Council of the European Union

Brussels, 13 September 2016
(OR. en)

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MI 568
ENT 167
CONSOM 211
SAN 321
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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	9 September 2016
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2016) 290 final PART 2/2
Subject:	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

Delegations will find attached document SWD(2016) 290 final PART 2/2.

Encl.: SWD(2016) 290 final PART 2/2

EUROPEAN
COMMISSION

Brussels, 9.9.2016
SWD(2016) 290 final

PART 2/2

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

{COM(2016) 560 final}
{SWD(2016) 289 final}

COMMISSION STAFF WORKING DOCUMENT

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ANNEX I

CALCULATION OF BIOAVAILABILITY OF LEAD

Appendices 9.4 and 9.5 to the Matrix Report available under

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

ANNEX II

ECONOMIC ANALYSIS: BEHAVIOURAL AND ATTENTION PROBLEMS (ADHD) MODEL

Appendix 9.6 to the Matrix Report available under

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

ANNEX III

REVISION OF THE LIMIT VALUES FOR LEAD IN TOYS

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

ANNEX IV

INTERVIEWS WITH STAKEHOLDERS - ECORYS

Annex III to the Ecorys Report available under

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

ANNEX V

TIE COMMENTS ON THE POSSIBLE LOWERING OF LEAD MIGRATION LIMITS

At the meeting of the Expert Working Group on Chemicals (8th December 2010), TIE was asked to find out more about the US views on the feasibility of lowering the US total lead limit from 300mg/kg to 100mg/kg. Please find attached a copy of the Toy Industry Association's (TIA) submission to the Consumer Product Safety Commission (CPSC).

TIE would like to take this opportunity to re-iterate that the EU toy industry association (TIE) takes the view that the existing EU approach that sets "heavy element" restrictions based upon migration should be maintained. Migration is a measure of exposure and hence measures the risk posed. Setting restrictions based upon total concentration is unscientific and deals only with the intrinsic hazard of a substance and does not directly measure risk.

The experts of the working group on chemicals have calculated revised migration limits for lead based upon bench mark dose data in the EFSA report on lead in food[1]. These revised limits for migration of lead from toy materials are as follows:

- 22mg/kg for scraped-off
- 2mg/kg for dry, brittle powder-like, pliable
- 0.5mg/kg for liquids, pastes

TIE requests that the Commission discusses this approach with all Member States and stakeholders and verify whether it is scientifically valid because it will result in the banning of important toy types such as finger paints, paints, crayons, inks etc.

Such toys would be banned because certain raw materials cannot be obtained in a sufficiently pure state owing to naturally occurring background traces of lead.

TIE has consulted with members on the impact of the revised lead limits and the wider effects are summarized below.

Ban of liquid toys such as liquid paints, poster paints, finger paints, crayons.

A 0.5mg/kg limit will mean that these toys would fail the lead migration test because critical raw materials like kaolin and titanium dioxide inevitably have naturally occurring traces of lead.

For chalks, powder paints and crayons that also use the same raw materials as paints, there will be problems satisfying the proposed limit of 2 mg/kg and these toys could also be banned.

Ban on the use of alloys like brass

[1] Scientific Opinion on Lead in Food, EFSA Journal 2010; 8(4):1570

Materials like the metal brass will be potentially banned from use. From EN71-3 testing data already available and information provided in the TIA submission to the CPSC, a 22mg/kg limit for scraped-off materials will be exceeded by some metal alloys that have a low level of lead such as brass. It is possible to find brass in toys in bushings, washers, screws, ferrules on tips of writing instruments etc.

Impractical to use certain recycled materials

The use of recycled plastics and recycled metals would be risky in that it is difficult to obtain sufficiently pure raw materials that will reliably meet a 22mg/kg limit.

Exposure of lead from food and toys

From information sent to the Expert Working Group on Chemicals, we can compare toys with drinking water (WHO proposed limit 10µg/L) and calculate that:

- For a child less than 1 year old it will drink on average 467 ml drinking water per day (US figures) giving rise to a potential total lead consumption of **4.7µg** (467ml x 10µg/L)

- In the case of a liquid toy, we assume 400mg ingested per day (RIVM study). Using the proposed migration limit of 0.5mg/kg we can calculate a potential total lead exposure of **0.2 µg** (400 mg x 0.5 mg/kg):

We can conclude that the protection regime for toys is over 20 times stricter than for drinking water.

Poorer Reliability of laboratory testing

Although there is not a problem detecting 0.5mg/kg lead in "clean" liquids using modern analytical equipment, the situation is different when the liquid is a paint and has to be tested using the EN71-3 migration test. As the maximum permitted limits are lowered the EN71-3 migration test method will inevitably suffer from even more inter-laboratory variation than it does at present with today's limits. There is good evidence to show that laboratories (including Notified Bodies) are struggling to get good inter-laboratory agreement when applying EN71-3. Even lower limits will make the problem worse and give rise to legal uncertainty as to the compliance of a toy or material.

Lower limits for lead will mean that analytical equipment like ICP-MS and AAS with graphite furnace will be required by test houses. This is expensive technology and not straight forward to operate, again exacerbating the issue mentioned above.

There are significant downsides to obliging test houses to re-equip:

1) Cost per test will increase as labs seek to recoup their investment

2) Fewer test houses will offer this testing, so prices may rise further

3) Factories that possess in-house laboratories will not be able to justify this level of investment in equipment and staff. In this case the monitoring they perform will be to higher limits and so offer no legal certainty of conformity. The assurance on conformity with the lower limits will have to be through a test conducted at a suitably equipped test house.

It will also be the case that XRF screen testing will be less useful because it will more frequently detect lead above the lower thresholds, which will necessitate laboratory testing. This questions the usefulness of the screen test.

Materials believed to be unaffected

Non-metals, surface coatings, virgin plastics and textiles, should be capable of meeting a 22mg/kg limit.

Conclusion

In conclusion, TIE believes the approach that uses a benchmark dose level from the EFSA report on lead in foods, should be reconsidered. The very low limits for liquid toys and powder-like materials will ban toys such as finger paints, poster paints, liquid paints and powder-like materials such as powder paints, crayons and chalks.

Considering that the proposed restrictions on lead are much more stringent than for lead in drinking water, TIE believes the proposed restrictions go too far and are wholly disproportionate to the implied risk.

The proposal to lower the lead limit for scraped-off materials to 22mg/kg will preclude the use of some materials but the wider impact will be negligible.

ANNEX VI

STATEMENT FROM EWIMA CONCERNING EUROPEAN DIRECTIVE 2009/48/EC:

FURTHER REDUCTION OF LEAD MIGRATION LIMITS

The manufacturers of art & craft materials and other colouring products classified as toys are deeply concerned that again a tremendous reduction in lead migration limits is discussed on a European level - especially concerning dry, brittle, pliable materials/toys and liquid materials/toys.

It is already a highly sophisticated task for manufacturers of the writing instruments industry to find adequate natural or man-made materials and to reformulate their products to ensure that art & craft materials and colouring products classified as toys comply with the current migration limits for lead of 13.5 mg/kg for dry, brittle or pliable materials / toys and 3.4 mg/kg for liquid materials / toys as well as with the respective migration limit of any other element.

In leads of coloured pencils, solid materials intended to leave a trace (e.g. chalks, wax crayons, pastels) or in water paint tablets, extenders are necessary for physical and mechanical properties, e.g. stability, breaking resistance and smooth abrasion without scrapping (up to 80% of a lead/solid painting media). Extenders are also used in viscous paints, e.g. finger paints (EN 71-7, Annex C).

Consistently in the whole industry, Kaolin (synonym: china clay, porcelain clay) - a natural product - is used as extender. Alternative materials are also from natural sources, e.g. chalkstone, talc or other grinded rock materials.

Several quality levels of Kaolin for industrial or consumer products from different mining resorts all over the world are available on the market.

Simple technical Kaolin qualities are not suitable for a use in toys (total lead content up to 4000 mg/kg), because the toys would not comply with legal requirements in Europe or in the US. Due to the natural variability in lead content from a natural material, suppliers refrain from providing confirmation / certification concerning total lead limits or migration limits.

Commonly, the element contamination of materials is delivered as total lead content by suppliers depending on the mining site:

- Dedicated qualities of Kaolin used in toys ranges between 70 mg/kg and 100 mg/kg lead.
- The lead content of Kaolin ("good quality") is in a range of 40 - 50 mg/kg lead.
- The lead content of Kaolin, marketed as "low in lead" or "very low in lead" is described as < 25 mg/kg.

Other suitable materials from natural sources, e.g. processed titanium dioxide (e.g. total lead content 60 mg/kg) or iron oxide - a widespread used pigment - are also containing lead.

It is likely that a substantial "dilution effect" concerning lead can not be expected due to the high amounts of extenders and pigments in the products.

Results of element migration analyses done by independent laboratories or by writing instruments manufacturers:

– Due to third party / notified body certificates for materials or finished products, lead migration is often described as <2 mg/kg or < 5 mg/kg (according to EN 71-3).

  However, results based on the detection limits of current analytical methods are neither helpful for a manufacturer's assessment concerning marketability of his product nor it is helpful for the current discussion.

– Current studies of writing instruments manufacturers on lead migration from several qualities of Kaolin used in toys result in 2 mg/kg lead to 16 mg/kg lead (see Table, p3).

Thereby not only the element content vary from batch to batch, also element's migration oscillate in a considerable range. A correlation between total lead content and lead migration can not be made. Natural material "low" or "very low" in lead do not necessarily lead to low or very low lead migration!

Migration of lead from a common talc is analysed to be 3 mg/kg.

Considering the analytical results, art & craft materials as well as colouring products are invariably unable to comply with the planned lead migration limits for dry, brittle or pliable materials of 2 mg/kg or the planned limits for liquid materials of 0.5 mg/kg.

As already mentioned in earlier statements of EWIMA (European Writing Instruments Manufacturers Association), exposition of certain elements including lead derive from natural sources in considerable amounts, due to their natural widespread occurrence on earth.

The natural "contamination" of materials or substances like kaolin from natural sources is technically unavoidable.

Referring to art & craft materials and other colouring products, alternative materials without lead content are not available since they are also from natural sources. Up-dated or innovative technical processes solving the problems are not technically feasible in the medium term.

The writing instruments manufacturers realize much to their surprise that the planned migration limits for liquid materials (when measured directly in the liquid) are at a similar level as lead contamination in foodstuff (see European Regulation (EC) No. 1881/2006).

A comparison of art & craft materials or other colouring products classified as toys with foodstuff in terms of risk exposure seems to be inadequate!

Art & craft materials and other colouring products classified as toys are not intended to be regularly consumed. They are neither foodstuff, nor does any information point on a numerous accidental consumption of such products by children.

The proposed restrictive migration limit is unjustified regarding intended use and foreseeable exposure of children. An explicit accidental consumption would be attributed to the same level as a long life daily consumption by the diet.

With respect to the proposed threshold limit values for lead, the manufacturers expect a massive, very likely restrictive impact on art & craft materials and colouring products currently classified as toys which are established in the market. As the proposed limits could not be matched for the foreseeable future, these well-established products stand no chance to be marketed as toys any longer.

In summary, the writing instruments manufacturers would like to suggest the following migration limit values for materials from natural sources - taking into account the natural variability in lead content and lead migration inside the mining site:

– dry, brittle, pliable materials: 9.0 mg/kg lead

– liquid materials: 3.4 mg/kg lead

– scraped off materials: 50 mg/kg lead

Table: Examples of lead migration analyses and total lead content analyses from natural sources (independent laboratories, writing instruments manufacturers):

Kaolin/Clay	**Natural Mineral Deposit (Country)**	**Lead – Migration according to EN71-3 (mg/kg)**	**Lead – Total Content (mg/kg)**
Kaolin	D	3 – 8	29 – 58
Kaolin	E	2 – 3	54 – 88
Kaolin	NZ	16	<25
Kaolin	TR	4	91
Clay (grinded)	CN	4	42

ANNEX VII

ANEC/BEUC POSITION ON REDUCING CHILDREN'S EXPOSURE TO LEAD FROM TOYS

Introduction

The European Commission is currently discussing a revision of the limit values for lead in toys. With regard to drawing material, four options are under consideration: 1) no policy change, 2) a self regulatory approach, 3) a partial revision of current limit values which would exempt lead containing raw materials (clay, kaolin or pigments) used in coloured pencils, chalks, wax crayons, pastels or in water paint tablets and 4) a complete revision of current limits reducing the limits for lead in all categories of toys and toy materials.

The Commission is arguing that option 4 which is most feasible for children's health would lead to a ban of coloured pencils, chalks, wax crayons, pastels or in water paint tablets as they cannot meet higher standards. The industry is claiming more stringent lead values for dry, brittle, pliable materials and for liquid materials will make disappear many drawing materials from the market.

In spring, the Commission carried out a public consultation which was only addressed to economic operators[1]. In parallel, the Commission is looking into the health related effects.

In this position paper, ANEC and BEUC reply to an invitation from the Commission to contribute our views primarily with regard to the specific sub-question of lead exposure stemming from drawing materials such as coloured crayons.

The exposure of children to lead needs successfully to be lowered

ANEC and BEUC criticized for many years that the limit values for heavy metals including for lead in the Toy Safety Directive are inappropriate to protect the safety of consumers.

The exposure of children to even low levels of lead is concern as it is neurotoxic, accumulates in the body and may be an endocrine disrupter. The exposure to lead even at very low levels is thus associated with a number of potential very severe chronic and lifelong negative health consequences such as:

– Damaging children's nervous system and brain development;

– Causing hyperactivity;

– Leading to learning disorders.

As lead is toxic, and children are exposed to it through various channels such as the inhalation and ingestion through food and drinking water but also toys, minimizing exposure to levels as low as reasonably achievable (ALARA principle) is urgently needed.

The European Food Safety Agency has pointed out that the current TDI is inadequate as exposure of children to lead through food consumption is already too high to exclude negative health effects. Moreover, EFSA pointed out that it is not possible to establish a safe

limit value for lead for the critical endpoints such as neurotoxicity and the endocrine system. Hence, a TWI (Tolerable Weekly Intake) or a TDI (Tolerable Daily Intake) cannot be set.

To protect better children's health, we call for a massive reduction of current limit values by a factor of 7 based on a 5% allocation2.

Coloured pens and paints are important for children's development but should not jeopardize children's health

Coloured pencils, wax crayons and other drawing materials can play an important role for the development of children's creativity. Therefore we are, of course, in favour of ensuring that those articles can be made available to children also in future presumed they can be made in such a way that they do not jeopardize children's health. A general exemption of drawing material from lower lead levels for toys is not the right way forward. If they cannot be made safe, it could also mean that they ultimately need to be banned.

Manufacturers are requested to make data available and for these data to be checked by independent parties

We doubt based on manufacturer's replies and on product test results from our member organisations that all those drawing materials would disappear from the market as they would be unable to meet stringent threshold limits for lead. Just half of the respondents (43) to the public consultation consider that certain toys have to be banned whilst 33 do not know and 5 do not expect this would be needed.

Furthermore, the results of the Commission public consultation shows that many manufacturers do use raw materials containing lead (39), little less manufacturers (28) do not make use of such raw materials and a considerable number of respondents does not know (14) if lead is present. This finding can be confirmed by several tests on toys of ANEC and/ or BEUC member organizations that have been carried out in recent years. In all tests there are toys with large differences concerning the content and release of hazardous chemicals including on lead3.

Manufacturers who claim that they cannot produce lead free drawing materials should make relevant information available e.g. to the sub-working group on chemicals in toys for an in-depth discussion and consideration.

Likewise, information should be made available to stakeholder concerning the possible economic impacts and development of prices for consumers. The public consultation of economic operators does not give a clear picture. Although a majority (63 out of 81) expect an increase in costs, 8 expect no increase in costs and 10 respondents do not know.

We recommend that the Commission carries out an independent assessment of the situation and not only to rely on claims of manufacturers.

Our recommendations

While we see drawing materials to be important for the development of children's creativity and therefore should also be available in the future, safety cannot be compromised and in case those items cannot be made safe, they ultimately might need to be taken off the market.

The EU Commission should:

– Favour option 4, i.e. carry out a complete revision of current limits reducing the limits for lead in all categories of toys and toy materials.

– Carry out an independent assessment of the situation as we cannot rely on the accuracy of manufacturer's replies to a public consultation when deciding on the level of safety for children.

ANEC and BEUC call for a massive reduction of current limit values of lead by a factor of 7 based on a 5% allocation.

Endnotes

The results can be found here:

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

– ANEC position paper on SCHER opinion: Evaluation of the migration limits for chemical elements in toys (July 2010), ANEC-CHILD-2010-G-093, http://www.anec.eu/attachments/ANEC-CHILD-2010-G-093.pdf

– The Swiss FRC tested in 2011 carnival make-up for children including coloured crayons. Some of the products were free of lead and one contained up to 3.8 mg/kg lead. German Stiftung Warentest tested colouring pencils, wax crayons and other drawing materials with regard to the release of heavy metals. No pencil contained lead in core and lacquer (threshold 10 mg/kg Pb). With regard to water paint tablets, 10 out of 11 contained no lead but one contained 270mg/kg Pb.

ANNEX VIII

COMPETITIVENESS PROOFING TOY RELATED INDUSTRY IMPACT OF NEW LEAD MIGRATION LIMITS ON THE COMPETITIVENESS OF EUROPEAN MANUFACTURERS

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

ANNEX IX

SENSITIVITY ANALYSIS

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1. INTRODUCTION

1.1 Scope of the Analysis

The present appendix aims at reviewing the economic analysis section of the Matrix study and updating with regard to the following aspects:

- Reviewing the financial assumptions (e.g. discount rates) and adjusting the prices used in the study for monetization proposes to the 2012 prices. The prices included in the study were the 2007 prices and therefore needed to be adjusted.

- Providing a sensitivity analysis for changes in the prevalence rate with regard to ADHD and IQ. The critical parameters for the financial analysis are the incidence rates and the prices assumed for the medical costs and productivity losses of mothers, children and adults.

From the economic point of view, the relevant parameter for sensitivity analysis is the *prevalence of the illness*. The current appendix aims at providing a range of values of potential benefits according to changes in the prevalence of the illness. For simulation proposes, the present appendix

1.2 Key conclusions

Considering (a) the adjusted values of the cost used for monetization and (b) the change in the discount rate, the total benefit resulting from a change in prevalence of **ADHD** will amount to:

- 15,134 million euros for Policy Option 1, equivalent to a per capita benefit per child of 931 euros

- 14,377 million euros for Policy Option2, equivalent to a per capita benefit per child of 884 euros.

- The changes in prevalence of ADHD of 0.02282%, at a 55% probability of continuing ADHD throughout the adulthood (as assumed by the Matrix Study), will generate a benefit of 757 million euros.

The sensitivity analysis concerning the IQ sub-model shows that:

- A change in IQ from 0.0970 to 0.1020 due to Policy options 1 and 2, assuming a 2% decrease in earnings for every one unit decrease in IQ would lead to benefits between 14.4 billion euros to 15.1 billion euros.

- even minor changes in IQ (0.0170) and even if we consider only a 0,80% decline in earnings due to a decrease in IQ it would still deliver significant returns in the scale of 1 billion Euros.

2. PREVALENCE OF ADHD - SENSITIVITY ANALYSIS OF SUB-MODEL

2.1 Financial assumptions

Table 0-1 Discount rate

Parameter	Assumption
Discount rate =	**4.00%**

Soure: Impact Assessment Guidelines

The IA support study considers a discount rate of 3.5%, while de IA guidelines recommend the use of a 4% discount rate which, will from this point of view reduce the overall size of the estimated benefits.

Table 0-2 Inflation: EU 27 Price index 2007=100 for 2005-2011

	2005	2006	2007	2008	2009	2010	2011
European Union (27 countries) 2005= 100	100.00	102.31	104.73	108.56	109.63	111.91	115.38
European Union (27 countries) 2007= 100	95%	98%	100%	104%	105%	107%	110%

Source: Eurostat

We have maintained the inflation rate of 2,7% as proposed by the study for the period 2012 onwards.

Table 0-3 Inflation Forecast 2012 onwards

	2012 onwards
Inflation forecast =	**2.70%**

2.2 Assumptions on the Prevalence of ADHD

Table 0-4 Assumptions on the Prevalence of ADHD

Prevalence of ADHD 0.2 ug/dl – 0.8 ug/dl	**3.40%**
Average prevalence of ADHD =	**5.29%**
% of children at 0.2-0.8 ug/dl =	**20.20%**
% of children at 0.8-1.3 ug/dl =	**29.60%**
% of children > 1.3 ug/dl=	**50.20%**
Relative risk of ADHD 0.8 ug/dl to 1.3 ug/dl =	**1.49**
Relative risk of ADHD > 1.3 ug/dl =	**1.82**
Prevalence of ADHD 0.8 ug/dl – 1.3 ug/dl	**5.06%**
Prevalence of ADHD 0.2 ug/dl – > 1.3 ug/dl	**6.18%**
Unit prevalence of ADHD change per 0.01 change in ug/dl (for > 1.3 ug/dl)	**0.02282%**
(4ug/dl-1.3ug/dl)/0.1ug/dl)+1)	271
Probability childhood ADHD continues into adulthood	**55.00%**
Lifetime QALY loss associated with ADHD in adulthood Annual QALY loss =	**0.070**
Lifetime QALY loss associated with ADHD in childhood Annual QALY loss =	**0.09**

Source: Matrix Study

Table 0-5 Change in prevalence of ADHD due to Policy Options

	Policy Option 0	**Policy Option 1**	**Policy Option 2**
µg lead/day	1.35	0.40	
Blood lead level in children	3.50	3.30	3.31
Decrease in blood lead level associated with		0.20	0.19
Change in prevalence of ADHD due to		**0.4564%**	**0.43%**

Source: Matrix Study

We have maintained all the assumptions presented in the study concerning the average prevalence, a risk of prevalence, and unit prevalence of ADHD change per 0.01 change in ug/dl (for > 1.3 ug/dl), which is the result of the use of the US EPA Integrated Exposure Uptake BioKinetic (IEUBK) model and amounts to 0.02282%. As a next step we will present and demonstrate the cost associated with the illness and the underlining cash flows to measure the total costs for the society of the changes in prevalence. After obtaining those data

we will be able to present the simulation of the impact on costs depending on the changes in the ADHD prevalence rates.

2.3 Assumptions Treatment costs and productivity loss

Table 0-6 Assumptions Treatment costs and productivity loss 2007-2012

	2007	2008	2009	2010	2011	2012
Annual treatment cost of ADHD - Euros =	1,340	1389	1454	1554	1712	1758
Annual treatment cost of a mother caring for a child with ADHD - Euros =	832	862	903	965	1063	1091
Annual productivity loss of a mother caring for a child with ADHD =	1,932	2003	2096	2240	2468	2534
Annual cost per worker	**4,221**	**4,375**	**4,580**	**4,894**	**5,392**	**5,537**
Annual number of work days lost Euros =	33.5	33.5	33.5	33.5	33.5	33.5
Cost per work day lost = €	126	131	137	146	161	165
Monetary value of a QALY	23,929	24804	25965	27745	30566	31391
1 year - 3 years	15270	15448	15629	15870	16057	16490
Productivity loss of adult ADHD patient	€ 19,994	20725	21695	23182	25540	26229

Source: Matrix study / DG ENTR Calculations

The reference values for 2007 were adjusted to 2012 prices using the assumptions presented in section 2.1 (Financial assumptions.)

2.3.1 Lifetime treatment costs of ADHD for child

The annual treatment cost of ADHD in euros at 2012 price levels is estimated to be of 1 758 per year. Considering a period of 62 year of average, the estimated lifetime treatment costs of ADHD for each child would be in the range of 76 963 euros (using as explained above a 4% discount rate and an inflation rate of 2.7%).

Table 0-7 - Lifetime treatment costs of ADHD for child

	Annual treatment cost of ADHD - Euros	discount factor	CF -Discounted annual treatment costs	NPV = Σ Discounted annual treatment costs
0	1758	1.00	1758	1758
1	1805	0.96	1736	3494
2	1854	0.92	1714	5208
3	1904	0.89	1693	6901
4	1956	0.85	1672	8572
5	2008	0.82	1651	10223

	Annual treatment cost of ADHD - Euros	discount factor	CF -Discounted annual treatment costs	NPV = Σ Discounted annual treatment costs
6	2063	0.79	1630	11853
7	2118	0.76	1610	13463
8	2175	0.73	1590	15053
9	2234	0.70	1570	16622
10	2295	0.68	1550	18172
11	2356	0.65	1531	19703
12	2420	0.62	1512	21215
13	2485	0.60	1493	22707
14	2553	0.58	1474	24181
15	2621	0.56	1456	25637
16	2692	0.53	1437	27074
17	2765	0.51	1419	28494
18	2840	0.49	1402	29896
19	2916	0.47	1384	31280
20	2995	0.46	1367	32647
21	3076	0.44	1350	33996
22	3159	0.42	1333	35329
23	3244	0.41	1316	36646
24	3332	0.39	1300	37945
25	3422	0.38	1284	39229
26	3514	0.36	1268	40497
27	3609	0.35	1252	41748
28	3706	0.33	1236	42984
29	3807	0.32	1221	44205
30	3909	0.31	1205	45410
31	4015	0.30	1190	46600
32	4123	0.29	1175	47776
33	4235	0.27	1161	48936
34	4349	0.26	1146	50083
35	4466	0.25	1132	51214
36	4587	0.24	1118	52332

	Annual treatment cost of ADHD - Euros	discount factor	CF -Discounted annual treatment costs	NPV = Σ Discounted annual treatment costs
37	4711	0.23	1104	53436
38	4838	0.23	1090	54526
39	4969	0.22	1076	55602
40	5103	0.21	1063	56665
41	5241	0.20	1050	57715
42	5382	0.19	1036	58751
43	5527	0.19	1023	59775
44	5677	0.18	1011	60785
45	5830	0.17	998	61783
46	5987	0.16	986	62769
47	6149	0.16	973	63742
48	6315	0.15	961	64703
49	6485	0.15	949	65652
50	6661	0.14	937	66590
51	6840	0.14	926	67515
52	7025	0.13	914	68429
53	7215	0.13	903	69332
54	7410	0.12	891	70223
55	7610	0.12	880	71103
56	7815	0.11	869	71972
57	8026	0.11	858	72830
58	8243	0.10	848	73678
59	8465	0.10	837	74515
60	8694	0.10	826	75341
61	8929	0.09	816	76157
62	**9170**	**0.09**	**806**	**76963**

Source: Matrix study and DG ENTR Calculations

2.3.2 Lifetime treatment costs of mother caring for child with ADHD

After adjusting the 2007 reference value of annual treatment cost of a mother caring for a child with ADHD of 832 euros per year to 2012 prices and considering a care period of 15

years, we arrive at a lifetime treatment costs of mother caring for child with ADHD of 15 918 euros per child.

Table 0-8 - Lifetime treatment costs of mother caring for child with ADHD

	Discount factor	Annual treatment cost of ADHD - Euros	CF - Discounted annual treatment costs	NPV = Σ Discounted annual treatment costs
0	1.00	1091	1091	1091
1	0.96	1121	1078	2169
2	0.92	1151	1064	3234
3	0.89	1182	1051	4285
4	0.85	1214	1038	5323
5	0.82	1247	1025	6347
6	0.79	1281	1012	7360
7	0.76	1315	999	8359
8	0.73	1351	987	9346
9	0.70	1387	975	10321
10	0.68	1425	962	11283
11	0.65	1463	950	12234
12	0.62	1503	939	13172
13	0.60	1543	927	14099
14	0.58	1585	915	15014
15	0.56	**1628**	**904**	**15918**

Source: Matrix Study, DG ENTR Calculations

2.3.3 Productivity loss of mother caring for child with ADHD

Annual productivity loss of a mother caring for a child with ADHD was estimated in 2007 at 1 932 euros which at 2012 prices represent an estimated loss of productivity amounting to 2 534 euros and during a 15 years period will represent a total loss of 36.963 euros per child.

Table 0-9 Productivity loss of mother caring for child with ADHD

	Discount factor	Annual productivity loss of a mother- Euros	CF -Discounted annual productivity loss of a mother	NPV = Σ Discounted annual productivity loss of a mother

	Discount factor	Annual productivity loss of a mother- Euros	CF -Discounted annual productivity loss of a mother	NPV = Σ Discounted annual productivity loss of a mother
0	1.00	2534	2534	2534
1	0.96	2603	2503	5037
2	0.92	2673	2472	7509
3	0.89	2745	2441	9949
4	0.85	2820	2410	12360
5	0.82	2896	2380	14740
6	0.79	2974	2350	17090
7	0.76	3054	2321	19411
8	0.73	3137	2292	21703
9	0.70	3221	2263	23966
10	0.68	3308	2235	26201
11	0.65	3398	2207	28408
12	0.62	3489	2179	30587
13	0.60	3584	2152	32739
14	0.58	3680	2125	34865
15	**0.56**	**3780**	**2099**	**36963**

Source: Matrix Study, DG ENTR Calculations

2.3.4 Productivity loss of adult ADHD patient

Table 0-10; Productivity loss of adult ADHD patient – 2007-12 Euros

	2007	2008	2009	2010	2011	2012
Productivity loss of adult ADHD patient	€ 19,994	20725	21695	23182	25540	26229

Source: Matrix Study, DG ENTR Calculations

The estimated value of the productivity loss of an adult ADHD patient is estimated to be of 26 229 euros at 2012 prices.

2.3.5 Lifetime QALY loss associated with ADHD in childhood and adulthood

Table 0-11 Monetary value of a QALY 2007-12

	2007	2008	2009	2010	2011	2012
Monetary value of a QALY	23,929	24804	25965	27745	30566	31391

Source: Matrix Study, DG ENTR Calculations

Table 0-12 Lifetime QALY loss associated with ADHD in childhood and adulthood

		Annual QALY loss associated with ADHD in childhood = 0.07			Annual QALY loss associated with ADHD in adulthood= 0.09		
	discount factor	Annual QALY loss	CF - Discounted Annual QALY loss	NPV = Σ Discounted Annual QALY loss	Annual QALY loss	CF -Discounted Annual QALY loss	NPV = Σ Discounted Annual QALY loss
0	1.00	0.0700	0.0700	0.0700	0	0.0000	0.0000
1	0.96	0.0700	0.0673	0.1373	0	0.0000	0.0000
2	0.92	0.0700	0.0647	0.2020	0	0.0000	0.0000
3	0.89	0.0700	0.0622	0.2643	0	0.0000	0.0000
4	0.85	0.0700	0.0598	0.3241	0	0.0000	0.0000
5	0.82	0.0700	0.0575	0.3816	0	0.0000	0.0000
6	0.79	0.0700	0.0553	0.4369	0	0.0000	0.0000
7	0.76	0.0700	0.0532	0.4901	0	0.0000	0.0000
8	0.73	0.0700	0.0511	0.5413	0	0.0000	0.0000
9	0.70	0.0700	0.0492	0.5905	0	0.0000	0.0000
10	0.68	0.0700	0.0473	0.6378	0	0.0000	0.0000
11	0.65	0.0700	0.0455	0.6832	0	0.0000	0.0000
12	0.62	0.0700	0.0437	0.7270	0	0.0000	0.0000
13	0.60	0.0700	0.0420	0.7690	0	0.0000	0.0000
14	0.58	0.0700	0.0404	0.8094	0	0.0000	0.0000
15	**0.56**	**0.0700**	**0.0389**	0.8483	0	0.0000	0.0000
16	0.53	0.0700	0.0374	0.8857	0.09	0.0481	0.0481
17	0.51	0.0700	0.0359	0.9216	0.09	0.0462	0.0943
18	0.49	0.0700	0.0346	0.9562	0.09	0.0444	0.1387
19	0.47	0.0700	0.0332	0.9894	0.09	0.0427	0.1814
20	0.46	0.0700	0.0319	1.0213	0.09	0.0411	0.2225
21	0.44	0.0700	0.0307	1.0520	0.09	0.0395	0.2620
22	0.42	0.0700	0.0295	1.0816	0.09	0.0380	0.2999
23	0.41	0.0700	0.0284	1.1100	0.09	0.0365	0.3365
24	0.39	0.0700	0.0273	1.1373	0.09	0.0351	0.3716
25	0.38	0.0700	0.0263	1.1635	0.09	0.0338	0.4053

		Annual QALY loss associated with ADHD in childhood = 0.07			Annual QALY loss associated with ADHD in adulthood= 0.09		
	discount factor	Annual QALY loss	CF - Discounted Annual QALY loss	NPV = Σ Discounted Annual QALY loss	Annual QALY loss	CF -Discounted Annual QALY loss	NPV = Σ Discounted Annual QALY loss
26	0.36	0.0700	0.0252	1.1888	0.09	0.0325	0.4378
27	0.35	0.0700	0.0243	1.2131	0.09	0.0312	0.4690
28	0.33	0.0700	0.0233	1.2364	0.09	0.0300	0.4990
29	0.32	0.0700	0.0224	1.2589	0.09	0.0289	0.5279
30	0.31	0.0700	0.0216	1.2804	0.09	0.0277	0.5556
31	0.30	0.0700	0.0208	1.3012	0.09	0.0267	0.5823
32	0.29	0.0700	0.0200	1.3211	0.09	0.0257	0.6080
33	0.27	0.0700	0.0192	1.3403	0.09	0.0247	0.6326
34	0.26	0.0700	0.0184	1.3588	0.09	0.0237	0.6564
35	0.25	0.0700	0.0177	1.3765	0.09	0.0228	0.6792
36	0.24	0.0700	0.0171	1.3936	0.09	0.0219	0.7011
37	0.23	0.0700	0.0164	1.4100	0.09	0.0211	0.7222
38	0.23	0.0700	0.0158	1.4258	0.09	0.0203	0.7425
39	0.22	0.0700	0.0152	1.4409	0.09	0.0195	0.7619
40	0.21	0.0700	0.0146	1.4555	0.09	0.0187	0.7807
41	0.20	0.0700	0.0140	1.4695	0.09	0.0180	0.7987
42	0.19	0.0700	0.0135	1.4830	0.09	0.0173	0.8161
43	0.19	0.0700	0.0130	1.4960	0.09	0.0167	0.8327
44	0.18	0.0700	0.0125	1.5084	0.09	0.0160	0.8487
45	0.17	0.0700	0.0120	1.5204	0.09	0.0154	0.8641
46	0.16	0.0700	0.0115	1.5319	0.09	0.0148	0.8790
47	0.16	0.0700	0.0111	1.5430	0.09	0.0142	0.8932
48	0.15	0.0700	0.0107	1.5537	0.09	0.0137	0.9069
49	0.15	0.0700	0.0102	1.5639	0.09	0.0132	0.9201
50	0.14	0.0700	0.0098	1.5738	0.09	0.0127	0.9327
51	0.14	0.0700	0.0095	1.5832	0.09	0.0122	0.9449
52	0.13	0.0700	0.0091	1.5923	0.09	0.0117	0.9566
53	0.13	0.0700	0.0088	1.6011	0.09	0.0113	0.9679
54	0.12	0.0700	0.0084	1.6095	0.09	0.0108	0.9787
55	0.12	0.0700	0.0081	1.6176	0.09	0.0104	0.9891
56	0.11	0.0700	0.0078	1.6254	0.09	0.0100	0.9991
57	0.11	0.0700	0.0075	1.6329	0.09	0.0096	1.0088
58	0.10	0.0700	0.0072	1.6401	0.09	0.0093	1.0180
59	0.10	0.0700	0.0069	1.6470	0.09	0.0089	1.0269
60	0.10	0.0700	0.0067	1.6536	0.09	0.0086	1.0355
61	0.09	0.0700	0.0064	1.6600	0.09	0.0082	1.0437

		Annual QALY loss associated with ADHD in childhood = 0.07			Annual QALY loss associated with ADHD in adulthood= 0.09		
	discount factor	Annual QALY loss	CF - Discounted Annual QALY loss	NPV = Σ Discounted Annual QALY loss	Annual QALY loss	CF -Discounted Annual QALY loss	NPV = Σ Discounted Annual QALY loss
62	**0.09**	0.0700	0.0062	1.6662	**0.09**	**0.0079**	**1.0516**

Source: Matrix Study, DG ENTR Calculations

2.4 Number of children aged 1 - 3 years

Table 0-13 : Evolution in the number of children aged 1 year - 3 years 2007-2012

	2007	2008	2009	2010	2011	2012F a)
Number of children aged 1 year - 3 years	15270	15448	15629	15870	16057	16260

Source:Eurostat, DG ENTR Calculations

a) forecast for 2012 considering the CAGR for the period 2007-2011

2.5 Total benefit due to reduction in the ADHD prevalence

Table 0-14 ***Benefits from the Treatment costs and productivity loss***

Treatment costs and productivity loss	2012	Average cost per child a)		Unit
		Policy Option 1	Policy Option 2	
Lifetime treatment costs of ADHD for child	76,963	351	334	Euros
Lifetime treatment costs of mother caring for child with ADHD	15,918	73	69	Euros
Productivity loss of mother caring for child with ADHD	36,963	169	160	Euros
Productivity loss of adult ADHD patient	26,229	66	63	Euros
Lifetime QALY loss associated with ADHD in adulthood b)	0.848	122	115	Euros
Lifetime QALY loss associated with ADHD in childhood b)	1.052	151	143	Euros
Total benefit per child - at 2012 prices		**931**	**884**	Euros
Total benefit due to ADHD (€m) c)		**15,134**	**14,377**	MEuros

a) Average cost per total number of child = Total cost per child with ADHD * prevalence rate

b) average value per child = Lifetime QALY loss associated with ADHD * Monetary value of a QALY (31391 euros at 2012 prices)

Considering (a) the adjusted values of the cost used for monetization and (b) the change in the discount rate, the total benefit resulting from a change in prevalence of **ADHD** will amount to:

- 15 134 million euros for Policy Option 1, equivalent to a per capita benefit per child of 931 euros
- 14 377 million euros for Policy Option2, equivalent to a per capita benefit per child of 884 euros.

2.6 Sensitivity analysis on (a) the change in prevalence of ADHD and (b) on the probability childhood ADHD continues into adulthood

The table below shows the different benefits resulting from changes in prevalence of ADHD. As mentioned in 2.2, the unit prevalence of ADHD change per 0.01 change in ug/dl (for > 1.3 ug/dl) was of 0.02282%. The table below allows us to quantify the economic impact of such a change. At a 55% probability rate (the one assumed in the Matrix Study), the expected benefit of such a reduction in prevalence would be 757 million euros (see the highlighted raw). Thus the table provides the monetization of benefits for a very large range depending on changes in prevalence. It shows for instance that the value of preventing 1 626 children from acquiring ADHD would have an impact to the society of at least 321 million euros.

Table 0-15 - Sensitivity analysis on the change in prevalence of ADHD and on Probability childhood ADHD continues into adulthood

	No children	%	Probability childhood ADHD continues into adulthood								
			30.0%	35.0%	40.0%	45.0%	50.0%	55%	60.0%	65.0%	70.0%
Change in prevalence of ADHD	**1626**	**0.01%**	321	323	325	327	329	332	334	336	338
	3711	**0.0228%**	**732**	**737**	**742**	**747**	**752**	**757**	**762**	**766**	**771**
	5337	**0.03%**	1053	1060	1067	1074	1081	1088	1095	1102	1109
	6963	**0.04%**	1374	1383	1392	1402	1411	1420	1429	1438	1447
	8589	**0.05%**	1695	1706	1718	1729	1740	1751	1763	1774	1785
	10215	**0.06%**	2016	2029	2043	2056	2070	2083	2096	2110	2123
	11841	**0.07%**	2337	2352	2368	2383	2399	2414	2430	2446	2461
	13467	**0.08%**	2658	2675	2693	2711	2728	2746	2764	2781	2799
	15093	**0.09%**	2979	2998	3018	3038	3058	3078	3097	3117	3137
	16719	**0.10%**	3299	3321	3343	3365	3387	3409	3431	3453	3475
	18345	**0.11%**	3620	3644	3668	3693	3717	3741	3765	3789	3813
	19971	**0.12%**	3941	3967	3994	4020	4046	4072	4098	4125	4151
	21597	**0.13%**	4262	4290	4319	4347	4375	4404	4432	4460	4489
	23223	**0.14%**	4583	4614	4644	4674	4705	4735	4766	4796	4827
	24849	**0.15%**	4904	4937	4969	5002	5034	5067	5099	5132	5165
	26475	**0.16%**	5225	5260	5294	5329	5364	5398	5433	5468	5503
	28101	**0.17%**	5546	5583	5619	5656	5693	5730	5767	5804	5841
	29727	**0.18%**	5867	5906	5945	5984	6023	6062	6101	6140	6179
	31353	**0.19%**	6188	6229	6270	6311	6352	6393	6434	6475	6516
	32979	**0.20%**	6508	6552	6595	6638	6681	6725	6768	6811	6854
	34605	**0.21%**	6829	6875	6920	6965	7011	7056	7102	7147	7192
	36230	**0.22%**	7150	7198	7245	7293	7340	7388	7435	7483	7530
	37856	**0.23%**	7471	7521	7570	7620	7670	7719	7769	7819	7868
	39482	**0.24%**	7792	7844	7896	7947	7999	8051	8103	8154	8206
	41108	**0.25%**	8113	8167	8221	8275	8329	8382	8436	8490	8544
	42734	**0.26%**	8434	8490	8546	8602	8658	8714	8770	8826	8882
	44360	**0.27%**	8755	8813	8871	8929	8987	9046	9104	9162	9220

	No children	%	Probability childhood ADHD continues into adulthood								
			30.0%	35.0%	40.0%	45.0%	50.0%	55%	60.0%	65.0%	70.0%
	45986	**0.28%**	9076	9136	9196	9256	9317	9377	9437	9498	9558
	47612	**0.29%**	9396	9459	9521	9584	9646	9709	9771	9834	9896
	49238	**0.30%**	9717	9782	9846	9911	9976	10040	10105	10169	10234
	50864	**0.31%**	10038	10105	10172	10238	10305	10372	10438	10505	10572
	52490	**0.32%**	10359	10428	10497	10566	10634	10703	10772	10841	10910
	54116	**0.33%**	10680	10751	10822	10893	10964	11035	11106	11177	11248
	55742	**0.34%**	11001	11074	11147	11220	11293	11366	11440	11513	11586
	57368	**0.35%**	11322	11397	11472	11547	11623	11698	11773	11848	11924
	58994	**0.36%**	11643	11720	11797	11875	11952	12030	12107	12184	12262
	60620	**0.37%**	11964	12043	12123	12202	12282	12361	12441	12520	12600
	62246	**0.38%**	12284	12366	12448	12529	12611	12693	12774	12856	12938
	63872	**0.39%**	12605	12689	12773	12857	12940	13024	13108	13192	13275
	65498	**0.40%**	12926	13012	13098	13184	13270	13356	13442	13528	13613
	67124	**0.41%**	13247	13335	13423	13511	13599	13687	13775	13863	13951
	68750	**0.42%**	13568	13658	13748	13839	13929	14019	14109	14199	14289
	70376	**0.43%**	13889	13981	14074	14166	14258	14350	14443	14535	14627
	72002	**0.44%**	14210	14304	14399	14493	14588	14682	14776	14871	14965
	73628	**0.45%**	14531	14627	14724	14820	14917	15014	15110	15207	15303
	74217	**0.4564%**	14647	14744	14842	14939	15036	**15134**	15231	15328	15426
	75843	**0.47%**	14968	15067	15167	15266	15366	15465	15565	15664	15764
	77469	**0.48%**	15289	15390	15492	15594	15695	15797	15898	16000	16102
	79095	**0.49%**	15610	15713	15817	15921	16025	16128	16232	16336	16439
	80721	**0.50%**	15931	16036	16142	16248	16354	16460	16566	16672	16777
	82347	**0.51%**	16251	16359	16467	16575	16683	16791	16899	17007	17115
	83973	**0.52%**	16572	16682	16793	16903	17013	17123	17233	17343	17453
	85599	**0.53%**	16893	17005	17118	17230	17342	17454	17567	17679	17791
	87225	**0.54%**	17214	17328	17443	17557	17672	17786	17900	18015	18129
	88851	**0.55%**	17535	17652	17768	17885	18001	18118	18234	18351	18467
	90477	**0.56%**	17856	17975	18093	18212	18330	18449	18568	18686	18805
	92103	**0.57%**	18177	18298	18418	18539	18660	18781	18901	19022	19143
	93729	**0.58%**	18498	18621	18743	18866	18989	19112	19235	19358	19481
	95355	**0.59%**	18819	18944	19069	19194	19319	19444	19569	19694	19819
	96981	**0.60%**	19139	19267	19394	19521	19648	19775	19903	20030	20157
	98607	**0.61%**	19460	19590	19719	19848	19978	20107	20236	20366	20495
	100233	**0.62%**	19781	19913	20044	20176	20307	20438	20570	20701	20833
	101859	**0.63%**	20102	20236	20369	20503	20636	20770	20904	21037	21171
	103485	**0.64%**	20423	20559	20694	20830	20966	21102	21237	21373	21509
	105111	**0.65%**	20744	20882	21020	21157	21295	21433	21571	21709	21847
	106737	**0.66%**	21065	21205	21345	21485	21625	21765	21905	22045	22185

	No children	%	Probability childhood ADHD continues into adulthood								
			30.0%	35.0%	40.0%	45.0%	50.0%	55%	60.0%	65.0%	70.0%
	108363	**0.67%**	21386	21528	21670	21812	21954	22096	22238	22380	22523
	109989	**0.68%**	21707	21851	21995	22139	22284	22428	22572	22716	22861
	111615	**0.69%**	22027	22174	22320	22467	22613	22759	22906	23052	23198
	113241	**0.70%**	22348	22497	22645	22794	22942	23091	23239	23388	23536
	114867	**0.71%**	22669	22820	22971	23121	23272	23422	23573	23724	23874
	116493	**0.72%**	22990	23143	23296	23448	23601	23754	23907	24060	24212
	118119	**0.73%**	23311	23466	23621	23776	23931	24086	24240	24395	24550
	119745	**0.74%**	23632	23789	23946	24103	24260	24417	24574	24731	24888

Source: Eurostat

3. IQ SUB-MODEL - SENSITIVITY ANALYSIS

3.1 Assumptions for parameters for IQ sub-model

Table 0-1 - Reduction in IQ

	Value	Ref
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl	**3.9**	Lanphear et al (2005)
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl	**5.8**	Lanphear et al (2005)
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl	**6.9**	Lanphear et al (2005)

Source: Matrix study

Table 0-2 - Change in IQ due to PO1, Percentage decrease in earnings for a 1 unit decrease in IQ

Unit IQ change per 0.01 ug/dl (for 0.2 ug/dl to 0.8 ug/dl level)	**0.01**	OBS
Reduction in IQ – 0.2 ug/dl to 0.8 ug/dl)	3.9	
/((10ug/dl-2.4ug/dl)/0.01ug/dl)+1)	761	
Change in IQ due to PO1	0.1020	
2.4 ug/dl)	2.4	(([(BBL PO0 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) – ((BBL PO1 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) =((3.5-2.4)/0.01 * .01) – ((3.3-2.4)/.01 * 0.01) = 0.102
Change in IQ due to PO2	0.097	The change in IQ due to PO2: (IQ PO0 –IQ PO2) = (([(BBL PO0 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) – ((BBL PO2 – 2.4 ug/dl)/.01]*(unit change in IQ per 0.01 change in ug/dl) =((3.5-2.4)/0.01 * .01) – ((3.31-2.4)/.01 * 0.01) = 0.097
Percentage decrease in earnings for a 1 unit decrease in IQ	2.00%	Grosse et al (2002)
annual earnings =	€ 21,332	(Eurostat, 2011) adjusted to 2012 at 2,7% inflation
Total lifetime earnings	€ 457,901	See table below

Source: Matrix study

3.2 Total lifetime earnings: annual earnings

Table 0-3 - Total lifetime earnings: annual earnings

	discount factor	Annual earnings	CF -Discounted Annual earnings	NPV = Σ Disccounted Annual earnings
0	1.00	21331.82	0	0
1	0.96	21908	0	0
2	0.92	22499	0	0
3	0.89	23107	0	0
4	0.85	23731	0	0
5	0.82	24371	0	0
6	0.79	25029	0	0
7	0.76	25705	0	0
8	0.73	26399	0	0
9	0.70	27112	0	0
10	0.68	27844	0	0
11	0.65	28596	0	0
12	0.62	29368	0	0
13	0.60	30161	0	0
14	0.58	30975	0	0
15	0.56	31812	0	0
16	0.53	32670	0	0
17	0.51	33553	0	0
18	0.49	34458	0	0
19	0.47	35389	0	0
20	0.46	36344	0	0
21	0.44	37326	0	0
22	0.42	38333	0	0
23	0.41	39368	0	0
24	0.39	40431	0	0
25	0.38	41523	0	0
26	0.36	42644	15381	15381
27	0.35	43796	15189	30570
28	0.33	44978	14999	45569
29	0.32	46192	14812	60381
30	0.31	47440	14627	75008
31	0.30	48720	14444	89451

	discount factor	Annual earnings	CF -Discounted Annual earnings	NPV = Σ Disccounted Annual earnings
32	0.29	50036	14263	103714
33	0.27	51387	14085	117799
34	0.26	52774	13909	131708
35	0.25	54199	13735	145443
36	0.24	55663	13563	159006
37	0.23	57166	13394	172400
38	0.23	58709	13226	185626
39	0.22	60294	13061	198687
40	0.21	61922	12898	211585
41	0.20	63594	12736	224321
42	0.19	65311	12577	236899
43	0.19	67074	12420	249319
44	0.18	68885	12265	261584
45	0.17	70745	12111	273695
46	0.16	72655	11960	285655
47	0.16	74617	11811	297466
48	0.15	76632	11663	309129
49	0.15	78701	11517	320646
50	0.14	80826	11373	332019
51	0.14	83008	11231	343250
52	0.13	85249	11091	354341
53	0.13	87551	10952	365293
54	0.12	89915	10815	376108
55	0.12	92343	10680	386788
56	0.11	94836	10546	397334
57	0.11	97396	10415	407749
58	0.10	100026	10284	418033
59	0.10	102727	10156	428189
60	0.10	105500	10029	438218
61	0.09	108349	9904	448122
62	**0.09**	**111274**	**9780**	**457901**

Source: DG ENTR Calculations

Table 0-4 - Change in lifetime earnings due to reduction in IQ per child

	Policy option 1	Policy option 2	OBS
Change in lifetime earnings due to reduction in IQ per child	€ 934.12	€ 888.33	a)
Number of children between the age of 2-3 in Europe	16,260	16,260	b)
Total benefit due to IQ (€m)	**€ 15,189**	**€ 14,444**	**c) = a*b**

Source: Matrix study.

Since :

a) Change in lifetime earnings due to reduction in IQ per child = Total lifetime earnings * Percentage decrease in earnings for a 1 unit decrease in IQ * Change in IQ due to PO

the key parameters that influence the total benefit estimated (we are taking as given the reference value for annual earnings and therefore for the lifetime earnings as presented before), are :

- Percentage decrease in earnings for a 1 unit decrease in IQ ,
- and change in IQ due to policy options

In the next section we will present the expect results of the benefits resulting from changes in these parameters.

3.3 Sensitivity analysis: Percentage decrease in earnings for a 1 unit decrease in IQ, and change in IQ due different policy options.

The table below presents the quantification of the total benefits of preventing a reduction in IQ. A change in IQ from 0.0970 to 0.1020 due to policy options PO1 or PO2, assuming a 2% decrease in earnings for a 1 unit decrease in IQ, would lead to benefits between 14.4 billion euros and 15.1 billion euros. However the table demonstrates that even minor changes in IQ (e.g. 0.0170) and only a minor decline in earnings resulting from the IQ decrease (e.g. 0,80%) will result in significant returns in the scale of 1 billion Euros.

Table 0-5 Sensitivity analysis: Percentage decrease in earnings for a 1 unit decrease in IQ, and Change in IQ due to Policy Options.

Change in IQ due to PO	Percentage decrease in earnings for a 1 unit decrease in IQ																	
	0.80%	**1.00%**	**1.20%**	**1.40%**	**1.60%**	**1.80%**	**2.00%**	**2.20%**	**2.40%**	**2.60%**	**2.80%**	**3.00%**	**3.20%**	**3.40%**	**3.60%**	**3.80%**	**4.00%**
0.0170	1013	1266	1519	1772	2025	2278	2531	2785	3038	3291	3544	3797	4050	4303	4557	4810	5063
0.0220	1310	1638	1966	2293	2621	2948	3276	3604	3931	4259	4586	4914	5242	5569	5897	6224	6552
0.0270	1608	2010	2412	2814	3216	3618	4021	4423	4825	5227	5629	6031	6433	6835	7237	7639	8041
0.0320	1906	2383	2859	3336	3812	4289	4765	5242	5718	6195	6671	7148	7624	8101	8577	9054	9530
0.0370	2204	2755	3306	3857	4408	4959	5510	6061	6612	7162	7713	8264	8815	9366	9917	10468	11019
0.0420	2502	3127	3752	4378	5003	5629	6254	6880	7505	8130	8756	9381	10007	10632	11257	11883	12508
0.0470	2799	3499	4199	4899	5599	6299	6999	7699	8398	9098	9798	10498	11198	11898	12598	13297	13997
0.0520	3097	3872	4646	5420	6195	6969	7743	8518	9292	10066	10840	11615	12389	13163	13938	14712	15486
0.0570	3395	4244	5093	5941	6790	7639	8488	9337	10185	11034	11883	12732	13580	14429	15278	16127	16975
0.0620	3693	4616	5539	6463	7386	8309	9232	10156	11079	12002	12925	13848	14772	15695	16618	17541	18465
0.0670	3991	4988	5986	6984	7981	8979	9977	10975	11972	12970	13968	14965	15963	16961	17958	18956	19954
0.0720	4289	5361	6433	7505	8577	9649	10721	11794	12866	13938	15010	16082	17154	18226	19298	20371	21443
0.0770	4586	5733	6880	8026	9173	10319	11466	12612	13759	14906	16052	17199	18345	19492	20639	21785	22932
0.0820	4884	6105	7326	8547	9768	10989	12210	13431	14653	15874	17095	18316	19537	20758	21979	23200	24421
0.0870	5182	6477	7773	9068	10364	11659	12955	14250	15546	16841	18137	19432	20728	22023	23319	24614	25910
0.0920	5480	6850	8220	9590	10960	12330	13700	15069	16439	17809	19179	20549	21919	23289	24659	26029	27399
0.0970	5778	7222	8666	10111	11555	13000	**14444**	15888	17333	18777	20222	21666	23110	24555	25999	27444	28888
0.1020	6075	7594	9113	10632	12151	13670	**15189**	16707	18226	19745	21264	22783	24302	25821	27339	28858	30377
0.107	6373	7967	9560	11153	12747	14340	15933	17526	19120	20713	22306	23900	25493	27086	28680	30273	31866
0.112	6671	8339	10007	11674	13342	15010	16678	18345	20013	21681	23349	25017	26684	28352	30020	31688	33355
0.117	6969	8711	10453	12196	13938	15680	17422	19164	20907	22649	24391	26133	27876	29618	31360	33102	34844
0.122	7267	9083	10900	12717	14533	16350	18167	19983	21800	23617	25433	27250	29067	30883	32700	34517	36334
0.127	7565	9456	11347	13238	15129	17020	18911	20802	22694	24585	26476	28367	30258	32149	34040	35931	37823
0.132	7862	9828	11794	13759	15725	17690	19656	21621	23587	25553	27518	29484	31449	33415	35381	37346	39312
0.137	8160	10200	12240	14280	16320	18360	20400	22440	24480	26520	28561	30601	32641	34681	36721	38761	40801

	Percentage decrease in earnings for a 1 unit decrease in IQ																	
	0.80%	**1.00%**	**1.20%**	**1.40%**	**1.60%**	**1.80%**	**2.00%**	**2.20%**	**2.40%**	**2.60%**	**2.80%**	**3.00%**	**3.20%**	**3.40%**	**3.60%**	**3.80%**	**4.00%**
0.142	8458	10572	12687	14801	16916	19030	21145	23259	25374	27488	29603	31717	33832	35946	38061	40175	42290
0.147	8756	10945	13134	15323	17512	19701	21889	24078	26267	28456	30645	32834	35023	37212	39401	41590	43779
0.152	9054	11317	13580	15844	18107	20371	22634	24897	27161	29424	31688	33951	36214	38478	40741	43005	45268
0.157	9351	11689	14027	16365	18703	21041	23379	25716	28054	30392	32730	35068	37406	39744	42081	44419	46757
0.162	9649	12062	14474	16886	19298	21711	24123	26535	28948	31360	33772	36185	38597	41009	43422	45834	48246
0.167	9947	12434	14921	17407	19894	22381	24868	27354	29841	32328	34815	37301	39788	42275	44762	47248	49735
0.172	10245	12806	15367	17929	20490	23051	25612	28173	30735	33296	35857	38418	40979	43541	46102	48663	51224
0.177	10543	13178	15814	18450	21085	23721	26357	28992	31628	34264	36899	39535	42171	44806	47442	50078	52713
0.182	10840	13551	16261	18971	21681	24391	27101	29811	32521	35232	37942	40652	43362	46072	48782	51492	54202
0.187	11138	13923	16707	19492	22277	25061	27846	30630	33415	36199	38984	41769	44553	47338	50122	52907	55692
0.192	11436	14295	17154	20013	22872	25731	28590	31449	34308	37167	40026	42885	45744	48604	51463	54322	57181
0.197	11734	14667	17601	20534	23468	26401	29335	32268	35202	38135	41069	44002	46936	49869	52803	55736	58670
0.202	12032	15040	18048	21056	24064	27071	30079	33087	36095	39103	42111	45119	48127	51135	54143	57151	60159
0.207	12330	15412	18494	21577	24659	27742	30824	33906	36989	40071	43153	46236	49318	52401	55483	58565	61648
0.212	12627	15784	18941	22098	25255	28412	31568	34725	37882	41039	44196	47353	50510	53666	56823	59980	63137

ANNEX X

SME TEST

Consultation with SMEs representatives	During the public consultation, the online questionnaire, hosted on the EU's website, was opened to all categories of economic operators involved in toy manufacturing and marketing. Information on the public consultation was promoted thought different business networks, e.g. Enterprise Europe Network and Toy Industry of Europe. Of the 81 replies received, 56 were submitted by SMEs, representing 70% of the respondents.
Measurement of the impacts on SMEs	The impacts on SMEs were not measures specifically in each of the options presented. This is because SMEs represents the majority in the toy sector. Statistics shows that of the 2000 companies involved in toy manufacturing and marketing in the EU, most of them are SMEs.
Asses mitigating measures	Costs on SMEs are expected to be higher than the costs on larger toy manufacturers. However, given the health risks and the range of health costs, they appear as proportionate in relation to the benefits to be obtained. At the end of the impact assessment, there was no indication of a disproportionate burden on SMEs. On the contrary, mitigating measures for SMEs, such as exemptions or longer transitional periods, would have undermined the objectives of the initiative, because SMEs are predominant in the toy sector.

ANNEX XI

Position Paper from Germany regarding the revision of the lead limit values for toys Made accessible to the Expert Group meeting of 23 May 2014

COM 2013-004 Annex 2

Stellungnahme zu Blei

Arbeitspapier der Europäischen Kommission zur Folgenabschätzung im Hinblick auf mögliche neue Regelungen zu Blei in Spielzeug
(Arbeitspapier *ENTR/TOYS/COM/2013/002*)

In dem Dokument ENTR/TOYS/COM/2013/002 hat die Europäische Kommission verschiedene Optionen für neue Regelungen zu Migrationsgrenzwerten für Blei in Spielzeug betrachtet. Zwei der Optionen waren Grundlage der Beratungen in der Sitzung des Ständigen Ausschusses für Spielzeugsicherheit am 3. Mai 2013 in Brüssel:

- Option 3a): Reduktion der Migrationsgrenzwerte für Blei auf 4 mg/kg für trockenes Material, 1 mg/kg für flüssiges Material und 47 mg/kg für abgeschabtes Material für alle Spielzeuge;
- Option 3b): Reduktion der Migrationsgrenzwerte für Blei auf 4 mg/kg für trockenes Material, 1 mg/kg für flüssiges Material und 47 mg/kg für abgeschabtes Material, mit Ausnahmen für Spielzeuge, die mit Rohstoffen hergestellt werden, die natürlicherweise mit Blei kontaminiert sind. Für diese Spielzeuge sollen die bisherigen Migrationsgrenzwerte von 13,5 mg/kg für trockenes Material, 3,4 mg/kg für flüssiges Material und 160 mg/kg für abgeschabtes Material beibehalten werden.

Für die Ableitung der vorgeschlagenen Migrationsgrenzwerte für Blei von 4 mg/kg für trockenes Material, 1 mg/kg für flüssiges Material und 47 mg/kg für abgeschabtes Material ist die Europäische Kommission von einem Allokationsfaktor von 10% für Blei in Spielzeug ausgegangen.

Die Bundesregierung bekräftigt erneut, dass aus Gründen des Verbraucherschutzes für die Festlegung von Migrationsgrenzwerten für Blei in Spielzeug grundsätzlich ein Allokationsfaktor von 5% herangezogen werden sollte. Dies entspricht auch dem Vorschlag der Unterarbeitsgruppe für chemische Stoffe in Spielzeug. Von der Unterarbeitsgruppe waren als neue Migrationsgrenzwerte 2 mg/kg für trockenes, brüchiges, staubförmiges oder geschmeidiges Material, 0,5 mg/kg für flüssiges Material und 23 mg/kg für abgeschabtes Material vorgeschlagen worden. Ein Allokationsfaktor von 5% steht auch im Einklang mit Erwägungsgrund 22 der Richtlinie 2009/48/EG.

Im Rahmen von Programmen zur Marktüberwachung („Monitoring") wurde in den Jahren 2010 und 2011 in Deutschland die Bleimigration aus 2496 Spielzeugen untersucht. Dabei wurden auch Spielzeuge aus Rohstoffen einbezogen, die natürlicherweise mit Blei kontaminiert sind. Eine Auswertung der Daten durch das Bundesinstitut für Risikobewertung (BfR) ist dieser Stellungnahme als Tabelle 1 und 2 beigefügt.

Aus den Daten geht hervor, dass 99% der Proben an abgeschabten Spielzeugmaterialien einen Wert für die Bleifreisetzung von 23 mg/kg unterschreiten. Der vorgeschlagene Migrationsgrenzwert von 23 mg/kg auf Basis eines Allokationsfaktors von 5% wird damit bereits zum jetzigen Zeitpunkt eingehalten.

Zu Spielzeugen, die Rohstoffe mit natürlicher Bleikontamination enthalten, zählen Fingermalfarben, Kreide, Knete, Minen von Buntstiften und Wasserfarben von Tuschkästen. Anhand der Daten wird deutlich, dass für diese Spielzeuge eine differenzierte Betrachtung angezeigt ist:
Bei allen untersuchten Kreideproben und bei mehr als 90% der untersuchten Knetmassen lag die Bleifreisetzung unterhalb eines Wertes von 2 mg/kg. Der vorgeschlagene Migrationsgrenzwert von 2 mg/kg auf Basis eines Allokationsfaktors von 5% für trockenes, brüchiges, staubförmiges oder geschmeidiges Material wird damit für Kreide und Knete bei entsprechender Rohstoffauswahl bereits jetzt eingehalten.
Bei Fingermalfarben (flüssiges Spielzeugmaterial) unterschreiten 90% der Proben einen Wert für die Bleifreisetzung von 1 mg/kg. Bei Buntstiftminen und Wasserfarben (trockenes, brüchiges, staubförmiges oder geschmeidiges Spielzeugmaterial) unterschreiten ca. 85% einen Wert von 4 mg/kg. Bei sorgfältiger Rohstoffauswahl können damit für diese Spielzeuge Migrationsgrenzwerte von 1 mg/kg bzw. 4 mg/kg auf Basis eines Allokationsfaktors von 10% eingehalten werden.

Das Schutzniveau für Kinder, das bereits jetzt am Markt realisiert ist, gilt es beizubehalten. Daher schlägt die Bundesregierung im Wege eines Kompromisses vor:

- im Grundsatz zur Ableitung von Migrationsgrenzwerten für Blei in Spielzeug einen Allokationsfaktor von 5% zur Anwendung zu bringen.
  Dies entspricht Migrationsgrenzwerten von 2 mg/kg für trockenes, brüchiges, staubförmiges oder geschmeidiges Material, 0,5 mg/kg für flüssiges Material und 23 mg/kg für abgeschabtes Material.

Und daneben im Sinne produktspezifischer Ausnahmen

- für Fingermalfarben, Buntstiftminen und Wasserfarben einen Allokationsfaktor von 10% zur Anwendung zu bringen.
  Dies entspricht Migrationsgrenzwerten für Fingermalfarben (flüssiges Material) von 1 mg/kg und für Buntstiftminen sowie Wasserfarben (trockenes, brüchiges, staubförmiges oder geschmeidiges Material) von 4 mg/kg.

Courtesy translation provided by the Commission services:

Position paper on lead

Working document of the European Commission on Impact Assessment of possible new provisions on lead in toys
(Working document *ENTR/TOYS/COM/2013/002*)

In Document ENTR/TOYS/COM/2013/002 the European Commission has examined several options for new provisions on migration limits for lead in toys. Two of the options were the basis for the discussions in the meeting of the Safety of Toys Committee of 3 May 2013 in Brussels:

- Option 3a): Reduction of the migration limits for lead to 4 mg/kg for dry material, 1 mg/kg for liquid material and 47 mg/kg for scraped-off material for all toys;
- Option 3b): Reduction of the migration limits for lead to 4 mg/kg for dry material, 1 mg/kg for liquid material and 47 mg/kg for scraped-off material, with exceptions for toys manufactured from raw materials which are naturally contaminated with lead. For those toys the current migration limits of 13,5 mg/kg for dry material, 3,4 mg/kg for liquid material and 160 mg/kg for scraped-off material would be kept.

For deriving the proposed migration limits for lead of 4 mg/kg for dry material, 1 mg/kg for liquid material and 47 mg/kg for scraped-off material the European Commission took an allocation factor of 10% for lead in toys as a basis.

The Federal Government stresses again that for reasons of consumer protection an allocation factor of 5% should be used in principle for setting migration limits for lead in toys. This corresponds to the proposal from the subgroup on chemicals in toys. The chemicals subgroup had proposed 2 mg/kg for dry, brittle, powder-like or pliable toy material, 0,5 mg/kg for liquid material and 23 mg/kg for scraped-off material as new migration limits. An allocation factor of 5% is also in line with recital 22 of Directive 2009/48/EC.

In the framework of programmes for market surveillance („monitoring") the migration of lead from 2496 toys was examined in Germany in 2010 and 2011. This included toys from raw materials which are naturally contaminated by lead. An assessment of the data by the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung - BfR) is attached to this position paper as Table 1 and 2 *(see Annex 3)*.

The data show that 99% of the samples of scraped-off toy material are below a value of lead release of 23 mg/kg. The proposed migration limit of 23 mg/kg based on an allocation factor of 5% is therefore already respected today.

Toys containing raw materials which are naturally contaminated with lead include finger paints, chalk, kneading dough, lead in colouring pencils and water colours in water colour boxes. The data show that for these toys a differentiated approach is appropriate:
In all chalk samples examined and in more than 90% of the kneading dough examined, the lead release was below 2 mg/kg. The proposed migration limit of 2 mg/kg based on an allocation factor of 5% for dry, brittle, powder-like or pliable material is therefore already respected today in the case of chalk and kneading dough, with proper choice of raw materials. In the case of finger paints (liquid toy materials) 90% of the samples are below 1 mg/kg of lead release. In the case of colouring pencil leads and water colours (dry, brittle, powder-like or pliable toy material) about 85% are below 4 mg/kg. When raw materials are carefully selected, migration limits of 1 mg/kg or 4 mg/kg respectively, based on an allocation factor of 10%, can be respected.

The level of protection for children, already achieved in the market today, should be maintained. This is why the Federal Government proposes the following compromise:

- To use in principle an allocation factor of 5% for deriving migration limits for lead in toys.
  This leads to migration limits of 2 mg/kg for dry, brittle, powder-like or pliable material, 0,5 mg/kg for liquid material and 23 mg/kg for scraped-off material.

And in addition, as product specific exceptions

- To use an allocation factor of 10% for finger paints, colouring pencil leads and water colours.
  This leads to migration limits of 1 mg/kg for finger paints (liquid material) and of 4 mg/kg for colouring pencil leads and water colours (dry, brittle, powder-like or pliable material).

Tabelle 1: Bleifreisetzung aus 2496 Spielzeugproben nach DIN EN 71-3: Median, 75 und 90. Perzentil sowie Maximalwerte (in mg/kg)

Spielzeug	Art des Materials	Anzahl Proben	Anzahl Proben mit quantifiziertem Wert	Bleimigration			
				Median [mg/kg]	75. Perzentil [mg/kg]	90. Perzentil [mg/kg]	Maximum [mg/kg]
Fingermalfarbe	flüssig, haftend	63	11 (17,5%)	n.n. (< 0,1)	0,4	1,3	1,4
Kreide	trocken, brüchig, staubförmig, geschmeidig	136	13 (9,5%)	n.n. (< 0,25)	1,2	1,5	1,9
Knete, Modelliermasse		47	10 (21%)	n.n. (<0,25)	1,5	2,6	4,9
Ming von Buntstiften		411	228 (58%)	1,5	2,2	6	164
Wasserfarben (Tuschkasten)		424	112 (26%)	n.n. (< 1,25)	1,5	10,2	59
Überzug Buntstifte	abschabbar	326	79 (24%)	n.n. (< 0,25)	1,5	1,8	15
Überzug Rassel/Greifling (Kinder < 36 Monate)		473	165 (35%)	n.n. (< 0,5)	1,5	2	11344
Überzug Steckspiel (Kinder < 36 Monate)		102	47 (46%)	n.n. (< 1,5)	1,7	4	21,5
Überzug Ziehfigur (Kinder < 36 Monate)		96	36 (37%)	n.n. (<1)	1,5	1,9	4,9
Figur/Puppe		323	113 (35%)	n.n. (< 0,5)	1,6	2,6	4210
Holzbaukasten/Kaufmannsladen		95	18 (19%)	n.n. (< 0,2)	1,6	1,6	1695
Alle abschabbaren Spielzeuge		**1415**	**458 (32%)**	**n.n. (< 0,5)**	**1,6**	**2**	**11344**

n.n. = nicht nachweisbar

abelle 2: Vergleich der Ergebnisse zur Bleimigration aus den verschiedenen Spielzeugmaterialien mit den vorgeschlagenen Grenzwerten
FSA-BMDL und Allokationsfaktor 5% bzw. 10%)

Spielzeug	Art des Materials	vorgeschlagener Grenzwert (mg/kg) 5% des EFSA-BMDL	Anzahl Proben, die den vorgeschlagenen Grenzwert einhalten		vorgeschlagener Grenzwert (mg/kg) 10% des EFSA-BMDL	Anzahl Proben, die den vorgeschlagenen Grenzwert einhalten	
ingermalfarbe	flüssig, haftend	0,5	47 / 63	75 %	1	56 / 63	90 %
reide	trocken, brüchig, staubförmig, geschmeidig	2	136 / 136	100 %	4	136 / 136	100 %
nete, Modelliermasse		2	43 / 47	91 %	4	46 / 47	98 %
ine von Buntstiften		2	299 / 411	73 %	4	355 / 411	86 %
asserfarben (Tuschkasten)		2	352 / 424	83 %	4	356 / 424	84 %
lle trockenen Spielzeugmaterialien		**2**	**834 / 1018**	**82 %**	**4**	**893/1018**	**88 %**
berzug Buntstifte	abschabbar	23	326 / 326	100 %	47	326 / 326	100 %
berzug Rassel/Greifling (Kinder < 36 Monate)		23	471 / 473	99,6 %	47	471 / 473	99,6 %
berzug Steckspiel (Kinder < 36 Monate)		23	102 / 102	100 %	47	102 / 102	100 %
berzug Ziehfigur (Kinder < 36 Monate)		23	96 / 96	100 %	47	96 / 96	100 %
igur/Puppe		23	315 / 323	97,5 %	47	318 / 323	98,5 %
olzbaukasten/Kaufmannsladen		23	96 / 96	100 %	47	96 / 96	100 %
lle abschabbaren Spielzeugmaterialien		**23**	**1405 / 1415**	**99 %**	**47**	**1408 /1415**	**99,5 %**

ANNEX XII

Further feedback from Germany: Origin of the 2,496 toy samples tested for their content of lead

Made accessible to the Expert Group meeting of 23 May 2014

EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Single Market for Goods
Internal Market and its International Dimension

SAFETY OF TOYS COMMITTEE MEETING

Document number:	ENTR/TOYS/COM/2013/011
Date:	04/10/2013

SUBJECT: Lead in toys - Further feedback from Germany

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Stellungnahme zu Blei – Angabe der Herkunftsländer

Arbeitspapier der Europäischen Kommission zur Folgenabschätzung im Hinblick auf mögliche neue Regelungen zu Blei in Spielzeug

(Arbeitspapier *ENTR/TOYS/COM/2013/002*)

Auf der Sitzung des Ständigen Ausschusses für Spielzeugsicherheit am 3. Mai 2013 hat die Europäische Kommission mögliche Optionen für neue Regelungen zu Blei in Spielzeug zur Diskussion gestellt (Dokument ENTR/TOYS/COM/2013/002). Die Bundesregierung hatte im Nachgang zur Sitzung die Daten, die ihr zu Blei in Spielzeug vorliegen, betreffend eine Stellungnahme einschließlich einer Auswertung des Bundesinstituts für Risikobewertung (BfR) an die Kommission und die anderen Mitgliedstaaten übermittelt. Für die weitere Diskussion bat die Kommission darum, in die tabellarische Auswertung auch die Herkunft (Herstellungsländer) der untersuchten Spielzeuge einzubeziehen.

Eine Aufschlüsselung der Daten durch das BfR ist dieser Stellungnahme als Tabelle 1 bis 3 beigefügt. Dabei wurden die aktuellen Daten aufbereitet und – sofern vorhanden – die Herstellungsländer angegeben. Da es in dem betroffenen Untersuchungszeitraum keine rechtliche Verpflichtung zur Angabe der Herstellungsländer gab, war die Information nicht bei allen Proben aus dem Handel verfügbar.

Die Daten wurden im Rahmen des Monitoring-Programms 2010 und 2011 von den zuständigen Behörden der Bundesländer gemessen und übermittelt. Ziel des Monitorings ist die Gewinnung von fundierten Daten für die Risikobewertung. Dabei wurden die Proben repräsentativ für Deutschland auf gesundheitlich nicht erwünschte Stoffe untersucht. Ziel der repräsentativen Probennahme beim Monitoring ist es, die Zusammensetzung der Stichprobe in wesentlichen Aspekten mit den tatsächlichen Marktbedingungen in Übereinstimmung zu bringen. Eine Festlegung der Beprobung von bestimmten Herstellungsländern gab es im Monitoring-Programm nicht.

Das Schutzniveau für Kinder, das bereits jetzt am Markt realisiert ist, gilt es beizubehalten. Daher bekräftigt die Bundesregierung ihren Vorschlag:

- im Grundsatz zur Ableitung von Migrationsgrenzwerten für Blei in Spielzeug einen Allokationsfaktor von 5% zur Anwendung zu bringen.
  Dies entspricht Migrationsgrenzwerten von 2 mg/kg für trockenes, brüchiges, staubförmiges oder geschmeidiges Material, 0,5 mg/kg für flüssiges Material und 23 mg/kg für abgeschabtes Material.

Und daneben im Sinne produktspezifischer Ausnahmen

- für Fingermalfarben, Buntstiftminen und Wasserfarben einen Allokationsfaktor von 10% zur Anwendung zu bringen.
  Dies entspricht Migrationsgrenzwerten für Fingermalfarben (flüssiges Material) von 1 mg/kg und für Buntstiftminen sowie Wasserfarben (trockenes, brüchiges, staubförmiges oder geschmeidiges Material) von 4 mg/kg.

Courtesy translation provided by the Commission services

Position on lead – Indication of originating countries

Working Document of the European Commission on Impact Assessment regarding possible new provisions on lead in toys

(Working Document *ENTR/TOYS/COM/2013/002*)

During the 3 May 2013 meeting of the Safety of Toys Committee, the European Commission presented possible options for new provisions on lead in toys for discussion (Document ENTR/TOYS/COM/2013/002). Following the meeting, the Federal Government communicated to the Commission and the other Member States the data in its possession on lead in toys in the framework of an opinion and an assessment of the Federal Institute for Risk Assessment (BfR). For the purposes of further discussion, the Commission asked to also specify in the table the origin (originating countries) of the toys that had been examined.

A breakdown of the data by BfR is enclosed as Tables 1 to 3. The current data were prepared and – to the extent available – the originating countries indicated. As there was no legal obligation to identify the originating countries at the time of the examination, this information was not available for all samples taken on the market.

The data were collected in the framework of the Monitoring Programme 2010 and 2011 of the competent authorities of the Bundesländer. The aim of the monitoring is to obtain well-based data for risk assessment. In this context representative samples for Germany were examined for substances that are not desirable from a health perspective. The aim of the representative sampling for monitoring is to ensure that the selected group of samples corresponds in essential aspects to the factual market conditions. The monitoring programme did not define the amounts of samples to be taken from certain originating countries.

The level of protection for children, which is already reality in the market, should be maintained. This is why the Federal Government confirms its proposal:

- to use, as a matter of principle, an allocation factor of 5% to derive migration limits for lead in toys.
  This results in migration limits of 2 mg/kg for dry etc. toy material, 0,5 mg/kg for liquid toy material and 23 mg/kg for scraped-off toy material.

Together with the following product-specific exceptions

- to use, for finger paints, colour pencil leads and water paints, an allocation factor of 10%.
  This results in migration limits of 1 mg/kg for finger paints (liquid material) and 4 mg/kg for colour pencil leads and water paints (dry etc. material).

Tabelle 1: Migration von Blei aus flüssigem Spielzeugmaterial, ausgewertet nach Herkunftsstaaten

flüssiges Spielzeug	Herkunftsstaat	Anzahl untersuchter Proben		Anzahl Proben <= 0,5 mg/kg (5% des EFSA-BMDL)		Anzahl Proben <= 1 mg/kg (10% des EFSA-BMDL)	
Fingermalfarben	Deutschland	29	46%	16	55%	25	86%
	Italien	10	16%	9	90%	9	90%
	Niederlande	6	10%	4	67%	4	67%
	China	12	19%	12	100%	12	100%
	ungeklärt	6	10%	6	100%	6	100%
	Gesamt	63	100%	47	75%	56	89%

Tabelle 2: Migration von Blei aus trockenem Spielzeugmaterial, ausgewertete nach Herkunftsstaaten

trockenes Spielzeug	Herkunftsstaat	Anzahl untersuchter Proben		Anzahl Proben <= 2 mg/kg (5% des EFSA-BMDL)		Anzahl Proben <= 4 mg/kg (10% des EFSA-BMDL)	
Kreide	Deutschland	2	1%	2	100%	2	100%
	China	57	42%	57	100%	57	100%
	ungeklärt	77	57%	77	100%	77	100%
	Gesamt	136	100%	136	100%	136	100%
Knete, Modelliermasse	Deutschland	23	49%	23	100%	23	100%
	China	20	43%	16	80%	19	95%
	ungeklärt	4	9%	4	100%	4	100%
	Gesamt	47	100%	43	91%	46	98%
Wasserfarbe/Tuschkasten	Deutschland	242	57%	190	79%	193	80%
	Europa	4	1%	4	100%	4	100%
	Frankreich	3	1%	3	100%	3	100%
	Italien	40	9%	40	100%	40	100%
	China	8	2%	8	100%	8	100%
	ungeklärt	127	30%	107	84%	108	85%
	Gesamt	424	100%	352	83%	356	84%
Mine von Buntstiften	Deutschland	100	24%	65	65%	85	85%
	Europa	16	4%	15	94%	15	94%
	Frankreich	12	3%	12	100%	12	100%
	Österreich	7	2%	0	0%	1	14%
	Vereinigtes Königreich	10	2%	6	60%	6	60%
	Brasilien	4	1%	4	100%	4	100%
	China	78	19%	66	85%	71	91%
	ungeklärt	184	45%	131	71%	161	88%
	Gesamt	411	100%	299	73%	355	86%
alle trockenen Materialien	Deutschland	367	36%	280	76%	303	83%
	Europa	20	2%	19	95%	19	95%
	Frankreich	15	1%	15	100%	15	100%
	Italien	40	4%	40	100%	40	100%
	Österreich	7	1%	0	0%	1	14%
	Vereinigtes Königreich	10	1%	6	60%	6	60%
	Brasilien	4	0%	4	100%	4	100%
	China	163	16%	147	90%	155	95%
	ungeklärt	392	39%	319	81%	350	89%
	Gesamt	1018	100%	830	82%	893	88%

Tabelle 3: Migration von Blei aus abschabbarem Spielzeugmaterial, ausgewertet nach Herkunftsstaaten

abschabbares Spielzeug	Herkunftsstaat	Anzahl untersuchter Proben		Anzahl Proben <= 23mg/kg (5% des EFSA-BMDL)		Anzahl Proben <= 47 mg/kg (10% des EFSA-BMDL)	
Überzug Rassel/Greifling (Kinder < 36 Monate)	Deutschland	296	63%	295	100%	295	100%
	Europa	17	4%	17	100%	17	100%
	Bulgarien	11	2%	11	100%	11	100%
	Niederlande	5	1%	5	100%	5	100%
	Tschechische Republik	2	0%	1	50%	1	50%
	Thailand	7	1%	7	100%	7	100%
	China	107	23%	107	100%	107	100%
	ungeklärt	28	6%	28	100%	28	100%
	Gesamt	473	100%	471	100%	471	100%
Überzug Steckspiel (Kinder < 36 Monate)	Deutschland	25	25%	25	100%	25	100%
	Europa	5	5%	5	100%	5	100%
	Bulgarien	3	3%	3	100%	3	100%
	Österreich	4	4%	4	100%	4	100%
	Thailand	19	19%	19	100%	19	100%
	China	34	33%	34	100%	34	100%
	ungeklärt	12	12%	12	100%	12	100%
	Gesamt	102	100%	102	100%	102	100%
Überzug Ziehfigur (Kinder < 36 Monate)	Deutschland	30	31%	30	100%	30	100%
	China	42	44%	42	100%	42	100%
	ungeklärt	24	25%	24	100%	24	100%
	Gesamt	96	0%	96	100%	96	100%
Überzug Buntstifte	Deutschland	79	24%	79	100%	79	100%
	Europa	16	5%	16	100%	16	100%
	Frankreich	12	4%	12	100%	12	100%
	Österreich	4	1%	4	100%	4	100%
	Brasilien	4	1%	4	100%	4	100%
	China	69	21%	69	100%	69	100%
	ungeklärt	142	43%	142	100%	142	100%
	Gesamt	326	100%	326	100%	326	100%
Holzbaukasten / Kaufmannsladen	Deutschland	35	37%	35	100%	35	100%
	Taiwan	1	1%	1	100%	1	100%
	China	17	18%	17	100%	17	100%
	ungeklärt	42	46%	41	98%	41	98%
	Gesamt	95	100%	94	99%	94	99%
Figur / Puppe	Deutschland	98	30%	98	100%	98	100%
	Europa	3	1%	3	100%	3	100%
	Bulgarien	6	2%	6	100%	6	100%
	Frankreich	1	0%	0	0%	0	0%
	Niederlande	3	1%	1	33%	3	100%
	Thailand	10	3%	9	90%	10	100%
	China	160	50%	158	99%	158	99%
	ungeklärt	42	13%	40	95%	40	95%
	Gesamt	323	100%	315	98%	318	98%
alle abschabbaren Spielzeugmaterialien	Deutschland	563	40%	562	100%	562	100%
	Europa	41	3%	41	100%	41	100%
	Bulgarien	20	1%	20	100%	20	100%
	Frankreich	13	1%	12	92%	12	92%
	Niederlande	8	1%	6	75%	8	100%
	Österreich	8	1%	8	100%	8	100%
	Tschechische Republik	2	0%	1	50%	1	50%
	Brasilien	4	0%	4	100%	4	100%
	Taiwan	1	0%	1	100%	1	100%
	Thailand	36	3%	35	97%	36	100%
	China	429	30%	427	100%	427	100%
	ungeklärt	290	20%	287	99%	287	99%
	Gesamt	1415	100%	1404	99%	1407	99%

ANNEX XIII

GLOSSARY

ADHD	Attention Deficit Hyperactivity Disorder
Bioavailability	the amount of each element in the toy which could be absorbed into the systemic circulation of a child
CSTEE	the Scientific Committee on Toxicity, Ecotoxicity and the Environment, an independent scientific committee appointed by the European Commission
EFSA	the European Food Safety Authority
IASG	Impact Assessment Steering Group
Notified Bodies	conformity assessment bodies notified under Directive 2009/48/EC
PVC	Polyvinyl Chloride
QALYs	Quality Adjusted Life Years
RIVM	the Dutch national institute for health and environment
SCHER	the Scientific Committee on Health and Environmental Risks, an independent scientific committee appointed by the European Commission
SMEs	Small and Medium-sized Enterprises
TDI	Tolerable Daily Intake
TFEU	Treaty on the Functioning of the European Union
TSD	the Toy Safety Directive 2009/48/EC
UNEP	United Nations Environment Programme