead/kg bw/day intake**
1.5 mth	4.65	0.52	4.3	0.290	0.086
4.5 mth	6.75	0.79	6.21	0.200	0.059
7.5 mth	8.3	1	7.62	0.163	0.048
10.5 mth	9.45	1.1	8.69	0.143	0.042
13.5 mth	10.3	1.2	9.47	0.131	0.039
1.5 yr	11.1	1.9	9.85	0.122	0.036
2.5 yr	13.9	2.1	12.5	0.097	0.029
3.5 yr	16	2.9	14.1	0.084	0.025
4.5 yr	18.4	3.1	16.3	0.073	0.022
6.5 yr	23.1	3.8	20.6	0.058	0.017
9.5 yr	32.4	6	28.4	0.042	0.012
12.5 yr	44.8	8.1	39.3	0.030	0.009
13.5 yr	50	9	43.9	0.027	0.008
16.5 yr	62.9	9	56.8	0.021	0.006

Table 27 Body Burden Data in mg/kg bw/day, Using Average Dutch Body Weight Data

				Policy option 0 0.7 µg lead/day	Policy option 1 0.2 µg lead/day
Age	Mean weight in kg	SD	25th %ile	µgLead/kg bw/day body burden	µgLead/kg bw/day body burden
1.5 mth	4.65	0.52	4.3	0.151	0.043
4.5 mth	6.75	0.79	6.21	0.104	0.030
7.5 mth	8.3	1	7.62	0.084	0.024
10.5 mth	9.45	1.1	8.69	0.074	0.021
13.5 mth	10.3	1.2	9.47	0.068	0.019
1.5 yr	11.1	1.9	9.85	0.063	0.018
2.5 yr	13.9	2.1	12.5	0.050	0.014
3.5 yr	16	2.9	14.1	0.044	0.013
4.5 yr	18.4	3.1	16.3	0.038	0.011
6.5 yr	23.1	3.8	20.6	0.030	0.009
9.5 yr	32.4	6	28.4	0.022	0.006
12.5 yr	44.8	8.1	39.3	0.016	0.004
13.5 yr	50	9	43.9	0.014	0.004
16.5 yr	62.9	9	56.8	0.011	0.003
17.5 yr	65.3	10	58.2	0.011	0.003

The tables below use the mean body weight data from the US National Health Statistics report from 2008 (McDowell et al., 2008).

Table 28 – Intake Data in mg/kg bw/day, Using Mean US Body Weights Data

			Policy option 0 1.35 µgPb/day		Policy option 1 0.4 µgPb/day	
Age	Males (mean weight in kg)	Females (mean weight in kg)	Males µgPb/kg bw/day intake	Females µgPb/kg bw/day intake	Males µgPb/kg bw/day intake	Females µgPb/kg bw/day intake
Birth to 2 months	5.2	4.9	0.260	0.276	0.077	0.082
3-5 months	7.3	6.8	0.185	0.199	0.055	0.059
6-8 months	8.4	8.1	0.161	0.167	0.048	0.049
9-11 months	9.7	9.2	0.139	0.147	0.041	0.043
1 year	11.6	10.9	0.116	0.124	0.034	0.037
2 years	14.1	13.4	0.096	0.101	0.028	0.030
3 years	15.8	15.8	0.085	0.085	0.025	0.025
4 years	18.6	17.9	0.073	0.075	0.022	0.022
5 years	22.1	20.5	0.061	0.066	0.018	0.020
6 years	24.2	23.4	0.056	0.058	0.017	0.017
7 years	26.6	27.3	0.051	0.049	0.015	0.015
8 years	31.4	30.7	0.043	0.044	0.013	0.013
9 years	34.6	36.7	0.039	0.037	0.012	0.011
10 years	40.1	42.4	0.034	0.032	0.010	0.009
11 years	46.8	49.2	0.029	0.027	0.009	0.008
12 years	50.8	52.9	0.027	0.026	0.008	0.008
13 years	57.8	57.4	0.023	0.024	0.007	0.007
14 years	63.1	58.8	0.021	0.023	0.006	0.007
15 years	70.2	60.9	0.019	0.022	0.006	0.007
16 years	76.1	61.5	0.018	0.022	0.005	0.007
17 years	75	66	0.018	0.020	0.005	0.006
18 years	77.2	67.6	0.017	0.020	0.005	0.006
19 years	80.2	67.4	0.017	0.020	0.005	0.006

Table 29 Body Burden Data in mg/kg bw/day, Using Mean US Body Weight Data

			Policy Option 0 0.7 µgPb/day		Policy option 1 0.2 µgPb/day	
Age	Males (mean weight in kg)	Females (mean weight in kg)	Males µgPb/kg bw/day body burden	Females µgPb/kg bw/day body burden	Males µgPb/kg bw/day body burden	Females µgPb/kg bw/day body burden
Birth to 2 months	5.2	4.9	0.135	0.143	0.038	0.041
3-5 months	7.3	6.8	0.096	0.103	0.027	0.029
6-8 months	8.4	8.1	0.083	0.086	0.024	0.025
9-11 months	9.7	9.2	0.072	0.076	0.021	0.022
1 year	11.6	10.9	0.060	0.064	0.017	0.018
2 years	14.1	13.4	0.050	0.052	0.014	0.015
3 years	15.8	15.8	0.044	0.044	0.013	0.013
4 years	18.6	17.9	0.038	0.039	0.011	0.011
5 years	22.1	20.5	0.032	0.034	0.009	0.010
6 years	24.2	23.4	0.029	0.030	0.008	0.009
7 years	26.6	27.3	0.026	0.026	0.008	0.007
8 years	31.4	30.7	0.022	0.023	0.006	0.007
9 years	34.6	36.7	0.020	0.019	0.006	0.005
10 years	40.1	42.4	0.017	0.017	0.005	0.005
11 years	46.8	49.2	0.015	0.014	0.004	0.004
12 years	50.8	52.9	0.014	0.013	0.004	0.004
13 years	57.8	57.4	0.012	0.012	0.003	0.003
14 years	63.1	58.8	0.011	0.012	0.003	0.003
15 years	70.2	60.9	0.010	0.011	0.003	0.003
16 years	76.1	61.5	0.009	0.011	0.003	0.003
17 years	75	66	0.009	0.011	0.003	0.003
18 years	77.2	67.6	0.009	0.010	0.003	0.003

In Table 28 and Table 29, gut absorption of 50% is applied to the intakes in Tables 3.2a and c, respectively. Therefore all body burdens are half of the intakes.

To give an initial indication of how body burdens relate to blood levels and potential effects in children, the EFSA panel calculated (EFSA 2010) that an intake of 0.5 microgram lead/kg bw/day from foods sources resulted in a blood lead level of 1.2 microgram lead/dL blood. This blood lead level is equivalent to the EFSA 2010 BenchMark Dose Level ($BMDL_{01}$) value for the most sensitive endpoint of developmental neurotoxicity in children (EFSA 2010). The relationship between intake and blood lead levels may not be linear (especially at high dose), due to complex biokinetics.

The above data illustrate the intakes and body burdens from lead in toy exposure only, at the migration limits of Policy Options 0 and 1, and not from any other sources. It should be noted that children will be exposed to lead in the air, water, soil, diet and potentially other sources (e.g. paint) in their environment, over and above toy exposure on a daily basis. A child's total potential exposure to lead should be taken into account, and the relative contribution of lead from toys calculated (see Step 3). RIVM (2008) recommended that the acknowledged contribution from toys should be no more than 5, 10 or 20% of the total exposure sources of lead and that this is a Risk Management Decision (RIVM 2008). The Scientific Committee on Health & Environmental Risks (SCHER) Opinion (2010) recommended that toy intake of all elements should be no more than 10% of a defined tolerable daily intake (TDI).

The comparison made in Table 30 provides assurance that the body weight **data from US sources (and similar data used in the USEPA IEUBK model in Section 3.3 below) are not dissimilar in range and magnitude to the data from the Dutch study, and therefore this provides some evidence that the output from the IEUBK model can be regarded as relevant to a European population of similar age and weight ranges.** The US data further indicate that the range of intakes for males and females are sufficiently similar that these populations can be considered together.

Table 30 – A Comparison of Data from the Dutch Analysis (in RIVM 2006) Versus the US Data (McDowell et al 2008).

	Dutch data (RIVM 2006)	USA data (2008 data)
Age range	1.5-17.5 years	2mth-19 years
bw range kg	4.6-65.3	4.9-67.4 (females) 5.2-80.2 (males)
µgPb/kg bw/day intake (Policy 0)	0.29-0.021	0.28-0.020 (females) 0.26-0.017 (males)

9.4.5 Exposure Calculations: Step 3 – Use of the IEUBK model to calculate blood levels of lead in children

A calculation of blood concentrations, taking into account multiple sources of all environmental lead exposures combined can be made using the US EPA **Integrated Exposure Uptake Biokinetic Model for Lead in Children** (IEUBK) model[56], which is broadly accepted as the best currently available model for estimating blood levels of lead in children. The IEUBK model was used in the published opinion by the CONTAM panel of EFSA in 2010, to look at exposures from dietary sources. The model and supporting guidance and technical manuals can be accessed via the US EPA website[57] .

The IEUBK model uses intake data in µg/day and uses a set of algorithms to describe the biokinetics of absorption & elimination (described in the technical guidance), and calculates a blood lead level in µg lead/dL blood. The background data (including body weights and blood volume data) are from US sources and are specified in the technical guidance provided on the EPA website.

[56] **Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Windows® 32-bit** [EPA 9285.7-42] (Updated May 2007) Version 1.1 for windows (latest version as of 5 April 2012) has been used for the calculations
[57] http://www.epa.gov/superfund/lead/products.htm

9.4.6 Exposure Calculations: Step 4 – Comparison of blood levels from different scenarios

Table 31 - Blood Lead levels in Children (microgram Lead/dL blood) Cerived Using IEUBK, Including Background Environmental Exposures.

Age range	Default estimates of Blood Levels (µg lead/dL blood)	Default estimates of Blood Levels including toys at Policy Option 0 migration limits (µg Lead/dL blood)	Default estimates of Blood Levels including toys at Policy Option 0 migration limits (µg Lead/dL blood)
0.5-1	3.0	3.4	3.1
1-2	3.5	3.7	3.5
2-3	3.2	3.4	3.3
3-4	3.0	3.2	3.1
4-5	2.5	2.7	2.6
5-6	2.1	2.3	2.2
6-7	1.9	2.1	2.0

Table 32 – Blood Lead Levels in Children (microgram Lead/dL blood) Derived Using IEUBK, for Toys Alone with no Background Environmental Exposures.

Age range	Blood levels from Toys alone Policy 0 migration limits (µg lead/dL blood)	Blood levels from Toys alone Policy 1 migration limits (µg lead/dL blood)
0.5-1	0.4	0.1
1-2	0.3	0.1
2-3	0.3	0.1
3-4	0.2	0.1
4-5	0.2	0.1
5-6	0.2	0.1
6-7	0.2	0.1

9.5 Conclusion

The following lead migration limits (mg/kg) translate into lead levels in blood (i.e. bioavailability) (ug/dL)

Table 33 Blood Lead Levels (ug/dL) at Policy Option 0 and 1 Migration Limits (Units of microgram lead/decilitre blood used as per the output of IUEBK model).

Toy Material	Migration Limits (mg/kg)	Bioavailability (lead in blood) (µg/dL)
Policy Option 0		
Dry, brittle, powder-like, pliable toy material	13.5	0.2-0.4 *
Liquid or sticky toy material	3.4	0.2-0.4 *
Scraped-off toy material	160	0.2-0.4 *
Policy Option 1		
Dry, brittle, powder-like, pliable toy material	4	0.1
Liquid or sticky toy material	1	0.1
Scraped-off toy material	47	0.1

* Age dependent. For an average 15kg child, age 1-3 years, the blood lead level is 0,3ug/dL.

9.6 Economic analysis

9.6.1 Behavioural and attention problems (ADHD) model

Figure A1 provides a detailed summary of the conceptual model used to estimate the economic value associated with impact of lead absorption on ADHD.

Table A1. Parameters for behavioural and attention problems (ADHD) sub-model

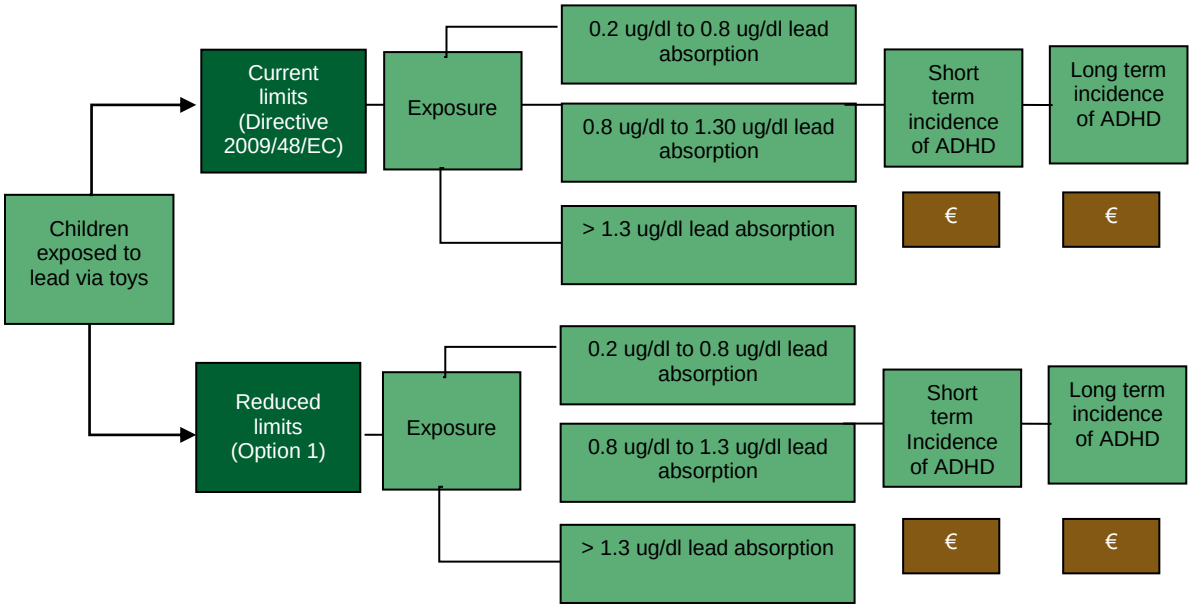

Table A1 outlines the parameter used to populate the conceptual model.

Table A1.

Parameter	Value	Source
Blood lead level in children under Policy Option 0	3.50	Level of lead absorption according to the migration limits (Section 6.1.1)
Blood lead level in children under Policy Option 1	3.30	Level of lead absorption according to the migration limits (Section 6.1.1)
Blood lead level in children under Policy Option 2	3.31	Level of lead absorption according to the migration limits (Section 6.1.1)
Decrease in blood lead level associated with Policy Option 1	0.20	Calculated
Decrease in blood lead level associated with Policy Option 2	0.19	Calculated
Prevalence of ADHD 0.2 ug/dl – 0.8 ug/dl	3.40%	Prevalence of ADHD 0.2 ug/dl – 0.8 ug/dl is calculated using the following equation:

Parameter	Value	Source
		Prevalence = average prevalence of ADHD/((% 0.2 ug/dl – 0.8 ug/dl + (% 0.8 ug/dl – 1.3 ug/dl * relative risk of ADHD at 0.8 ug/dl – 1.3 ug/dl) + ((% > 1.3 ug/dl * relative risk of ADHD at > 1.3 ug/dl) Average prevalence of ADHD = 5.29% Polanczyk et al (2007) % of children at 0.2-0.8 ug/dl = 20.2% Froehlich et al (2009)) % of children at 0.8-1.3 ug/dl = 29.6% Froehlich et al (2009)) % of children > 1.3 ug/dl= 50.2% Froehlich et al (2009)) Relative risk of ADHD 0.8 ug/dl to 1.3 ug/dl = 1.49 (Froehlich et al (2009)) Relative risk of ADHD > 1.3 ug/dl = 1.82 Froehlich et al (2009)
Prevalence of ADHD 0.8 ug/dl – 1.3 ug/dl	5.1%	Prevalence of ADHD 0.2 ug/dl – 0.8 ug/dl is calculated using the following equation: Prevalence of ADHD 0.2ug/dl – 0.8 ug/dl * Relative risk of ADHD 0.8 ug/dl to 1.3 ug/dl = 3.4% * 1.49 = 5.1%
Prevalence of ADHD 0.2 ug/dl – > 1.3 ug/dl	6.2%	Prevalence of ADHD > 1.3 ug/dl is calculated using the following equation: Prevalence of ADHD > 1.3 ug/dl * Relative risk of ADHD > 1.3 ug/dl = 3.4% * 1.82 = 6.2%
Unit prevalence of ADHD change per 0.01 change in ug/dl (for > 1.3 ug/dl)	0.02%	The unit change in prevalence of AHD was calculated to be a continuous relationship using the following formula: Unit change in prevalence of ADHD per ug/dl (> 1.3 ug/dl) = (Prevalence of ADHD >1.3 ug/dl)/((4ug/dl-1.3ug/dl)/0.1ug/dl)+1) = 6.2%/271 = 0.02%
Change in prevalence of ADHD due to Policy Option 1	0.46%	The change in prevalence of ADHD under PO1 is calculated as: (prevalence of ADHD PO0 – prevalence of ADHD PO1) = (([(BBL PO0 – 1.3 ug/dl)/.01]*(unit prevalence of ADHD per 0.01 change in ug/dl) – ((BBL PO1 – 1.3 ug/dl)/.01]*(unit prevalence of ADHD per 0.01 change in ug/dl) =((3.5-1.3)/0.01 * .02) – ((3.3-1.3)/.01 * 0.02) = 0.43%
Change in prevalence of ADHD due to Policy Option 2	0.43%	The change in prevalence of ADHD under PO2 is calculated as: (prevalence of ADHD PO0 – prevalence of ADHD PO2) = (([(BBL PO0 – 1.3

Parameter	Value	Source
		ug/dl)/.01]*(unit prevalence of ADHD per 0.01 change in ug/dl) – ((BBL PO2 – 1.3 ug/dl)/.01]*(unit prevalence of ADHD per 0.01 change in ug/dl) =((3.5-1.3)/0.01 * .02) – ((3.3-1.3)/.01 * 0.02) = 0.43%
Probability childhood ADHD continues into adulthood	55%	Faraone (2005)
Lifetime treatment costs of ADHD for child	€ 67,041	The lifetime treatment costs associated with ADHD is calculated as: ∑(annual treatment cost*inflation)*(1-discount rate) Annual treatment cost of ADHD = €1,340 Hakkaart-van Roijen et al (2007) Inflation = 2.7% (Eurostat, 2011) Discount rate = 3.5% (HM Treasury, Green Book)
Lifetime treatment costs of mother caring for child with ADHD	€ 12,563	The lifetime treatment costs associated with a mother caring for a child with ADHD is calculated as: ∑(annual treatment cost*inflation)*(1-discount rate) Annual treatment cost of a mother caring for a child with ADHD = €832 Hakkaart-van Roijen et al (2007) Inflation = 2.7% (Eurostat, 2011) Discount rate = 3.5% (HM Treasury, Green Book)
Productivity loss of mother caring for child with ADHD	€ 29,182	The productivity costs associated with a mother caring for a child with ADHD is calculated as: ∑(annual productivity loss*inflation)*(1-discount rate) Annual productivity loss of a mother caring for a child with ADHD = €1,932 Hakkaart-van Roijen et al (2007) Inflation = 2.7% (Eurostat, 2011) Discount rate = 3.5% (HM Treasury, Green Book)
Productivity loss of adult ADHD patient	€ 19,994	The productivity costs associated with a with a ADHD patient is calculated as: ∑((annual work days lost * (cost per work day *inflation)*(1-discount rate)

Parameter	Value	Source
		Annual number of work days lost = 33.5 Graaf et al (2007) Cost per work day lost = €126 (Eurostat, 2011) Inflation = 2.7% (Eurostat, 2011) Discount rate = 3.5% (HM Treasury, Green Book)
Lifetime QALY loss associated with ADHD in childhood	0.8762	The lifetime QALY loss associated with a with a child ADHD patient is calculated as: ∑(annual QALY loss)*(1-discount rate) Annual QALY loss = 0.07 Denchev et al (2010) Discount rate = 3.5% (HM Treasury, Green Book)
Lifetime QALY loss associated with ADHD in adulthood	1.2302	The lifetime QALY loss associated with a with a adult ADHD patient is calculated as: ∑(annual QALY loss)*(1-discount rate) Annual QALY loss = 0.09 Denchev et al (2010) Discount rate = 3.5% (HM Treasury, Green Book)
Monetary value of a QALY	€23,929	Monetary value of a QALY is based on the National Institute for Clinical Excellence recommendation of a threshold of £20,000 - £30,000 per QALY (NICE, 2007). The lower bound of the threshold was used and adjusted for exchange rates (DGBudget, 2012)
Policy Option 1 benefits		
Change in lifetime treatment costs of ADHD for child due to decrease in lead	€ 306.1	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * Lifetime treatment costs of ADHD for child = 0.46%* €67,041 = € 306.1
Change in lifetime costs treatment costs of mother caring for child with ADHD due to decrease in lead	€ 57.4	Change in lifetime treatment costs = change in prevalence of ADHD due to PO2 * lifetime treatment costs of mother caring for child with ADHD = 0.46%* € 12,563 = € 57.4

Parameter	Value	Source
Change in productivity loss of mother caring for child with ADHD due to decrease in lead	€ 133.3	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * lifetime productivity loss of mother caring for child with ADHD = 0.46%* € 29,182 = € 133.3
Change in productivity loss of adult ADHD patient due to decrease in lead	€ 76.1	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * lifetime productivity loss of adult ADHD patient * probability ADHD continues into adulthood = 0.46%* € 19,994 * 0.55 = € 76.1
Change in lifetime QALY loss associated with ADHD in childhood due to decrease in lead	€ 95.7	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * lifetime QALY loss associated with ADHD child * monetary value of a QALY = 0.46%*0.8762*€23,929 =€ 95.7
Change in lifetime QALY loss associated with ADHD in adulthood due to decrease in lead	€ 134.4	Change in lifetime treatment costs =change in prevalence of ADHD due to PO1* lifetime QALY loss of adult ADHD * monetary value of a QALY = 0.46%* 1.2302 * €23,929 = € 134.4
Total benefit per child	€ 803.0	Total benefit = change in lifetime treatment costs of ADHD child + change in lifetime treatment costs of mother caring for ADHD child + change in productivity loss of mother caring for child with ADHD + change in productivity loss of adult ADHD patient + Change in QALY loss of childhood ADHD + Change in QALY loss of adult ADHD = € 306.1 +€ 57.4 +€ 133.3 +€ 76.1 +€ 95.7 +€ 134.4 =€ 803.0
Number of children between the age of 2-3 in Europe	16,011,195	Eurostat (2010)
Total benefit due to ADHD (€m)	€ 12,856.6	Total benefit due to ADHD = total benefit per child * number of children = € 803.0 *16,011,195

Parameter	Value	Source
		= € 12,856.6
Policy Option 2 benefits		
Change in lifetime treatment costs of ADHD for child due to decrease in lead	€ 290.8	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * Lifetime treatment costs of ADHD for child = 0.43%* €67,041 = € 290.8
Change in lifetime costs treatment costs of mother caring for child with ADHD due to decrease in lead	€ 54.5	Change in lifetime treatment costs = change in prevalence of ADHD due to PO2 * lifetime treatment costs of mother caring for child with ADHD = 0.43%* € 12,563 = € 54.5
Change in productivity loss of mother caring for child with ADHD due to decrease in lead	€ 126.6	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * lifetime productivity loss of mother caring for child with ADHD = 0.43%* € 29,182 = € 126.6
Change in productivity loss of adult ADHD patient due to decrease in lead	€ 72.3	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * lifetime productivity loss of adult ADHD patient * probability ADHD continues into adulthood = 0.43%* € 19,994 * 0.55 = € 72.3
Change in lifetime QALY loss associated with ADHD in childhood due to decrease in lead	€ 91.0	Change in lifetime treatment costs = change in prevalence of ADHD due to PO1 * lifetime QALY loss associated with ADHD child * monetary value of a QALY = 0.43%* 0.8762 * €23,929 = € 91.0
Change in lifetime QALY loss associated with ADHD in adulthood due to decrease in lead	€ 127.7	Change in lifetime treatment costs =change in prevalence of ADHD due to PO1* lifetime QALY loss of adult ADHD * monetary value of a QALY = 0.43%* 1.2302 * €23,929 = € 127.7
Total benefit per child	€ 762.8	Total benefit = change in lifetime treatment costs of ADHD child + change in lifetime treatment costs of mother caring for ADHD child + change in productivity loss of mother caring for child with ADHD + change in productivity loss of adult ADHD patient + Change in QALY loss of childhood ADHD + Change in QALY loss of adult ADHD = € 290.8 +

Parameter	Value	Source
		€ 54.5 + € 126.6+€ 72.3+ € 91.0+€ 127.7= € 762.8
Number of children between the age of 2-3 in Europe	16,011,195	Eurostat (2010)
Total benefit due to ADHD (€m)	€ 12,213.8	Total benefit due to ADHD = total benefit per child * number of children = € 762.8 *16,011,195 = € 12,213.8

Sub-group analysis

The results of the assessment on the effect of policy options on the level of blood in children showed a small decrease in lead – that is 3.4 ug/dl to 3.3 ug/dl. However, due to the uncertainty around the rate of compliance of toy manufactures to migration limits this reduction in lead could be underestimated.

The economic model outlined above has the ability to value greater changes in lead based on the thresholds within the literature – i.e. 0.2 ug/dl to > 1.3 ug/dl. Therefore, sub-group analysis was conducted to estimate the benefit of greater reduction in blood lead levels.

Table A1.1 summarises the results of the sub-group analysis. Table A.1 shows the economic value that could be generated as children move between risk levels. For example, it estimated € 11,031 per child could be saved by reducing a child's blood lead level from > 1.3 ug/dl to < 0.2 ug/dl.

Table A1.1 Subgroup analysis – behavioural/attention problems (ADHD)

Lifetime savings per child		Risk level (post-policy option)			
BBL definition by risk level	Risk level (pre policy option)	No risk	Low risk	Medium risk	High risk
< 0.2 ug/dl	No risk				
0.2 ug/dl - 0.8 ug/dl	Low risk	€ 6,055			
0.8 ug/dl - 1.3 ug/dl	Medium risk	€ 9,019	€ 2,964		
>1.3 ug/dl	High risk	€ 11,031	€ 4,976	€ 2,012	

9.6.2 IQ model

Figure A2 provides a detailed summary of the conceptual model used to estimate the economic value associated with impact of lead absorption on ADHD.

Figure A2. Conceptual model – IQ

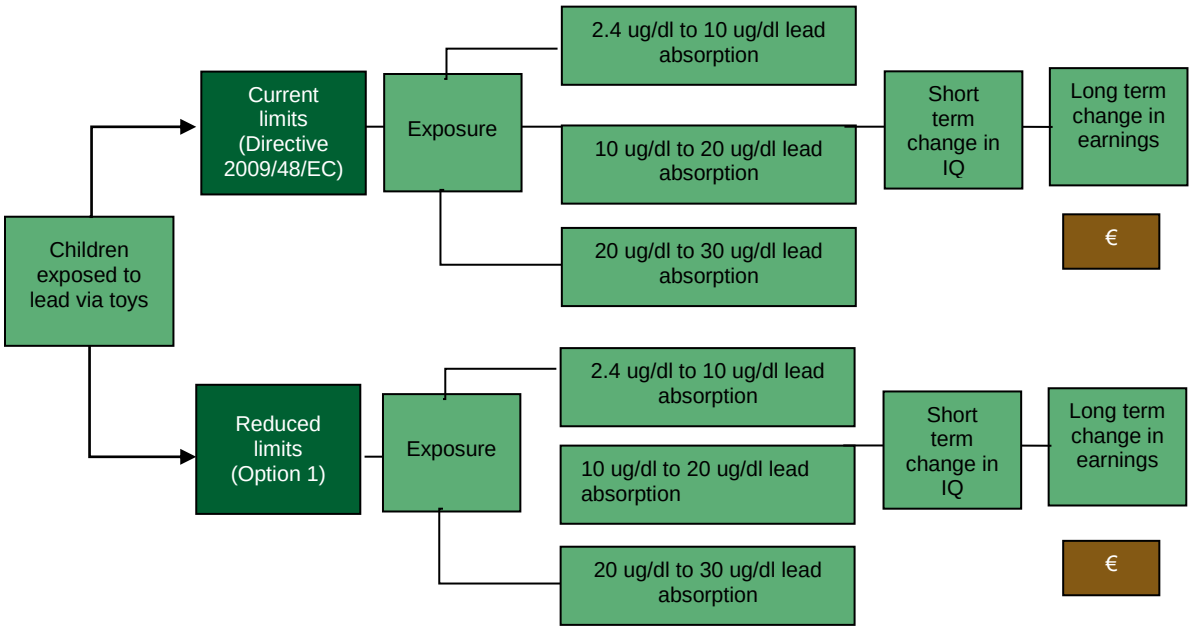

Table A1 outlines the parameter used to populate the conceptual model

Table A1. Parameters for IQ sub-model

Parameter	Value	Source
Blood lead level in children under Policy Option 0	3.50	Level of lead absorption according to the migration limits (Section 6.1.1)
Blood lead level in children under Policy Option 1	3.30	Level of lead absorption according to the migration limits (Section 6.1.1)
Blood lead level in children under Policy Option 2	3.31	Level of lead absorption according to the migration limits (Section 6.1.1)
Decrease in blood lead level associated with Policy Option 1	0.20	Calculated
Decrease in blood lead level associated with Policy Option 2	0.19	Calculated
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl	3.9	Lanphear et al (2005)
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl	5.8	Lanphear et al (2005)
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl	6.9	Lanphear et al (2005)

Parameter	Value	Source
Unit IQ change per 0.01 ug/dl (for 0.2 ug/dl to 0.8 ug/dl level)	0.01	The unit change in IQ was calculated to be a continuous relationship using the following formula: Unit IQ change per ug/dl (0.2 ug/dl to 0.8 ug/dl) = (Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl)/((10ug/dl-2.4ug/dl)/0.01ug/dl)+1) = 3.9/761 = 0.01
Change in IQ due to PO1	0.102	The change in IQ due to PO1: (IQ PO0 – IQ PO1) = (([(BBL PO0 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) – ((BBL PO1 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) =((3.5-2.4)/0.01 * .01) – ((3.3-2.4)/.01 * 0.01) = 0.102
Change in IQ due to PO2	0.097	The change in IQ due to PO2: (IQ PO0 – IQ PO2) = (([(BBL PO0 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) – ((BBL PO2 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) =((3.5-2.4)/0.01 * .01) – ((3.31-2.4)/.01 * 0.01) = 0.097
Percentage decrease in earnings for a 1 unit decrease in IQ	2.0%	Grosse et al (2002)
Total lifetime earnings	€551,195	The lifetime earnings is calculated using the following formula: Lifetime earnings = ∑(annual earnings*inflation)*(1-discount rate) Where: annual earnings = €20,771 (Eurostat, 2011) Inflation = 2.7% (Eurostat, 2011) Discount rate = 3.5% (HM Treasury, Green Book)
Policy option 1 benefits		
Change in lifetime earnings due to reduction in IQ per child	€ 1,130	Change in lifetime earnings due to reduction in IQ per child is calculated as: Reduction in IQ due PO1* percentage change in earnings for 1 unit decrease in IQ * lifetime earnings = 0.102 * 2% * €551,195 = € 1,130

Parameter	Value	Source
Number of children between the age of 2-3 in Europe	16,011,195	Eurostat (2010)
Total benefit due to IQ (€m)	€ 18,091	Total benefit due to IQ = change in lifetime earnings per child * number of children = € 1,130 *16,011,195 = € 18,091
Policy option 2 benefits		
Change in lifetime earnings due to reduction in IQ per child	€ 1,073	Change in lifetime earnings due to reduction in IQ per child is calculated as: Reduction in IQ due PO1* percentage change in earnings for 1 unit decrease in IQ * lifetime earnings = 0.097 * 2% * €551,195 = € 1,073
Number of children between the age of 2-3 in Europe	16,011,195	Eurostat (2010)
Total benefit due to IQ (€m)	€ 17,187	Total benefit due to IQ = change in lifetime earnings per child * number of children = € 1,073 *16,011,195 = € 17,187

Sub-group analysis

The results for the impact assessment on the effect of policy options on the level of blood in children showed a small decrease in lead – that is 3.4 ug/dl to 3.3 ug/dl. However, due to the uncertainty around the rate of compliance of toy manufactures to migration limits this reduction in lead could be underestimated.

The economic model outlined above has the ability to value greater changes in lead based on the thresholds within the literature – i.e. 2.4 ug/dl to 30 ug/dl. Therefore, sub-group analysis was conducted to estimate the benefit of greater reduction in blood lead levels.

Table A1.2 summarises the results of the sub-group analysis. Table A1.2 shows the economic value that could be generated as children move between risk levels. For example, it estimated

€76,065 per child could be saved by reducing a child's blood lead level from 20-30 ug/dl to <2.4 ug/dl.

Table A1.2 Subgroup analysis - IQ

Lifetime savings per child		Risk level (post-policy option)			
BBL definition by risk level	Risk level (pre policy option)	No risk	Low risk	Medium risk	High risk
< 2.4 ug/dl	No risk				
2.4 ug/dl -10 ug/dl	Low risk	€ 42,993			
10 ug/dl - 20 ug/dl	Medium risk	€ 63,939	€ 20,945		
20 ug/dl - 30 ug/dl	High risk	€ 76,065	€ 33,072	€ 12,126	