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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Council Directive

amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Identification

The initiative is foreseen for adoption in 2014.

The lead DG is DG ENTR. DG SANCO, DG TRADE, DG ENV, SG and the LS are associated in the process.

1.2. Organisation and timing

This consolidated impact assessment completes the findings of an earlier impact assessment

- by including newly available data on the occurrence of lead in toys (instead of assuming that all toy materials would contain lead at the height of the applicable limit value);

- by using 5% of the new toxicological reference value for lead as the basis for new limit values (instead of 10%).

To support the preparation and drafting of the earlier impact assessment, a Commission inter-service steering group (IASG) was established. DG TRADE, DG SANCO, DG ENV and SG participated. The IASG met 3 times.

1.3. Consultation and expertise

The Commission informed all concerned stakeholders (Member States, industry, consumer protection associations, standardisation bodies, Notified Bodies (NBs)) on its initiative during the meeting of the Expert Group on Toy Safety in April 2011; several Member States supported the revision of the limit values for lead. Some preferred to do so based on a Tolerable Daily Intake (TDI) allocation of 5%, another referred to a TDI allocation of 10% coupled with an exception or with a transitional period. The Expert Group did not object to the use of a TDI allocation of 10%. One Member State called for an impact assessment to be performed. Subsequently, a number of Member States expressed support for Option 3 b) (5% allocation and exemption for the Arts and Crafts toys) examined further below.

Following this, the Commission received position papers from the toy industry (Annexes V and VI), indicating that the Commission's initiative would have important impacts on the sector's competitiveness. The main impact highlighted by industry was its incapacity to continue marketing certain categories of toys. Taking this into account, the Commission further consulted the toy sector via a targeted public consultation[1]. The targeted group of stakeholders received information on the initiative and was invited to express their opinion on the identified problems, options and other relevant issues. The consultation was published on the "Your voice in Europe" portal, as well as on the DG ENTR webpage dedicated to toy safety and ran from 13 February 2012 to 07 May 2012. Additionally, business associations were informed about the consultation via email and were asked to circulate the information amongst their members. The results of the consultation were eventually published and business associations were duly informed about their publication.

[1] http://ec.europa.eu/enterprise/sectors/toys/public-consultation-lead/index_en.htm

The Commission also collected position papers from consumer protection associations, in particular from ANEC[2] and BEUC[3] (Annex VII). ANEC and BEUC support the revision of the limit values for lead in toys, in order to increase as much as possible children's protection against lead exposure and related health consequences.

The consultation was complemented by interviews[4] with stakeholders carried out by two external consultants in the framework of their respective studies[5]: one on health costs related to children exposure to lead via toys[6], the other on the initiative's effects on the competiveness of the toy sector.[7]

The consultants' studies, in particular the health costs study, and thus the earlier impact assessment were based on the assumptions that

- All toy materials would contain lead at the level of the applicable migration limit values[8]. However, new data available from market surveillance monitoring exercises in Germany[9,10] in 2010 and 2011, and from a limited market surveillance action in Sweden[11], suggest that most of the toy materials contain only very low levels of lead, with few exceptions.
- the revised limit values should be calculated starting from 10% of the new toxicological reference value for lead, namely the $BMDL_{01}$ relating to neuro-developmental effects.

  However, the Toy Safety Directive 2009/48/EC sets the allocation of the toxicological reference value for lead (and five further metallic elements or compounds, namely arsenic, cadmium, chromium-VI, mercury, organic tin) strictly at 5%, due to them being considered particularly toxic as referred to in recital 22 of the Directive.

This consolidated impact assessment therefore

- considers that only few toys (respectively toy materials) may have to be adapted to new limit values for lead;
- sets the allocation at 5% of the $BMDL_{01}$.

The above two elements and their impact for the establishment of new limit values for lead in toy materials were discussed with all stakeholders at the meeting of the Expert Group on Toy Safety in May 2014. A range of Member States preferred a 5% allocation of the toxicological

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2 The European consumers voice in standardisation

3 The European consumers association

4 http://ec.europa.eu/enterprise/sectors/toys/documents/index_en.htm#h2-7

5 Options considered by the IASG constantly evolved through discussions. Therefore, not all external consultants had the opportunity to include all the changes of the options in their studies and assess them comprehensively.

6 http://ec.europa.eu/enterprise/sectors/toys/files/reports-and-studies/final-report-lead-in-toys-matrix-insight_en.pdf

7 http://ec.europa.eu/enterprise/sectors/toys/files/reports-and-studies/final-report-lead-in-toys-ecorys_en.pdf

8 http://ec.europa.eu/enterprise/sectors/toys/files/reports-and-studies/final-report-lead-in-toys-matrix-insight_en.pdf, p. 31: factor F2 which "is regulated by the migration limit set at the EU level ".

9 German Ministry of Economic Affairs, Position paper on lead, 31 May 2013. See Annex XI to this consolidated impact assessment.

10 German Ministry of Economic Affairs, Position paper on lead, 2 October 2013. See Annex XII to this consolidated impact assessment.

11 Swedish Chemicals Agency (Kemi). Data made available in December 2013.

reference value, while others favoured 10%. Stakeholders from the toy industry and consumer representatives were equally split in their views.

1.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the earlier impact assessment and issued its opinion on 16 January 2013. The Impact Assessment Board made several recommendations and, in the light of the latter, the revised earlier impact assessment clarifies the regulatory framework and provides additional background on lead exposure sources. It also enhances the baseline scenario. Additional clarifications were also made as regards several tables and figures, and calculation assumptions used. Some of the arguments used to discard certain options were clarified.

Building on the revised earlier impact assessment, this consolidated impact assessment includes data on the presence of lead in toys and the origin of such toys as recently reported by Germany and Sweden and uses a 5% allocation of the toxicological reference value for lead.

2. CONTEXT

2.1. The Toy Safety Directive

The Toy Safety Directive 2009/48/EC (TSD) modernised the legal framework for toy safety in the EU. Applicable as of 20 July 2011 (for the chemical requirements a longer transition period has been foreseen, namely 20 July 2013) the TSD increases the level of safety for toys while ensuring their free movement on the market.

The TSD introduces strict requirements for chemical substances in toys, and allows for a constant alignment of these requirements to the latest scientific developments by means of amending the chemical provisions. It contains an obligation to systematically review the occurrence of hazardous chemicals in toys, taking into account new scientific evidence and/or concerns raised by Member States. Similar provisions exist in other pieces of legislation, e.g. *the restriction of lead in jewellery is accompanied by an obligation of review 5 years after its* entry into force[12]. Thus, the Commission can propose amendments to certain chemical requirements when new scientific data is made available.

In particular, the TSD contains specific migration limits for lead which are based on scientific evidence available in 2008, i.e. at the time of the legislative procedure. The current migration limits build on the Dutch National Institute for Health and Environment (RIVM) report[13] and on different scientific opinions, and they are based on the TDI, the weight of a child and the kind and amount of toy material ingested. A specific percentage of the TDI is allocated to toys, meaning that intake from toys cannot exceed 5% or 10% of the daily intake (from all sources, food and non-food products included). For lead, with an allocation of 5%, these limits are as follows: 13.5 mg/kg for toys made of dry materials, 3.4 mg/kg for toys made of liquid materials and 160 mg/kg for toys made of scraped-off materials. These limits apply only to toys where lead is accessible via sucking, licking or swallowing. Thus, they are mainly intended to protect children between 0 to 3 years of age (where such behaviour exists), but they also protect older children, when they have a similar behaviour.

[12] Commission Regulation (EU) No 836/2012, OJEU L 252, 19.9.2012, p. 4

[13] http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

Independent scientific committees appointed by the European Commission (e.g. the Scientific Committee on Health and Environmental Risks - SCHER) can evaluate scientific data provided by other scientific committees or institutions on request. This was the case for the above mentioned RIVM report, whose methodology for establishing limit values for toys was validated by SCHER in 2010.

The former Toy Safety Directive 88/378/EEC established bioavailability limits for chemicals in toys, including lead. The bioavailability level for lead, according to this directive, should not exceed 0.7 µg/day. The European standard EN 71-3 Migration of certain elements has translated this into an upper limit of migration of lead from toy material, corresponding to 90 mg/kg. This transposition was based on the hypothesis that the average intake of any toy material is 8 mg/day, whether dry, liquid or scraped-off.

2.2. Lead in toys

Toys may contain lead; it can be intentionally added in materials or present in toys due to raw materials naturally contaminated.

For example metal alloys and painted parts may be contaminated by lead. Interviews with industry associations (see Annex IV) suggest that metal parts and regular paint are not the most important sources of lead contamination. When parts and painted materials are coated and the toy material is solid (e.g., metal parts, painted plastic toys), migration of lead can occur only from scraped-off material. Modern synthetic paints, moreover, do not contain lead, unlike in the past. Dust from metal alloy parts in constructional toys (such as screws, bushings, washers) are a source of scraped-off material, but may lead to problems for industry if it is considered a powder-like material for which a tighter limit value would apply.

For liquid toys and brittle or pliable toy materials, manufacturers may incidentally use raw materials that are naturally contaminated by lead. Colouring pigments (such as titanium dioxide), and softeners or fillers (such as kaolin and clay) are used in Arts and Crafts toys such as modelling clay, colour pencils, paint tablets, powder paint, liquid finger paints and poster paints, pastels and wax crayons. These materials are often an important element in the toy (up to 80% of the material as in colour pencil leads), and have a crucial role for the technical functioning of the product (e.g., ensuring gradual abrasion without breaking, enabling opaque colouring).

According to information received from the industry (see Annex VI) there are currently no alternatives to replace lead in certain toys. This is because the presence of lead in these toys is due to naturally contaminated raw materials. There are no suitable substitutes for these raw materials either, according to the same sources mentioned above.

For the purpose of the sector's overview, liquid, sticky and brittle, dry or pliable toys will be referred to as Arts and Crafts toys. The first category of toys above falls under the heading of "Other toys".

2.3. Overview of the toy sector

There are about 2,000 companies involved in the toys and games sector in the EU. Most are small and medium-sized enterprises (SMEs). The toy industry directly employs nearly 100,000 people in the EU in production, research and development, marketing, sales, distribution, and many other services.

The total production of toys in the EU in 2010 was mostly generated by France, Germany, Italy, Ireland, Spain, the UK, Denmark, the Czech Republic, Malta and Poland.

The total exports of toys[14] from EU27 countries to non-EU countries in 2010 was €1.05 billion. The total imports of traditional toys from non-EU countries to EU27 in 2010 was €6.96 billion.

Toys are manufactured globally but China is by far the biggest exporter of toys in the world. Some 85% of all toys on the European market are produced in China, by both EU and non-EU manufacturers. The toys that come onto the European market find their way to final consumers via different routes.

Figure 1 - Value chain for the toy sector

As depicted in the figure above, the toy value chain consists of different types of actors that each play their own distinct role. The way these various actors interact with each other depends largely on their position in the supply chain. While the bigger economic operators typically have full control over product design, manufacturing and distribution, many retailers tend to have control only over manufacturing and distribution, with traders only having control over the distribution but not in any significant way over design and manufacturing.

The picture illustrates the roles of different actors. It all starts by creating a concept and designing a toy according to the applicable legislation. Different suppliers interact, delivering the assemblies, parts or chemicals used before starting the production in a factory. The finalised product leaves the factory and is shipped to its corresponding market, e.g., the EU market. Once declared that it can freely move and be stored and sold by retailers, and toys end up on the shelves of shops. The end user, the consumer, will buy the product and take it

[14] Traditional toys not including video games

home. In this specific case, the end users are children playing with the toys. Their number[15] is estimated at 80 million within the EU.

3. PROBLEM DEFINITION

3.1. Children's exposure to lead - the problem that requires action

Lead is a heavy metal which takes both organic and inorganic forms. 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[16] as the result of human activities and due to its extensive use in industrial processes.

Humans are exposed to lead via multiple sources: dietary (water, food) and non-dietary (air, soil, consumer products such as toys). The Scientific Committee on Health and Environmental Risks (SCHER) considers that the exposure to lead via toys should not exceed a maximum of 10% of the lead's daily intake (from all sources)[17].

Lead exposure has particularly damaging effects on children, as they are in fact more susceptible to lead than adults for two main reasons:

- A developing brain is more susceptible to neurotoxicity of lead than a fully-developed adult brain[18];
- Children, especially under the age of six, absorb greater amounts of lead than adults, even when the absolute exposure to lead is identical[19].

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

[15] Number of children below 14 years, who are covered by the TSD

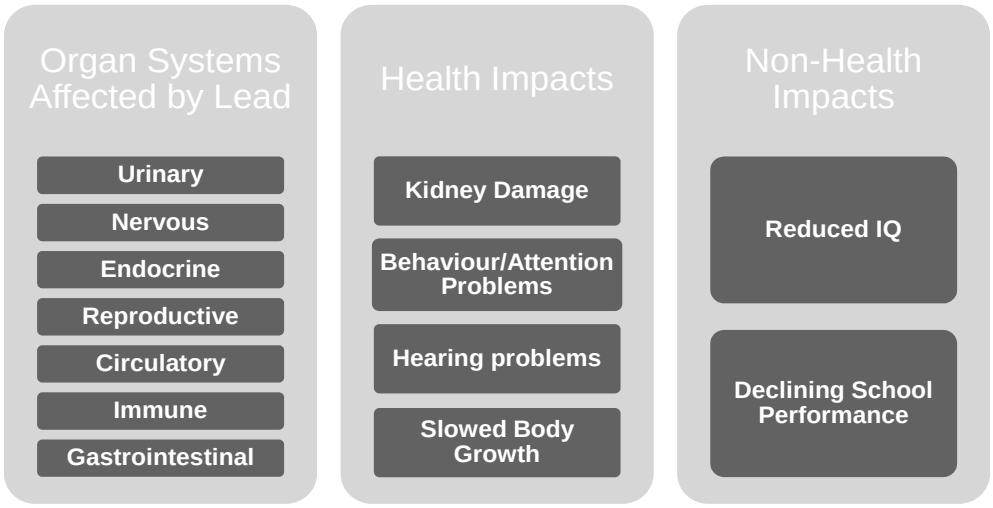
[16] European Food Safety Agency (EFSA) http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm

[17] SCHER Opinion on the Evaluation of the Migration Limits for Chemical Elements in Toys, 2010, http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_126.pdf

[18] Lindsky and Sehneider, 2002

[19] 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 2 – Effects and impacts of lead exposure in children



The current lead limit values in the TSD reduce to trace levels the amount of lead which may occur in toys. Below these limit values, it is considered that exposure to lead has no critical health effects. However, these limit values, adopted in 2009, have been recently invalidated by new scientific evidence.

In 2010, the European Food Safety Authority (EFSA)[20] concluded that for lead, as a toxic metal, there is no threshold below which exposure to lead has no critical health 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.

The new toxicological reference value is the $BMDL_{01}$ relating to neuro-developmental effects. The $BMDL_{01}$ is the lower confidence limit (95% percentile) of the benchmark dose of a 1% extra risk of intellectual deficits in children measured by the Full Scale IQ score, i.e., a decrease in IQ by 1 point on that scale[21]. The $BMDL_{01}$ is equivalent to an intake of 0.5 µg lead/kg bodyweight/day.

In light of these findings, it is necessary to revise the limit values for lead in toys.

3.2. Toys containing lead - a problem driver for lead exposure

3.2.1. Possible sources for lead in toys

Lead is present in a wide range of materials in the environment, in both organic and inorganic form (Table 3). Consequently, children may absorb lead through dietary or non-dietary exposure, and face health consequences.

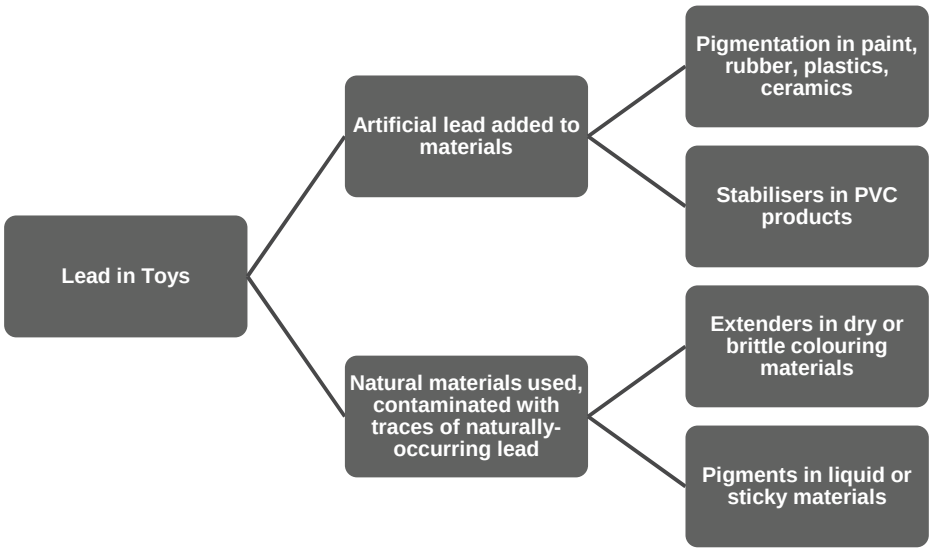
Toys represent one of many channels of children's exposure to lead.

[20] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm
[21] EFSA CONTAM Panel (2013) Scientific Opinion on Lead in Food, p. 5, p. 98.

Lead can be present in toys either because:

- Lead is intentionally added to non-contaminated materials (artificial lead); or
- Raw materials, which are contaminated with traces of naturally-occurring lead, without any added value for the functioning of the toy have to be used to produce the toy.

Figure 3 – Sources of lead in toys



The two most common ways in which toy manufacturers use (added) lead are:

- For pigmentation in paint, rubber, plastics and ceramics. Examples of toys that could contain lead for pigmentation include painted blocks, metal cars, tea sets, etc.
- As a stabiliser in PVC[22] 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 toys that could contain added lead as a stabiliser include 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 resistance 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[23] – i.e. primarily in the Arts and Crafts industry.
- As pigments (e.g., iron oxides, titanium dioxide, barium sulphate), in liquid or sticky materials to render them opaque. Examples of toys that could contain natural materials

[22] Polyvinyl chloride (PVC) is the third most widely produced plastic.
[23] WECF, 2009

contaminated with traces of lead include paints[24] – i.e. primarily in the Arts and Crafts industry.

Toys that contain traces of naturally occurring lead include: chalks, coloured pencils, fibre pens, finger paints, drawing games (Spiro games), modelling materials, water colours, wax crayons, window colour, fancy products[25].

3.2.2. Toys actually containing lead – Results of market monitoring exercises

In May 2013 data from German market monitoring programmes, carried out in 2010 and 2011, provided detailed migration data on lead in toys[26] from 2,496 toy samples tested. Tests included toys made with contaminated natural raw materials such as finger paints, colour pencil leads or water paint tablets. The results of the market monitoring are shown in the table below. Very few other data on lead in toys are available.

The table below shows that on average (see column "median"; the median is also called "50 percentile": 50% of the samples examined have a lead content that is below the 50 percentile expressed in mg lead/kg toy material. Of course the remaining 50% of the samples are above the median.) lead was not detected in the toys tested, with the exception of colour pencil leads with 1.5 mg/kg lead.

The 90 percentiles (90% of the samples tested have a lead content that is below the 90 percentile expressed in mg lead/kg toy material. The 90 percentile encompasses near to all samples.) again show some higher value for colour pencil leads (6 mg/kg), but also for water paint tablets (10.2 mg/kg).

In conclusion, the market monitoring results suggest that colour pencil leads and water paint tablets, which belong to the Arts and Crafts toys, had a somewhat higher lead content than most other toys. In all cases, however, the 90 percentile was clearly, or even considerably, below the current TSD limit values for lead.

These conclusions were supported by a limited market surveillance action in Sweden[27] regarding colour pencil leads.

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24 EWIMA,2011

25 See Annex VI, EWIMA position paper

26 German Ministry of Economic Affairs, Position paper on lead, 31 May 2013. See Annex XI.

27 Swedish Chemicals Agency (Kemi). Data made available in December 2013.

Table 1 – Lead migration from 2,496 toy samples tested according to EN 71-3 in 2010 and 2011 during market surveillance monitoring programmes in Germany

Toy	Type of toy material and current TSD limit value in mg/kg	Number of tested samples	Number of samples with a quantifiable lead content	Median (50 percentile) in mg/kg	90 percentile in mg/kg
Finger paints	Liquid 3.4	63	11 (18%)	nd (<0.1)	1.3
Chalks	Dry 13.5	136	13 (9.5%)	nd (<0.25)	1.5
Modelling clays		47	10 (21%)	nd (<0.25)	2.6
Colour pencil leads		411	228 (58%)	1.5	6
Water paint tablets		424	112 (26%)	nd (<1.25)	10.2
Colour pencil coatings	Scraped-off 160	326	79 (24%)	nd (<0.25)	1.8
Rattle coatings (< 36 months)		473	165 (35%)	nd (<0.5)	2
Puzzle coatings (< 36 months)		102	47 (46%)	nd (<1.5)	4
Pull-along toy coatings (< 36 months)		96	36 (37%)	nd (<1)	1.9
Dolls / figures		323	113 (35%)	nd (<0.5)	2.6
Wooden construction sets, shops		96	18 (19%)	nd (<0.2)	1.6
All scraped-off toy materials		**1415**	**458 (32%)**	**nd (<0.5)**	**2**

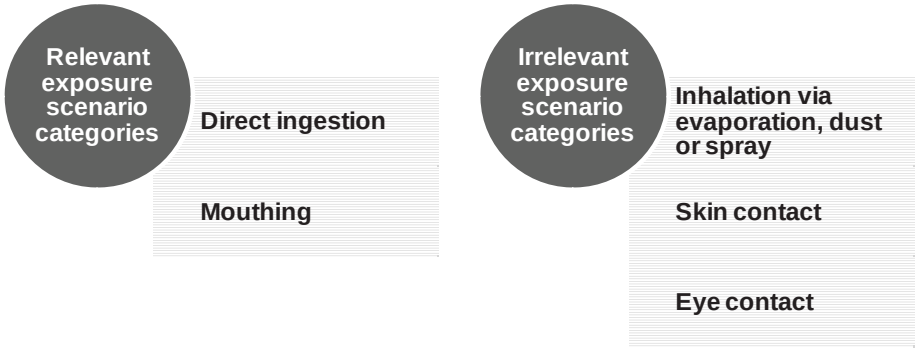
"Dry" means Dry, brittle, powder-like and pliable toy material
"Liquid" means Liquid or sticky toy material
" Scraped-off " means Scraped-off toy material
nd … not detectable (<Limit of Detection LOD, mg/kg)

3.2.3. Exposure of children to lead

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[28]. The table below summarises children's exposure to lead.

[28] RIVM, 2008, http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

Figure 4 – Exposure scenario categories



The scenarios of direct ingestion and mouthing are relevant for 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 years 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 main 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 policy making communities. RIVM[29] estimates that 8 mg of scraped-off, 100 mg of brittle and 400 mg of liquid or sticky toy material are ingested by a child every day. This implies that if such toys contain traces of lead, a small amount of lead will be ingested by children. As children of a young age are constantly exposed to toys, toys partially manufactured with or containing lead are a problem driver for lead exposure in children and its resulting neurotoxic effects. This is true even if the proportion of children's lead exposure due to toys is small, in particular in the context of more relevant exposure sources (i.e. water and food).

3.3. Consequences of exposure to lead

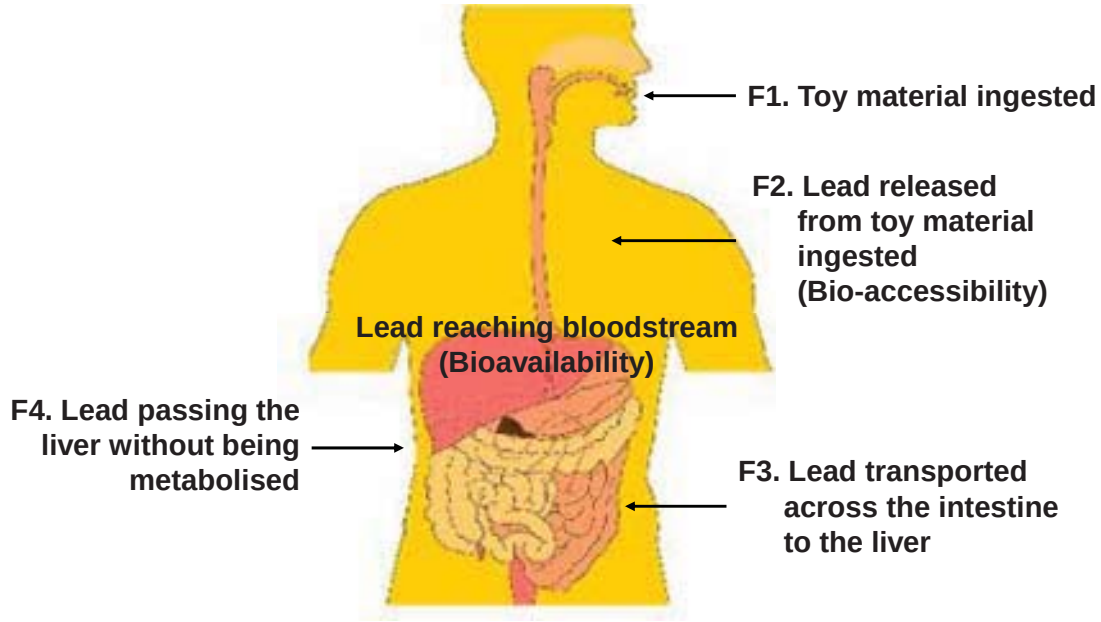
The consequences of exposure to lead manifest themselves only once the chemical is absorbed in the blood stream and accumulates in organs and tissues. Thus, the health impacts of children's exposure to toxic metals, including lead, via toys can only be measured through the bioavailability of the material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

[29] RIVM, 2008, http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

amount of each element in the toy which could be absorbed into the systemic circulation of a child'[30].

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. If the toy contains lead, during digestion in the gastro-intestinal tract, lead might be partially or totally released from the toy material ingested. The 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 (i.e. eliminated via urine). Other part will not be metabolised and it will hence reach the blood. This non-metabolised part exerts toxicity in the organs and tissues, with consequences for the child's health. This process is outlined in the table below.

Figure 5 – Process of bioavailability



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 small quantities absorbed over a longer period of time, the most widespread health impacts include:

- kidney damage, which manifests as a loss of function and decreased reabsorption (UNEP, 2012)[31];
- hearing problems caused by slowed nerve conduction in the auditory pathway (Schwartz, 1991)[32];

30 Scientific Committee on toxicity 2004, http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out235_en.pdf

31 UNEP (Undated), Lead Exposure and Human Health. Available at http://www.chem.unep.ch/pops/pdf/lead/leadexp.pdf [Access on February 2012]

32 Lead, blood pressure, and cardiovascular disease in men and women. Schwartz J Environ Health Perspect. 1991 February

- behaviour and attention problems (MedlinePlus, 2011)[33], 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 may reduce IQ and productivity[34] as a result of its effect on the nervous system, or it may affect fertility rate, through its effects on the reproductive system. Both the health related and non-health related impacts of lead absorption may imply a reduction in individual quality of life, increased treatment costs for society and generate a reduction in the individual's productivity. More evidence on these impacts is presented in Annex II.

3.4. Scale of the problem

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, as shown in the following table:

Table 2 - 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%)[35]. For young children, this particularly includes some calcium supplements, infant formulae and breast milk.
Water	Primarily from steel and iron industries, as well as from lead production and processing operations. Lead exposure via water, this is generally higher for those living near hazardous waste sites[36].
Total Diet	For children between 0 and 7 years old, estimates of reported dietary exposure range from 0.21 to 3.10 µg/kg bodyweight per day[37].
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. Bioavailability of atmospheric lead has decreased rapidly over the past forty years, because of regulations banning the usage of lead in petrol. For children, air exposure is split into outdoor air and environmental tobacco smoke. Daily outdoor air lead exposure is estimated to be between 0.001 and 0.003 µg/kg bodyweight per day in children. Daily environmental tobacco smoke lead exposure between 0.012 and 0.052 µg/kg bodyweight per day in children[38].

[33] MedLine Plus (2011), Lead poisoning. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/002473.htm [Accessed November 2011]
[34] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm
[35] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm
[36] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm
[37] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm
[38] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm

Soil & Dust	Important source of lead exposure for children. This includes, e.g. lead dust in carpets and dust near waste sites. It is estimated that children are exposed to between 0.18 and 0.80 µg/kg bodyweight on a daily basis[39].

The Scientific Opinion on Lead in Food, issued by the Panel on Contaminants in the Food Chain at the European Food Safety Agency (EFSA)[40] shows that the dietary lead exposure estimates for children exceed the new toxicological reference value $BMDL_{01}$ (which is equivalent to 0.5 µg lead/kg bodyweight/day), as summarised in the table below.

Table 3 – Dietary lead exposure estimates for children and toxicological reference value

Children's age, years and consumption	**Dietary lead exposure estimate µg/kg bodyweight/day**	**How many times does the exposure exceed the $BMDL_{01}$ (0.5 µg lead/kg bodyweight/day) ?**
1 – 3 mean consumption	1.10 – 3.10	2 – 6
1 – 3 high consumption	1.71 – 5.51	3 – 11
4 – 7 mean consumption	0.80 – 2.61	2 – 5
4 – 7 high consumption	1.30 – 4.83	3 – 10

A lead intake at the level of the $BMDL_{01}$ is considered to be the highest tolerable exposure level for lead[41]. Since the current average blood lead levels in European children are higher than this highest tolerable exposure level, and since no threshold for the neuro-developmental effects has been established, **any additional exposure must be avoided as far as possible**[42].

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.

3.5. Who is affected, in what ways and to what extent?

Children playing and being exposed to toys containing lead traces are the main affected parties. The exposure is made mainly via the mouthing and direct ingestion of toy materials containing lead. The mouthing behaviour is specific for young children aged from 0 to 3 years. Therefore they will be the main beneficiaries of the potential measures aiming at

[39] EFSA 2010, http://www.efsa.europa.eu/en/efsajournal/pub/2831.htm

[40] http://www.efsa.europa.eu/en/efsajournal/doc/2831.pdf

[41] ECHA Committee for Risk Assessment (RAC) (2013) Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use. Adopted on 10 December 2013. ECHA/RAC/RES-O-0000003487-67-04/F. http://echa.europa.eu/documents/10162/d6026d8c-3ebb-4507-bd8f-d1c942493075

[42] ECHA RAC (2013) Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use.

reducing levels of exposure to lead from toys. Statistics show there are 16 million children below 3 years of age in the EU[43].

3.6. Establishment of revised lead limit values

3.6.1. New scientific knowledge about lead requires revised limit values for lead in toys

The lead limit values in the Toy Safety Directive 2009/48/EC[44] (TSD) as adopted are 13.5 - 3.4 - 160 mg/kg in dry - liquid - scraped-off toy materials, respectively. They are based on a Tolerable Daily Intake (TDI) of 3.6 µg/kg bodyweight/day[45,46] as the toxicological reference value. They are equally based on the requirement of the TSD that the lead intake from toys should not exceed 5% of the TDI[47], due to the particular toxicity of lead.

Due to new scientific knowledge published by the European Food Safety Agency (EFSA), there is no longer a (lower) threshold for neuro-developmental effects from lead. Therefore there is no longer a TDI[48,49].

The new basis, or toxicological reference value, for establishing a lead limit for children is the $BMDL_{01}$ relating to neuro-developmental effects. The $BMDL_{01}$ is the lower confidence limit (95% percentile) of the benchmark dose of a 1% extra risk of intellectual deficits in children measured by the Full Scale IQ score, i.e., a decrease in IQ by 1 point on that scale[50]. The $BMDL_{01}$ is equivalent to an intake of 0.5 µg lead/kg bodyweight/day.

3.6.2. Approach of the Toy Safety Directive: 5% of the toxicological reference value

As referred to above, during the establishment of the TSD it was considered that the limit values for several elements which are particularly toxic, amongst which lead, should be set "at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee"[51].

The opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) from 2004[52] recommended that toys should not contribute above a maximum of 10% of the total lead intake by children. The successor to the CSTEE, the Scientific

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43 16,011,195 million children. http://ec.europa.eu/enterprise/sectors/toys/files/reports-and-studies/final-report-lead-in-toys-matrix-insight_en.pdf. P. 46.

44 Directive 2009/48/EC on the safety of toys. OJ L 170, 30.6.2009, p. 1.

45 RIVM Report 2008, pp. 114, 120-122. http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

46 µg/kg bw/day … microgram per kilogram bodyweight per day

47 Recital 22 of the Toy Safety Directive 2009/48/EC. OJ L 170, 30.6.2009, p. 1.

48 EFSA CONTAM Panel (2013) Scientific Opinion on Lead in Food. EFSA Journal 8(4), 1570 (replaces EFSA's opinion of 2010) http://www.efsa.europa.eu/en/efsajournal/pub/1570.htm

49 SCHER (2011) Opinion on a Lead Standard in Drinking Water. – The opinion is largely based on the EFSA CONTAM Panel (2010) opinion, replaced by the Panel's opinion of 2013 (see footnote above). http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_128.pdf

50 EFSA CONTAM Panel (2013) Scientific Opinion on Lead in Food, p. 5, p. 98.

51 Recital 22 of the TSD.

52 Scientific Committee on toxicity 2004, http://ec.europa.eu/health/archive/ph_risk/committees/sct/documents/out235_en.pdf

Committee for Health and Environmental Risks (SCHER), concurred with the approach to limit the uptake to 10% of a toxicology-based reference value[53].

The TSD therefore set the limit values for lead (and five further metallic elements or compounds, namely arsenic, cadmium, chromium-VI, mercury, organic tin)[54] at only 5% of the then existing toxicology-based reference value, the TDI[55]. Since the TDI is no longer the toxicological reference value but instead the $BMDL_{01}$, the present consolidated impact assessment considers an allocation of 5% of the $BMDL_{01}$.

The table below shows the limit values for lead in toys, revised in accordance with the approach of the TSD.

Table 4. Limit values for lead in toys

Toy material	**Lead limits, mg/kg**	
	Directive 2009/48/EC as adopted	**Revision: 5% allocation of the $BMDL_{01}$**
Dry	13.5	2
Liquid	3.4	0.5
Scraped-off	160	23

"Dry": Dry, brittle, powder-like or pliable toy material
"Liquid": Liquid or sticky toy material
"Scraped-off": Scraped-off toy material

To note that, according to the new scientific knowledge, lead is a non-threshold substance: It exerts toxic effects even at most minor concentrations. Lead should therefore not be present in toys, and the limit values should be set, as recommended by standard EN 71-9[56], at the lowest level achievable, which would be the Limit of Quantification (LOQ) of the analytical method applied.

This would mean that the revised limit values for lead in toys should be set at the LOQ of lead as given in EN 71-3 which is designed to test the migration of lead (and of the other metal elements and compounds listed in Annex II, section III, No. 13 of the TSD)[57], namely at 0.122 mg/kg in any toy material.

However to keep consistency with the TSD this consolidated impact assessment considers the limit values given in the table above.

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53 Scientific Committee on Health and Environmental Risks (SCHER), Opinion on the "Evaluation of the Migration Limits for Chemical Elements in Toys", adopted on 1 July 2010. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_126.pdf

54 TSD Annex II, Part III, point 13.

55 National Institute for Public Health and the Environment (RIVM), Chemicals in Toys - A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM report 320003001/2008. Table 8-1 TDIs and sensitising potential for the different elements (p. 114) and tables 8-2, 8-3 and 8-4 (pp. 120 – 122).

56 EN 71-9:2005+A1, Annex A, section A.10.

57 EN 71-3:2013, Table E.5.

3.6.3. Analytical feasibility of the revised limit values

As referred to above EN 71-3 reports a typical Limit of Quantification (LOQ) for lead of 0.122 mg/kg. This is at least 4 times lower than the revised limit values proposed in the table above. Toys can therefore be tested for the revised limit values already today, without any investment into laboratory equipment or laboratory capacity.

3.7. Which toys are affected?

3.7.1. Types of toys affected

In May 2013 data from German market monitoring programmes, carried out in 2010 and 2011, provided detailed migration data on lead in toys[58]. Almost 2,500 toy samples were tested for lead, including toys made with contaminated natural raw materials such as finger paints, colour pencil leads or water paint tablets which belong to the Arts and Crafts toys. The results of the market monitoring are shown in the table below. Very few other data on lead in toys are available.

The table shows that the overwhelming majority of the toys tested already complied with the lead limit values derived from a 5% allocation of the $BMDL_{01}$. Compliance rates varied from 91% to 100%. This reflects the variability of samples encountered in any market surveillance activity and can broadly be considered as reflecting compliance. Only finger paints, colour pencil leads and water paint tablets had lower compliance rates, namely 75%, 73% and 83%, respectively.

[58] German Ministry of Economic Affairs, Position paper on lead, 31 May 2013. See Annex XI.

Table 5. Compliance of 2496 toys in market surveillance programmes 2010 – 2011 in Germany

Toy	Type of toy material	Number of tested samples	Lead limit value mg/kg 5% allocation	%age of compliant toy samples
Finger paints	Liquid	63	0.5	75
Chalks	Dry	136	2	100
Modelling clays		47		91
Colour pencil leads		411		73
Water paint tablets		424		83
All dry toy materials		1018		82
Colour pencil coatings	Scraped-off	326	23	100
Rattle coatings (< 36 months)		473		99.6
Puzzle coating s (< 36 months)		102		100
Pull-along toy coatings (< 36 months)		96		100
Dolls / figures		323		97.5
Wooden construction sets, shops		96		100
All scraped-off toy materials		1415		99

"Dry" means Dry, brittle, powder-like and pliable toy material
"Liquid" means Liquid or sticky toy material
" Scraped-off " means Scraped-off toy material

3.7.2. Origin of the toys affected

A detailed look at the countries of origin of those finger paints, colour pencil leads and water paint tablets[59] is given in the table further below. It reveals the following:

- **Finger paints:** Only 55% of finger paints from one Member State complied with a 5% allocation of the $BMDL_{01}$ while the figure for another was 67% and for a third, 90%. However 100% of finger paints from China or of unknown origin were compliant with such a limit value.

  A simulation with a 10% allocation of the $BMDL_{01}$, reflecting the opinion of SCHER[60], again gave low compliance rates for the 3 Member States of 86%, 67% and 90% (the latter two unchanged) for finger paints. Thus many of these finger paints were non-compliant with the limit values in both simulations.

[59] German Ministry of Economic Affairs, Position paper on lead, 2 October 2013. See Annex XIII.
[60] 10% would still be in line with the opinion of SCHER (2010) Opinion on the "Evaluation of the Migration Limits for Chemical Elements in Toys", adopted on 1 July 2010. See footnote above.

This was confirmed by analyses carried out on 3 finger paints on the Swedish market, originating from a further Member State and from China[61]. These finger paints were non-compliant in simulations with both a 5% and a 10% allocation of the $BMDL_{01}$.

In conclusion, it is possible to manufacture compliant finger paints, while non-compliant finger paints on the market pose a health risk to children since they do not even comply with a 10% allocation.

- **Colour pencil leads:** In the case of one Member State, no colour pencil leads complied with a 5% allocation of the $BMDL_{01}$ while the figure for another was 60% and for a third, 65%. The figure for China was 85%, while only 71% of colour pencil leads of unknown origin were compliant with such a limit. However 100% of colour pencil leads from a further Member State and from Brazil as well as 94% identified as being 'from Europe' complied with the 5% allocation limit.

  Under a simulation with a 10% allocation of the $BMDL_{01}$ the compliance rates rose in certain cases. However for the three Member States above, compliance rates were still only 14%, 60% (unchanged) and 85%. For China it was 91% and it was 88% for colour pencil leads of unknown origin. Thus colour pencil leads from many origins remained non-compliant.

  Furthermore, from 3 colour pencil leads on the Swedish market (from 2 Member States and Indonesia), only 1 was compliant with the 5% allocation, although all 3 products were compliant under a simulation with a 10% allocation.

  Thus, while the data show that it is possible to manufacture in compliance with a 5% allocation of the $BMDL_{01}$, the colour pencil leads of a majority of origins can be considered to pose a health risk to children since they remained non-compliant in a simulation with a 10% allocation of the $BMDL_{01}$.

- **Water paint tablets:** In the case of one Member State only 79% of water paint tablets complied with the 5% allocation of the $BMDL_{01}$ (rising to only 80% with a 10% allocation). However 100% of those from two other Member States, those identified as being 'from Europe', those from China and those of unknown origin were compliant with such a limit. The analyses of water paint tablets on the Swedish market also showed that all 3 samples (from three further Member States) complied.

  Thus the water paint tablets from a large majority of origins were compliant, while most non-compliant paint tablets on the market pose a health risk to children since they did not even comply with a 10% allocation.

In conclusion, most of the finger paints, colour pencil leads and water paint tablets which did not comply with the 5% allocation of the $BMDL_{01}$ remained non-compliant even with a 10% allocation, and these toys can be considered to pose a risk to the health of children. On the other hand, it is possible for manufacturers to produce such kinds of toys that comply with a 5% allocation of the $BMDL_{01}$.

[61] Swedish Chemicals Agency (Kemi). Data made available in December 2013.

Table 6. Origin and compliance rates of finger paints, colour pencil leads and water paint tablets in market surveillance programmes 2010 – 2011 in Germany

Toys and their origin	Number of tested samples	Compliant toy samples, in %	
		5% allocation: limit value 2 mg/kg	10% allocation: limit value 4 mg/kg
Finger paints			
DE	29	55	86
IT	10	90	90
NL	6	67	67
China	12	100	100
Unknown	6	100	100
TOTAL	63	75	89
Colour pencil leads			
DE	100	65	85
FR	12	100	100
AT	7	0	14
UK	10	60	60
Europe	16	94	94
Brazil	4	100	100
China	78	85	91
Unknown	184	71	88
TOTAL	411	73	86
Water paint tablets			
DE	242	79	80
FR	3	100	100
IT	40	100	100
Europe	4	100	100
China	8	100	100
Unknown	127	84	85
TOTAL	424	83	84

3.8. Estimation of health benefits and of economic costs

In case of no action, the limits established in the Toy Safety Directive 2009/48/EC would remain unchanged, i.e. 13.5 mg/kg in dry materials, 3.4 mg/kg in liquid materials and 160 mg/kg in scraped-off materials.

Children would continue to be exposed, via toys, to a high amount of lead, which can lead to kidney damages, hearing problems, behaviour and attention problems, and slowed body growth.

These health consequences raise long-term costs related to:

- a reduction in health related quality of life, measured as Quality Adjusted Life Years (QALYs)[62]
- an increase in health cost due to medical treatment, such as drug cost, hospital treatment cost, etc.

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

- a reduction in productivity, measured as work days loss due to the health condition, multiplied by the average wage.

Economic costs are related to:

- Increase in production costs;
- Reduction in the product range. It would be difficult to continue to market certain toys (e.g. colouring pencils) as they would not meet the safety limits anymore;
- Poorer quality or performance of some toys (e.g. range of colours; abrasion characteristics, etc.).

To estimate the above benefits and costs, the earlier impact assessment based its calculations on the assumptions that

- All toys comply with the current TSD limit values and thus contain lead at the level of these limit values;
- The allocation of the toxicological reference value for the revision of the limit values is 10%.

In contrast to this, on the basis of newly available information, this consolidated impact assessment assumes that

- Toys contain lead at only a very minor level as shown further above by the market monitoring results of 2010 and 2011 in Germany, only some Arts and Crafts toys (finger paints, colour pencil leads, water paint tablets) may exceed the proposed revised limit values;
- The allocation of the toxicological reference value is 5% since the current lead limits in the TSD are equally based on a 5% allocation.

Thus benefits and costs may in general only relate to the adaptation of the lead content of the Arts and Crafts toys referred to above. Since "On average, about 6.5% of toy sales in the EU are art and crafts toys (according to TIE statistics)." [63],

- the health benefit figures of the earlier impact assessment will be multiplied with 6.5% (0.065) for the purpose of this consolidated impact assessment.

  This is a very crude approach and may underestimate the health benefits, since the proposed revised limit values of this consolidated impact assessment are only half as high as the limit values proposed in the earlier impact assessment, due to the allocation of only 5% (instead of 10%). However, halved limit values do not translate into half a lead concentration in the blood of children, and also not to doubled health benefits.

  On balance, therefore, it may be sufficient to retain that the health benefit figures in this consolidated impact assessment are approximate, and could be higher;

- the economic costs will be left as estimated in the earlier impact assessment.

[63] http://ec.europa.eu/enterprise/sectors/toys/files/reports-and-studies/final-report-lead-in-toys-ecorys_en.pdf . P. 69.

This is again quite approximate, since manufacturers of Arts and Crafts toys may have to make additional efforts to find raw materials that are even less contaminated with lead. However, efforts will not cost double as much since there is no relation between the search effort and the level of contamination. Furthermore, as shown above by the market monitoring data, there are indeed Arts and Crafts toys on the market that comply with the proposed revised lead limit values. It is therefore well possible to find appropriate raw materials and place the resulting toys at a competitive price on the market.

On balance, therefore, it may be sufficient to retain that the economic cost figures are only approximate.

3.9. EU right to act

1. Legal base

The toy safety legislation is based on Article 114 TFEU guaranteeing the functioning of the internal market.

2. Subsidiarity test

According to the principle of subsidiarity (Article 5.3 of the TFEU), action on EU level should be taken only when the aims envisaged cannot be achieved sufficiently by Member States alone and can, by reason of the scale or effects of the proposed action, be better achieved by the EU. The preceding analysis has shown that children are equally exposed to lead, and this exposure leads to health consequences. Thus, the TSD aims at guaranteeing an equal level of protection to all EU children, while eliminating obstacles to the free movement of toys with the EU market.

Individual actions undertaken by Member States, intended to protect children's health from lead exposure via toys, would result in children being unequally protected within the EU. Additionally, such individual measures could lead to a fragmentation of the internal market and create barriers to toys' trade.

4. OBJECTIVES

4.1. General policy objectives

The general objective of this initiative is to ensure a high level of health protection, while safeguarding the free movement of goods within the EU. The absence of a common harmonised level of protection would encourage Member States to take disparate national measures to protect their consumers; such national measures would jeopardise the free movement of toys on the EU market. Germany for example considers that the limit values currently contained in the TSD are not strict enough and requested permission to apply stricter values, in order to better protect the health of children[64].

[64] OJEU, 28.5.2011, C 159, p. 23.

4.2. Specific policy objectives

The specific objectives of this initiative are:

- To reduce children's exposure to lead via toys by taking stock of the latest scientific findings, and
- To maintain the free movement of toys within the EU.

4.3. Operational policy objectives

The specific objectives to be accomplished by this initiative are:

- To apply the maximum amount of lead which should not be exceeded, and
- To ensure that this maximum amount applies to all toys marketed on the EU market.

4.4. Consistency with other policies and objectives

At EU level, the presence of lead in ceramics and plastic materials which come into contact with food is already restricted[65]. The REACH Regulation bans the use of lead compounds in paint[66]. The presence of lead and its compounds in jewellery is also restricted, in order to reduce health risks[67]. Lead is also restricted in foodstuffs (major source of exposure) by Regulation 1881/2006[68]. For example, the maximum amount allowed in milk is 0.020 mg/kg and in cereals 0.20 mg/kg. In drinking water (other major source of lead exposure), the Drinking water directive establishes a maximum amount of 10 µg/l as from December 2013. With regard to drinking water in particular, the Scientific Committee on Health and Environmental Risks (SCHER) recommends, in its 2011 opinion on lead in drinking water, a further reduction of the lead exposure as a warrant for the reduction of the risks on health. Further restrictions for lead are being considered in the framework of the Codex Alimentarius[69] and a so-called Annex XV dossier has been submitted by Sweden under the REACH Regulation for the purposes of restricting lead and its compounds in articles which are supplied to the general public and can be placed in the mouth by children, if the concentration of lead (expressed as metal) in the article is equal to or greater than 0.05% by weight. As regards the classification of lead at EU level for adequate risk management, Sweden submitted a proposal for a harmonised classification of lead as a reprotoxic substance[70]. The use of lead in food and non-food products is internationally restricted as well. In the US for example, lead in not allowed in toys and child care articles at concentrations above 100 ppm. In drinking water, the Safe Drinking water Act sets out a maximum contamination goal of 15 ppm.

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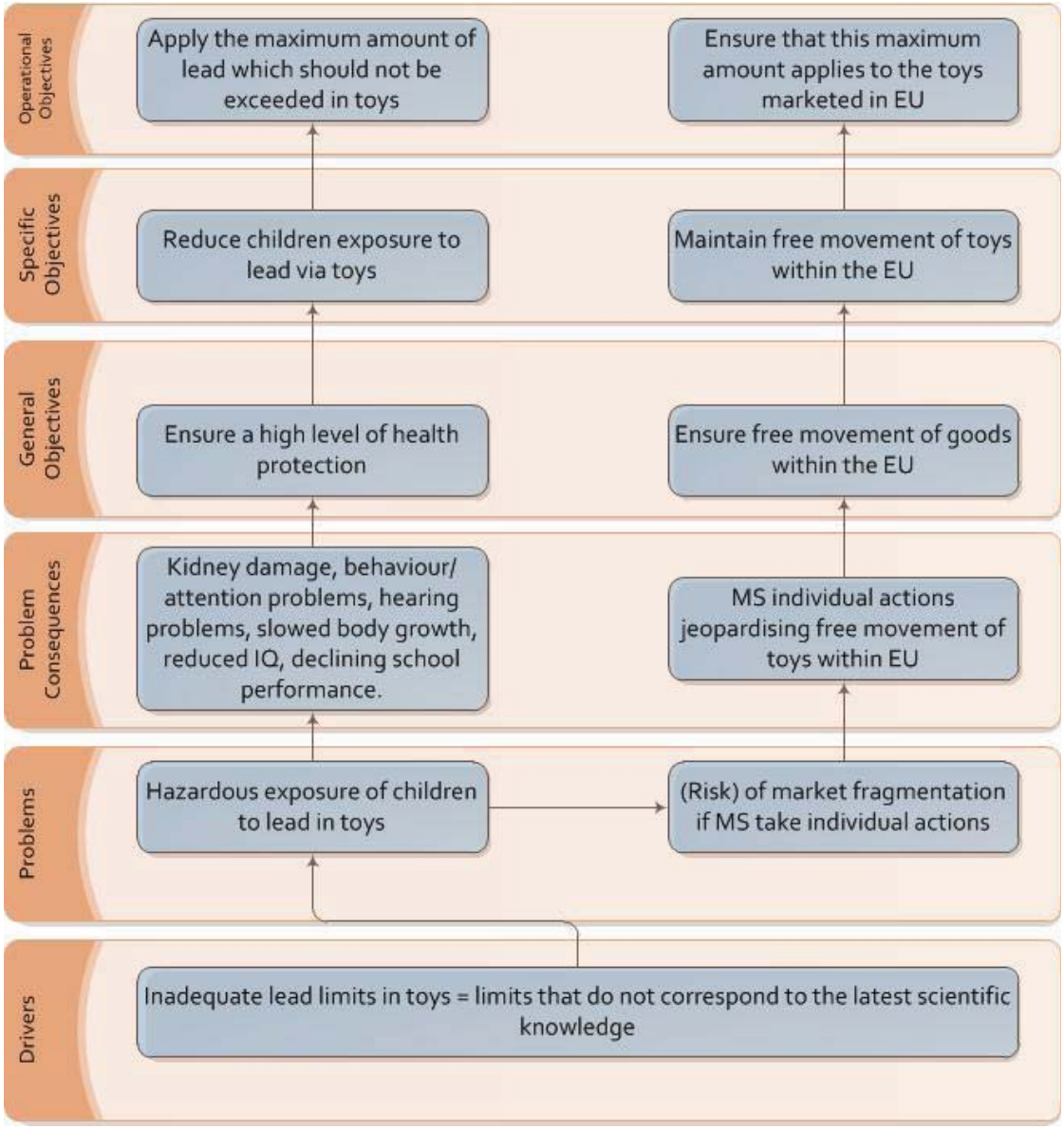
65 Commission Regulation (EU) No 10/2011, OJEU L 12, 15.1.2011, p. 1
66 Regulation (EC) No 1907/2006 (REACH), OJEU, L 396, 30 December 2006
67 Commission Regulation (EU) No 836/2012, OJEU, L 252, 19.09/2012, p.4
68 OJEU, L 364, 20.12.2006, p.5
69 http://www.codexalimentarius.org/
70 http://echa.europa.eu/harmonised-classification-and-labelling-consultation/-/substance/698/search/+/term

Figure 6 – Problem and objectives tree



5. POLICY OPTIONS

The policy options as proposed by the Commission and as consulted with stakeholders are the following:

Baseline option: Maintaining children's exposure to lead via toys at the level determined by the TSD in 2009, without taking into account the evolution of the lead related scientific knowledge. The limit values to be maintained are as follows: 13.5 mg/kg in dry materials, 3.4 mg/kg in liquid materials and 160 mg/kg in scraped off materials.

Option 1: Soft law / self-regulatory approach: Inviting the toy industry to put in place voluntary agreements on reducing lead exposure via toys.

Option 2: Labelling of toys containing lead in order to raise awareness amongst consumers on the health risks due to exposure to lead via toys.

Option 3: Revision of the current limit values for lead. This option presents three alternatives (sub options):

Option 3a): Complete revision of the current limit values: reducing the limit values for lead in *all toys and all categories of toy material* in line with the latest scientific knowledge,

- with mitigating measures;
- with no mitigating measures.

This option would imply the following limit values: 2 mg/kg in dry materials, 0.5 mg/kg in liquid materials and 23 mg/kg in scraped-off materials.

Option 3b): Partial revision of the current limit values: reducing the limit values for lead in *all toys and all categories of toy material* in line with the latest scientific knowledge *except those toys made with raw materials naturally contaminated with lead*. This option would imply the following limit values: 2 mg/kg in dry materials, 0.5 mg/kg in liquid materials and 23 mg/kg in scraped-off materials, except for clay, kaolin, pigments and others, where the limits would remain as follows: 13.5 mg/kg in dry materials, 3.4 mg/kg in liquid materials and 160 mg/kg in scraped-off materials.

Option 3c): Revision of the current limit values according to feasibility: reducing the limit values for lead in all toys, in line with what is feasible for the industry according to the current state of the art. This option is based on EWIMA's position paper (Annex VI). This option would imply the following limit values: 9 mg/kg in dry materials, 3.4 mg/kg in liquid materials and 50 mg/kg in scraped-off materials.

Sub-options for mitigating measures:

Option3a) I - Extended transitional period for the Arts and Crafts industry, due to the negative economic impacts expected. This will allow more time for putting in place innovative solutions to replace certain raw materials for example.

Option 3a) II - Extended transitional period for SMEs, for which the costs will be higher than for larger companies.

Option 3a) III - Exemption of SMEs from the new limits.

6. ANALYSIS OF IMPACTS

The impact assessment will focus on economic and social impacts. Those will be assessed in relation to economic operators involved in the manufacturing and marketing of toys, and in relation to children exposed to lead via toys.

Environmental impacts will not be assessed in this impact assessment. Environmental protection per se is not within the objectives of the Toy Safety Directive (TSD). The disposal of toys is governed by a number of existing Directives such as WEEE[71], ROHS[72], the Waste

[71] Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE).

[72] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

Directive[73] and Packaging and Packaging Waste[74]. Other relevant horizontal legislation includes the Batteries Directive[75] and REACH[76]. No direct environmental impacts are thus expected from this initiative under the TSD.

Social impacts

Social impacts in this specific case translate into health impacts and impacts on employment.

Health impacts translate into benefits for children's health. The main benefits expected are:

- ***an increase in health related quality of life*** (measured as quality adjusted life years QALYs, because there would less lead exposure exerting toxicity and causing diseases);
- ***a decrease in health costs due to medical treatments that can be avoided*** (such as drug costs, hospital treatment costs, etc., because there would be less lead exposure which could otherwise exert toxicity and cause diseases);
- ***an increase in productivity*** (because there would be less work days lost due to otherwise poor health condition).

The assessment of the health impacts is based on the assumption that 100% of toys subject to the EU legislation would comply with it. This assumption is based on evidence suggesting that a very small percentage of toys tested fail to meet the current requirements in terms of chemical substances[77].

In addition, this consolidated impact assessment assumes that only a limited range of toys, namely some Arts and Crafts toys referred to further above (finger paints, colour pencil leads and water paint tablets), would exceed the proposed revised lead limit values.

This assessment further takes into account that the children most exposed are those below 3 years of age, because of their pronounced mouthing behaviour. Their number is estimated at 16 million in the EU (see the assumptions in more detail in Annex II and Annex IX).

Impacts on **employment** translate into jobs lost in the toy sector. Higher compliance costs may provide incentives for offshoring production, in order to reduce labour costs. One can assume that these are mainly design and marketing related jobs, as most of the toy production is outsourced. Affected Member States are those where most of the toy companies are established (e.g. Italy, France and Germany).

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73 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.

74 European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

75 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC.

76 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

77 In the last 4 years, RAPEX has only reported 64 toys infringing the migration limits set by Directive. The Joint Market Surveillance Action on TOYS coordinated by PROSAFE in 2006 shows similar results.

Economic impacts

Economic impacts translate into **costs for the economic operators**. These costs are estimated to be higher for SMEs than for big companies as higher production costs combined with a smaller range and scale of product lines increase the unit costs more. Three types of costs are important for the present analysis, according to the consultation's findings:

- ***Raw material costs*** implying the search for higher quality raw materials, which are more rare and thus more expensive. These costs are one-time adaptation costs.

- ***Analytical costs*** imply the costs related to quality control procedures for the production process and final product. This involves the testing of raw materials and ultimately the toy material itself. Testing can be done in house or externally. Such testing may face various difficulties and may become complex and more costly if lead limits are reduced. First, higher quality raw material (i.e. raw materials with a low lead content) does not necessarily ensure lower lead migration in toy material. Second, the toy must meet the migration limits for other chemical elements which may also be present. Natural raw materials may contain up to 90 chemical elements, and the TSD regulates 19 of them. Thus, the raw materials may contain less lead, but still have to comply with limit values for other chemical substances in order for the final toy to be compliant. These analytical costs may imply also training costs to adapt to more complex testing procedures and possibly costs for new testing equipment. Some of these costs, such as new testing equipment and training are one-time adaptation costs. All the others are considered as recurrent costs.

  Concerning the testing costs for lead as such, compliance testing for the reduced limit values for lead proposed in this consolidated impact assessment should be possible already today and thus without additional costs, because the Limit of Quantification (LOQ) for lead according to EN 71-3 is 4 times lower than the lowest limit value proposed;

- ***Developmental costs*** imply the development of toys that can meet the reduced migration limits and retain their technical function. Reformulation of products by use of substitute materials, such as artificial pigments, may impair the quality of use of the product (e.g. the breaking resistance of colouring pens). These costs are considered as being recurrent costs. This is because human and physical capital needs to be replaced over time. Testing costs are fixed production costs per product in the toy catalogue, but they are recurrent over time for quality control and monitoring reasons. Material related costs are variable costs of production.

  Additionally, these costs are putting pressure on budgets for new product development and thus on the sector's capacity to innovate (in terms of the costs of research and development involved).

On the upside, higher health and safety standards offer **opportunities for marketing** toys by referring to enhanced safety for small children (combined with their educative role). This could also be an asset on the global market, where consumer safety regulation is often less strict. According to the results of the public consultation (Annex III), 21% of respondents consider that tightening the limit values for lead will improve their competitive position on the market due to the enhanced quality of their products.

Due to a lack of representative quantitative information on some of the impacts, qualitative statements were the best available data on which the report had to base itself. The quantifications, i.e. a thorough analysis has been carried out for the impacts deemed the most relevant (i.e. health impacts and economic cost impacts). Other impacts, in particular those related to the competitiveness of the toys sector have been acknowledged but could only be underpinned with qualitative statements.

The baseline option

Economic impacts

The baseline option will not imply any additional costs for economic operators, testing laboratories nor national authorities in charge of market surveillance, because no change compared to the current applicable situation is expected. The current situation (namely the new TSD adopted in 2009) generated economic costs amounting to **26 million euro**[78]**.**

Social impacts

a) Health impacts

The baseline option will not bring about any improvement to the protection of children's health. Children will continue to be exposed to lead via toys since they ingest toy material due to their mouthing behaviour. Part of the lead contained in the ingested material will remain in the child's body, and will be absorbed into his/her blood - the bioavailability fraction of lead.

This bioavailability fraction of lead exerts toxicity and causes health consequences such as: kidney damages, hearing problems, behaviour and attention problems and slowed body growth. The related health costs will remain. The baseline option results in a life time total health costs of **€ 9,234 million for ADHD and € 6,526 million for IQ.**[79] No additional health benefits are expected from the baseline option (see Annex I and II for the explanation of calculations).

b) Impacts on employment

The baseline option will not imply any job losses in the toy sector, as no change compared to the current applicable situation is expected. The current situation (namely the new TSD adopted in 2009) was estimated to generate around **200 job losses**, accounting for **2.5 million euro**[80]**. There are, of course, no incremental benefits expected from the baseline scenario.**

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78 The impact of the 2009 revision of the Toy Safety Directive was assessed in 2007: http://ec.europa.eu/enterprise/sectors/toys/files/toys_final_report_30_july_2007_en.pdf . The costs considered were financial costs (administrative, distributional, manufacturing and comitology costs) and other economic costs (enforcement and compliance costs and costs of delay to innovation and in authorisation). Ecorys (Annex VIII) estimated the order of magnitude of the most likely impact of the 2009 revision of the Directive on production of a loss in competitiveness on the domestic and global markets at 26 million euro.

79 http://ec.europa.eu/enterprise/sectors/toys/files/reports-and-studies/final-report-lead-in-toys-matrix-insight_en.pdf

80 http://ec.europa.eu/enterprise/sectors/toys/files/toys_final_report_without_annexes_en.pdf

Table 7 - Summary of monetised costs for the baseline option

Baseline scenario	Total costs (million)	Total benefits (million)	
Economic impacts	26	**ADHD**	**Reduced IQ**
Social impacts	2.5	9,234	6,526

Option 1) Soft law / self-regulatory approach: While a voluntary agreement may present some advantages for economic operators such as manufacturers or distributors, it risks not being the most time efficient, because of its non-binding character. It also raises major uncertainties as to the sector capacity to self-regulate, even if the industry showed an excellent record on compliance, following enforcement activities carried out by Member States. This record on compliance refers to mandatory rules established by legislation. There is no certainty that this compliance record would have been the same in the case of non-mandatory rules. Considering that optional rules, without any enforcement (or sanctions) possibilities, would not be equally respected appears as a logical assumption, especially when most of the toy production is based in China, where we register the highest level of non-compliance. This is supported by the results of the joint market surveillance action results published in 2010, showing that 64% of the toys not complying with the toy safety chemical requirements were coming from China. RAPEX reports also show that the share of Chinese non-compliant toys found on the EU market is very important (e.g., 54% in 2011).

Companies tend to maximise their profit and this does not come hand in hand with fully protecting consumers. Assuming that self-regulation would take place in a certain sector, uncertainties still exist as to the number of economic operators willing to implement the measures, and thus as to the real benefits for children's health. Finally, the health of children is a too important and too sensitive issue to be left unregulated. Thus, this **option** has been **discarded** and will not be assessed further.

Option 2) Labelling of toys containing lead may imply fewer costs for economic operators, as it is less expensive to put in place labelling systems than ensuring compliance with newer and stricter safety rules. Also, evidence shows that information to consumers is a vital part of any product. Labelling increases the consumer's awareness and its ability to make a reasoned choice. It also increases the provider's commercial reputation.

However, research on the way consumers would perceive warnings and other type of information provided is necessary before introducing them. Such research should be done across consumers from all social, economic and cultural groups, in order to test if the level of perception is similar and to judge the usefulness of such warnings or labelling. In the meantime, children would continue to be exposed to a high amount of lead exerting toxicity and resulting in diseases.

It is noteworthy that consumers are not fully aware about the presence of lead in consumers' products and the related health consequences. Therefore labelling or warning on toys only could be misleading and disproportionate for the consumer, as the main exposure to lead comes from food and air, where such labelling is currently neither provided nor foreseen. Parents buying toys would believe that the presence of lead and its health consequences is an issue specifically related to toys, while this is a general problem concerning all exposure sources (food and non-food sources). Additionally, such warnings, if present, would be

reaching the appropriate target to be protected – children – only indirectly, as they would be addressed at parents, not at children. Parents are the ones generally concerned by warnings, as they are the ones to buy toys. However, there is no information currently showing how such labelling would reach parents or care takers, as depicted above.

Additionally, in relation to lead exposure, one cannot fully rely on labelling and warnings recommending adult supervision. Adult supervision even if fully applied, cannot fully prevent lead exposure. Thus, this **option** has been **discarded** and will not be assessed further.

Option 3) Revision of the current limit values for lead

This option will imply additional costs for certain economic operators as well as health benefits the magnitude of which will vary depending on the selected sub-option.

Sectors upstream the toy manufacturing industry in the value chain would not be affected much by policy option 3). The toy industry is a small client for mining companies providing the raw materials. They would not be impacted by policy option 3) because they provide several qualities to large industrial clients across various sectors. Mining firms do not market their materials, such as kaolin and clay, specifically for toys producers. They choose a suitable material from the available product range as price takers. For similar reasons, policy option 3) also hardly affects manufacturers of pigments and colorants.

Testing facilities would see an increase in demand from toy manufacturers as a result of policy option 3). They will need to test different qualities of raw materials and intermediates to assess whether they meet the chemicals related requirements, including those on lead. Testing facilities may need some more sophisticated equipment to reach the required accuracy and reliability, particularly for liquid toys such as paints. Because testing laboratories may need to make additional investments specifically for the analysis of toys, the number of facilities that will continue to offer services to toy manufacturers may decline, and the price level of external testing may increase.

Downstream in the value chain, wholesale and retail providers are not likely to be very much affected. Apart from small and specialized retail shops, retailers offer a wide spectrum of toys and Art and Crafts products.

Consumers may be able to purchase certain products (e.g. colouring pencils), which participate to the development of children's creativity, if these go out of the market. They may shift their expenditure to other toys and games, at least partly.

Option 3a) Complete revision of the current limit values

Economic impacts

Industry would be affected in its capacity to market certain toys, made from naturally lead contaminated raw materials. Industry sees three major **threats to their competitive position** following Option 3a):

- Increase in production costs;
- Reduction in the product range. It would be difficult to continue to market certain toys (e.g. colouring pencils) as they would not meet the safety limits anymore;

– Poorer quality or performance of some toys (e.g. range of colours; abrasion characteristics, etc.).

The costs would be **higher for SMEs,** for which possibly more complex testing procedures and the costly search for suitable raw materials, combined with a smaller range and scale of product lines, increase unit costs more. Furthermore, SMEs are more focused on local markets, rather than exports to third countries. This may limit the marketing advantage of child safety. Next to this, additional marketing and product development costs will put a bigger strain on SMEs resources, being fixed costs.

On the positive side, SMEs stand to benefit more if option 3) lowers competition on the EU market and lose less if competition increases on export markets. This is because SMEs are more focused on local markets rather than export to third countries. SMEs are not less likely to **pass on a cost increase into prices.** This can reflect that they occupy a niche in a monopolistically competitive market. If this niche is mostly local, relatively sheltered from price competition, pass-on of costs is possible. Free entry and high competition may lead to zero profits in the long run. Costs then will be passed on into prices via the mechanism of entry and exit of firms. Prices would need to increase to reflect cost increases; demand would fall and fewer firms would survive. This is supported by the SMEs views expressed during the public consultation[81] - SMEs represented 70% of the respondents to the public consultation.

According to Ecorys (Annex VIII), policy option 3a) results in an estimated impact that would amount to **89 million euro** of production value. The **worst case scenario** would be a **de-facto ban of certain toys** (e.g. colouring pencils) based on the industry declarations that natural materials cannot consistently meet the lead migration limits (at least not without violating some other regulation on chemical elements[82]) and substitutes are not readily available. This potential ban may lead to further loss of production up to a total displacement of these toys in the EU. This would imply a loss of **217 million euro.**

However, the ban of certain toys from the market following option 3a) is not an absolute certainty. Position papers from industry association claim that some toys could be banned from the market following option 3a), but there are currently no means for Member States or the Commission to verify whether this statement is fully reliable. Furthermore, this statement is not fully supported by the results of the public consultation. When replying to questions related to policy option 3a), certain toy manufacturers state that they will be able to continue manufacturing those toys, while others acknowledge not knowing yet if this will be still possible or not.

As regards the marketing of the same products labelled "not toys", suggested by stakeholders, this option is not possible. The directive sets out a clear definition of a toy (products intended, whether or not exclusively, to be use in play by children under 14 years of age). All products entering into this category are de facto toys, and economic operators cannot circumvent this legal classification by labelling them as not being toys.

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81 http://ec.europa.eu/yourvoice/ipm/forms/dispatch?userstate=DisplayPublishedResults&form=leadintoys

82 The presence of lead in toys and other consumer articles is regulated based on content or migration. Raw materials may comply with a content limit but not with a migration limit and vice versa (e.g. a material may have a high content but only a small amount would migrate and vice versa)

Social impacts

a) Health impacts

Option 3a) Complete revision of the current limit values presents the highest benefits for children's health, as the exposure to lead via toys will be reduced by lowering the levels of lead. This reduction of the bioavailability fraction of lead would result in an incremental benefit compared to the baseline option of:

Table 8 - Incremental benefits of option 3a)

Benefits	**Baseline option**		**Option 3a)**	
	ADHD	**IQ**	**ADHD**	**IQ**
Health benefits				
Lifetime treatment cost of ADHD	€ 220	-	€ 200	-
Lifetime treatment cost of mother caring for a child with ADHD	€ 41	-	€ 38	-
Quality of life s (QALY)				
Lifetime health related quality of life quality of life	€ 165	-	€ 150	-
Productivity benefits				
Productivity cost associated with mother caring for a child with ADHD	€ 96	-	€ 87	-
Productivity cost associated with child	€ 55	€ 408	€ 50	€ 334
Unit cost per child	€ 577	€ 408	€ 525	€ 334
Total cost (€m)	€ 9,234	€ 6,526	€ 8,399	€ 5,350
Incremental benefit per child			**€ 52**	**€ 73**
Total Incremental benefit (million)			**€836**	**€1,176**

For details on the health benefits calculations see Table 2 of the relevant study (in Annex I).
The health benefits shown in the table above are 6.5% of the benefits calculated in the relevant study (in Annex I). For explanation see section 3.8 of this consolidated impact assessment.

It is important to stress that it is not possible to aggregate the benefits related to ADHD and those related to the IQ because the relationship between lead and health and non-health impacts is not mutually exclusive. For example, the effect of lead on ADHD could affect the

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.

b) Impact on employment

According to the Ecorys study (Annex VIII), policy option 3a) results in an estimated impact that would amount to **662 lost jobs,** representing **8.5 million euro**. The **worst case scenario** - a **de-facto ban of certain toys** – would amount to **2,112 lost jobs** representing **27.5 million euro.** These estimations are based on wage costs, and the share of personnel in production costs is used to compute wage costs.

Industry challenged this policy option. According to the results of the public consultation and position papers received from industry associations (see Annexes III, V and VI), this option would lead to the potential ban of certain toys from the market. This is because these toys are made with raw materials naturally lead contaminated, and suitable substitutes are not available.

This policy option is however supported by consumer associations, in particular ANEC and BEUC (see Annex VII). While acknowledging that certain toys made with naturally contaminated raw materials (e.g. colouring pencils, finger paints) are important for the development of children's creativity and therefore should also be available in the future, ANEC and BEUC consider that children's safety cannot be compromised.

Table 9 - Summary of monetised costs and benefits for Option 3a)

Option 3a) Complete revision	**Total costs (million €)**	**Total benefits (million €)**	
Economic impacts	89	**ADHD**	**Reduced IQ**
Social impacts	8.5	836	1,176

Sub-option 3a) I - Extended transition period for the art and crafts industry would bring about an unequal situation among economic operators manufacturing and marketing toys made from naturally contaminated raw materials and other economic operators manufacturing and marketing toys. The latter would also be affected by the measures, although not to the same extent as their toys would not risk to be banned from the market, but would not be able to benefit from the transitional period granted. Also, there is no certainty that an extended transitional period would benefit industry for searching and finding any substitutes for naturally contaminated raw materials. Thus, at the expiration of the extended transitional period, art and crafts manufacturers may face the same situation, while children continued to be exposed to a high amount of lead resulting in health risks. These health risks are associated with important impacts on health as shown in the health benefits tables above and below. Thus, this **option** has been **discarded** and will not be assessed further.

Sub-option 3a) II - Extended transitional period for SMEs and Sub-option 3a) III - Exemption of SMEs from the new limits would strongly undermine the benefits generated by the measures. SMEs are predominant in the toy sector. Available statistics show that they

represent 85% of the companies involved in toy manufacturing and marketing. Thus, the measures would apply only to 15% of toys companies, and the intended health benefits would be limited to their market share only. Thus, these **options** have been **discarded** and will not be assessed further.

Option 3b) Partial revision of the current limit values

Economic impacts

The costs for the industry would be less significant than for option 3a), as toys made from naturally contaminated raw materials would be exempted from the revision of the current limits. The industry would be exposed to a tightening of the safety rules on lead, without facing a potential ban of some of their products.

As regards impacts on SMEs, testing facilities wholesale and retail providers and consumers, the same considerations as under policy option 3a) are applicable.

According to the Ecorys study (Annex VIII), policy option 3b) would result in an impact on production which amounts to **41 million euro.**

Social impacts

a) Health impacts

Option 3b) partial revision of the current limit values would bring about partial improvement to children's health, as they will be less exposed to lead via certain categories of toys. However, they will continue to be exposed to toys containing naturally lead contaminated raw materials. These toys are estimated to constitute around 6.5% of the global toys market share. The reduction of the bioavailability fraction of lead would result in incremental benefits compared to the baseline option as given in the table further below.

For the purposes of fine-tuning the calculation of benefits, a sensitivity analysis has been carried out. The two most important variables, the probability and the prevalence rate with regard to ADHD and reduced IQ have been updated. The financial assumptions (e.g. discount rates) have been reviewed and the prices used in the study for monetization proposes (from 2007) adjusted to 2012 prices. This analysis (see Annex IX) aims at providing a range of values of potential benefits according to changes in the prevalence of the illness. The key conclusions are as follows:

- the total benefit resulting from a change in the prevalence of ADHD will amount to 984 million euros for Policy Option 3a), and 935 million euros for Policy Option 3b). When considering a 55% probability of continuing ADHD throughout the adulthood, the benefit generated is 49 million euros.
- the total benefit resulting from a change in the prevalence of reduced IQ will amount to 982 million euros for policy option 3a) and to 936 million euros for policy option 3b). Even a minor decline of reduced IQ (e.g. 0, 80 % would still deliver significant benefits in the scale of 65 million Euros.

Table 10 - Incremental benefit of option 3b)

Benefits	Baseline Option		Option 3b)	
	ADHD	Reduced IQ	ADHD	Reduced IQ
Health cost benefits				
Lifetime treatment cost of ADHD	€ 220	-	€ 201	-
Lifetime treatment cost of mother caring for a child with ADHD	€ 41	-	€ 38	-
Quality of life s (QALY)				
Lifetime health related quality of life quality of life	€ 165	-	€ 151	-
Productivity benefits				
Productivity cost associated with mother caring for a child with ADHD	€ 96	-	€ 87	-
Productivity cost associated with child	€ 55	€ 408	€ 50	€ 338
Unit cost per child	€ 577	€ 408	€ 527	€ 338
Total cost (€m)	€9,234	€6,526	€8,440	€5,410
Incremental benefit per child			**€ 50**	**€ 70**
Total Incremental benefit (million)			**€ 794**	**€ 1,117**

For details on the health benefits calculations see Table 2 of the relevant study (in Annex I).
The health benefits shown in the table above are 6.5% of the benefits calculated in the relevant study (in Annex I). For explanation see section 3.8 of this consolidated impact assessment.

b) Impact on employment

In terms of employment, this option would generate **330 jobs lost**, representing **3.9 million euro**.

Table 11 - Summary of monetised costs and benefits for Option 3b)

Option 3b) Partial revision	Total Costs (million €)	Total Benefits (million €)	
Economic impacts	41	**ADHD**	**Reduced IQ**
Social impacts	3.9	794	1,117

Option 3c) Revision of the current limit values according to feasibility

This option would bring about a situation where health measures are not based on available scientific evidence and appropriate risk assessment methods, but are arbitrarily established on the basis of the Art and Crafts industry's statement of its capacity to find low-lead (or even lead-free) raw materials. Additionally, limiting the measures to what is considered to be feasible at the time of the measures will not trigger any incentive such as looking into better raw materials, substitute materials, innovative products and reducing lead exposure. Furthermore, children's exposure to lead would remain important, generating health risks. These health risks lead to important health impacts. Thus, this **option** has been **discarded** and will not be assessed further.

7. COMPARING THE OPTIONS

Table 12 - Summary of economic and social impacts

Economic and social costs (million €)		**Health benefits[83] (million €)**	
Baseline option			
Production costs	Job losses	ADHD	Reduced IQ
26	2.5	9,234	6,526
Total economic costs: **28.5**		**9,234**	**6,526**
Option 3a) Complete revision			
Production costs	Job losses	ADHD	Reduced IQ
89	8.5	836	1,176
Total economic costs: **97.5**		**836**	**1,176**
Option 3b) Partial revision			
Production costs	Job losses	ADHD	Reduced IQ
41	3.9	794	1,117
Total economic costs: **44.9**		**794**	**1,117**

The table above shows that the current TSD already provides considerable health benefits (some € 9 billion regarding ADHD, some € 6.5 billion regarding the IQ) with regard to the old Toy Safety Directive 88/378/EEC. At the same time the economic and social costs were relatively low (some € 30 million).

Both option 3a) (= revision of the limit values for all toys) and option 3b) (= revision of the limit values for all toys with the exception of the Arts and Crafts toys) provide health benefits

[83] It is not possible to aggregate these savings; aggregating them could lead to double counting of benefits.

which are an order of magnitude higher than the estimated economic costs. Comparing them shows for option 3a) € 42 million higher benefits regarding ADHD, and € 59 million higher benefits regarding IQ. Thus the IQ benefit increase alone is higher than the increase in economic costs, which is € 53 million. The increase in ADHD benefits is € 42 million. This speaks in favour of option 3a).

Further health benefits from strengthened lead limit values for toys may arise from avoiding other health related consequences, as referred to in section 3.3 of this consolidated impact assessment. These benefits have not been quantified here, but their occurrence supports further the choice of option 3a) as the one providing the highest health benefits.

A summary of the options regarding the health benefits, economic costs and effectiveness considerations is given in the table below.

Table 13 – Summary table comparing the options

Option	Health benefits	Economic costs	Effectiveness
Baseline scenario – No change to TSD	Although an improvement in terms of children's health will follow from the implementation of the TSD (compared to the old TSD), children will continue to be exposed to an amount of lead scientifically proven to be harmful.	Since the current limits already entered into force in 2013, the industry would incur no additional costs.	There is a danger of possible fragmentation of the toys market in the Arts & Crafts area, due to some Member States establishing national limits according to the latest scientific findings.
Option 3a) Complete revision of the lead limit values: Adoption of limit values based on a 5% allocation of the $BMDL_{01}$	This option would assure the highest level of health protection of children in the EU.	Although most toy producers would be unaffected, this option would entail some adaptation costs for the affected Arts & Crafts producers.	The most positive balance of health benefits and negative economic impacts. The complete alignment of the lead limits with the latest scientific findings would prevent Member States from taking individual actions which might potentially lead to market fragmentation.
Option 3b): Partial revision of the current lead limit values: Adoption of limit values based on a 5% allocation of the $BMDL_{01}$	This option would assure a high level of health protection of children in the EU.	This option will entail lower costs for the affected industry than Option 3a).	A similarly positive balance of health benefits and negative economic impacts as option 3a). There remains a danger of possible fragmentation of the toys market in the Arts & Crafts area, due to some Member States establishing national limits according to the latest scientific findings.

8. MONITORING AND EVALUATION

No new monitoring and evaluation tools are foreseen specifically for this initiative. The TSD contains an obligation for Member States to send to the Commission a report on the application of the Directive, including its amendments. Such report has to be sent by July 2014, and every five years thereafter. It has to contain an evaluation of the situation concerning the safety of toys and of the effectiveness of the Directive, as well as a presentation of the market surveillance activities performed by each Member State. Member States will in particular report on the following indicators: number of controls performed, number of non-compliant toys found and number and nature of measures taken against economic operators.

Following these reports, the Commission has to draw up and publish a summary of the national reports.

These enforcement actions foreseen by the TSD will apply also to this initiative.