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Proposal for a

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Directive 2009/48/EC on the safety of toys lays down, in the table under point 13 of part III of Annex II, migration limits, from toys or components of toys, for a range of elements, including lead, in dry, liquid and scraped-off toy material. In order to ensure adequate protection of children, Directive 2009/48/EC empowers the Commission to amend point 13 of part III of Annex II for the purpose of its adaptation to technical and scientific developments. In accordance with Article 46(1) of Directive 2009/48/EC, those measures shall be adopted following the regulatory procedure with scrutiny referred to in Article 47(2) of the Directive.

With the objective of strengthening the limit values for lead in toys on the basis of the latest scientific evidence from the European Food Safety Authority (EFSA), the Commission prepared a draft directive which was put to the vote in the Toy Safety Committee established by Article 47 of Directive 2009/48/EC. The Committee did not deliver an opinion on the draft directive at its meeting of 14 January 2015.

In accordance with Article 5(a) of Decision 1999/468/EC, in case the Committee gives a negative opinion or where no opinion is delivered, the Commission is obliged to submit a proposal relating to the measures to be taken to the Council and to forward it to the European Parliament at the same time. The Council has to act on the proposal by a qualified majority within two months from the date of referral. If the Council opposes the proposed measure, it is not adopted. If the Council envisages adopting the proposed measure, or if the Council does not act, the proposed measure is submitted to the European Parliament. If the European Parliament opposes the proposed measure by a majority of its component members within four months from the date of referral to the Council, it is not adopted. If the European Parliament does not oppose within that time period, the proposed measure must be adopted.

An erratum to the 2008 report of the Dutch National Institute for Public Health and the Environment (RIVM) underlying the migration limits in the table under point 13 of part III of Annex II of Directive 2009/48/EC was published shortly after the Committee meeting of 14 January 2015. The erratum considered that the limits for elements in dry and liquid toy material had been calculated erroneously in 2008. The calculation had been based on amounts of material that were assumed to be ingested by children once every day, however ingestion would happen only once every week. Consulted by the Commission on the matter, the Scientific Committee for Health and Environmental Risks (SCHER) contended in April 2016 that the daily ingestion was appropriate, thereby confirming that the methodology of the 2008 RIVM report to calculate safe limits for elements in toys is correct. Accordingly, the same methodology should be applied for revising the limits for lead in toys; the present proposal does so.

• Consistency with existing policy provisions in the policy area

As the abovementioned scientific evidence shows, the level of protection against exposure to lead, as established in 2009 in point 13 of part III of Annex II to Directive 2009/48/EC is no longer appropriate. Therefore, it is necessary to amend the current migration limits for lead and align them with the latest scientific data, in order to reduce children's exposure to lead.

In its Decision 2012/160/EU, the Commission acknowledged that the 2009 migration limits for lead no longer offer an appropriate level of protection for children.

- **Consistency with other Union policies**

At EU level, the presence of lead in ceramics and plastic materials which come into contact with food is already restricted. Regulation (EC) No 1907/2006 ("REACH") restricts the use of lead carbonates and sulphates in paint and the marketing of lead in jewellery. REACH also restricts the marketing and use of lead in articles supplied to the general public, but exempts toys from this restriction in view of the specific migration limits for lead in toys laid down in Directive 2009/48/EC.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legal basis for the proposal is Article 46(1)(b) of Directive 2009/48/EC on the safety of toys.

- **Subsidiarity (for non-exclusive competence)**

The objective of the proposal is to ensure a high level of safety for children whilst re-establishing the internal market. Individual actions undertaken by Member States, such as the differing national limit which Germany is allowed to maintain - following the judgment of the General Court of 14 May 2014 in case T-198/12 - until the date of entry into force of EU provisions setting new limits for lead in toys, lead to unequal levels of protection for European children as well as a fragmentation of the internal market and create barriers to trade in toys.

Since Directive 2009/48/EC exhaustively sets the rules for ensuring toy safety and the internal market for toys, amending the Directive with regard to the applicable limits for lead is the only way to ensure the required high level of safety for children and the functioning of the internal market.

- **Proportionality**

In view of the neurodevelopmental effects of lead on children, which result in particular in learning deficits, exposure of children to lead should be reduced to the maximum extent possible, including exposure through toys. This objective does not imply developing policy in new areas since EU legislation on toy safety exists, including an empowerment to the Commission to adopt implementing acts to achieve the objective. Other measures than amending the current migration limits for lead and aligning them with the latest scientific data would be less effective in terms of protection of children, who are a particularly vulnerable segment of the population.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

The Commission informed all concerned stakeholders (Member States, industry, consumer protection associations, standardisation bodies, Notified Bodies) 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 a 5% allocation and exemption for the arts and crafts toys.

Following this, the Commission received position papers from the toy industry, 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. 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 7 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 published and business associations were duly informed about their publication.

The Commission also collected position papers from consumer protection associations, in particular from ANEC and BEUC. 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 with stakeholders carried out by two external consultants in the framework of their respective studies: one on health costs related to children exposure to lead via toys, the other on the initiative's effects on the competiveness of the toy sector (see below).

The impact of the 5% allocation and the fact that only few toys/toy materials may have to be adapted to new limit values for lead 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 reference value, while others favoured 10%. Stakeholders from the toy industry and consumer representatives were equally split in their views.

- **Collection and use of expertise**

Two studies were carried out by external consultants: one on health costs related to children exposure to lead via toys (http://ec.europa.eu/DocsRoom/documents/6655/attachments/1/translations/en/renditions/native), the other on the initiative's effects on the competiveness of the toy sector (http://ec.europa.eu/DocsRoom/documents/6654/attachments/1/translations/en/renditions/native).

- **Impact assessment**

The Commission prepared an impact assessment on the 'Revision of the limit values for lead in toys' to underpin this amendment [insert link to summary when publicly available] which received a positive opinion from the Impact Assessment Board (Ares(2013)66470 - 18/01/2013).

The impact assessment examined the several policy alternatives: (1) baseline "no change" scenario, (2) complete revision of the current limits, (3) partial revision of the current limits, and (4) soft law /self-regulatory approach. Under the baseline scenario, no new costs are foreseen, but the scenario would not bring any improvement to the protection of children's health. The complete revision, in line with latest scientific knowledge, will present the highest benefits as it would result in a high protection of children from lead exposure, but may come at a significant cost to the industry, as certain categories of toys might be completely banned

from production in the worst case. The partial revision would not reduce the exposure of children for those toys that may actually contain too much lead, leading to much more limited benefits than the complete revision, but would avoid the potential ban from the market of certain toys and would entail limited costs for industry. Soft law /self-regulatory approaches would imply limited costs for industry, but would be most of the time inefficient and would lead therefore to limited increase in the level of children's protection.

The final proposal opts for the complete revision, which will present the highest benefits as it would result in a high protection of children from lead exposure; it was also considered that data from 2 500 toy samples in Germany showed that toys placed on the market complied at rates of 91% to 100% with the stricter lead limits envisaged by the proposal. The following impacts were estimated for the complete revision option as laid down in the proposal:

Health impacts: The reduced exposure of children to lead in toys would result in an incremental benefit compared to the "no change" scenario of € 836 million for behaviour and attention problems (ADHD) and € 1 176 million for reduced IQ.

Economic impacts: Industry would be affected in its capacity to market certain toys[1], made with raw materials naturally contaminated with lead. Industry foresees an increase in production costs, and a reduction in the product range. The option results in an estimated impact that would amount to € 89 million of production value. The worst case scenario would be a de-facto ban of certain toys. This potential ban may lead to a further loss of production up to a total displacement of these toys in the EU. This would imply a loss of € 217 million as a worst case.

Social costs (impact on employment): The selected option results in an estimated impact that would amount to 662 lost jobs, representing € 8,5 million. The worst case scenario - a de-facto ban of certain toys – would amount to 2 112 lost jobs representing € 27,5 million.

- **Regulatory fitness and simplification**

The proposal does not exempt micro-enterprises, because the risks for children's health from exposure to the highly toxic metal lead in toys are no different whether the toys are manufactured by micro-enterprises or by other enterprises.

The proposal contains no specific provisions to minimize compliance costs for SMEs and other stakeholders, since Directive 2009/48/EC, which is being amended by the present proposal, does not contain such provisions either.

The risks which the proposal aims to address, namely risks for children's health from exposure to the highly toxic metal lead in toys, only occur in the physical world, through exposure to physical toys. Accordingly, the "Digital Check" and the question whether the proposal is internet ready and appropriate for both the physical and digital environment is irrelevant.

4. BUDGETARY IMPLICATIONS

None.

[1] These toys are arts and crafts toys, which make up for about 6.5 % of the toy sales in the EU on average. See: Ecorys (2012) Competitiveness Proofing Toy Related Industry. Impact of new lead migration limits on the competitiveness of European manufacturers. Study for DG Enterprise and Industry in the framework of the Impact Assessment. Page 69.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Directive 2009/48/EC has been transposed by all Member States; only Germany is allowed to temporarily maintain its national limit for lead (see above). The three current migration limits for lead are contained in one row in the table in point 13 of part III of Annex II. The amendment of the migration limits implies replacing the current three migration limits in the table by three new migration limits. The implementation in Member State law will imply the same. Accordingly, an implementation plan does not appear necessary.

No monitoring and evaluation tools are foreseen specifically for this proposal. Directive 2009/48/EC contains an obligation for Member States to send to the Commission a report on the application of the directive, including its amendments. Such a report had 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.

- **Explanatory documents (for directives)**

A similar past amendment (Commission Directive 2012/7/EU) has not created any implementation issues, and neither have other amendments (Commission Directives 2014/79/EU, 2014/81/EU, 2014/84/EU, (EU) 2015/2115, (EU) 2015/2116 and (EU) 2015/2117). Accordingly, the process is by now routine and explanatory documents on the transposition do not appear necessary.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 of the proposal replaces the current migration limits of point 13 of part III of Annex II to Directive 2009/48/EC for lead by the following new migration limits: 2,0 mg/kg in dry toy material , 0,5 mg/kg in liquid toy material and 23 mg/kg in scraped-off toy material.

Article 2 of the proposal lays down the obligation for Member States to transpose the amended migration limits by the date falling 18 months after publication in the Official Journal of the European Union, to apply them from that date and to communicate the transposition measures to the Commission.

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(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[2], and in particular Article 46(1)(b) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Directive 2009/48/EC lays down migration limits for toys or components of toys, for a range of elements, including lead, in dry, liquid and scraped-off toy material. The limits for lead are 13,5 mg/kg, 3,4 mg/kg and 160 mg/kg in each toy material, respectively.

(2) Those limits were based on the recommendations of the Dutch National Institute for Public Health and the Environment (RIVM) in a 2008 report[3]. The RIVM recommendations were based on the conclusion that exposure of children to lead may not exceed a certain level, called 'tolerable daily intake'. In that report, a tolerable daily intake of 3,6 microgram per kilogram body weight per day was determined as the toxicological reference value for lead.

(3) Since children are also exposed to lead from sources other than toys, only a certain percentage of the toxicological reference value should be allocated to toys. The Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE) recommended that 10% of the maximum tolerable intake of lead should be allowed as the maximum contribution from toys[4]. The Scientific Committee for Health and Environmental Risks (SCHER) concurred with the approach that the uptake of lead from toys should not exceed 10% of a toxicology-based reference value[5]. Furthermore, since lead is considered particularly toxic, its limits in Directive 2009/48/EC were set at half the level considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces of lead that are compatible with good

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2 OJ L 170, 30.6.2009, p. 1.

3 'Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements', J.G.M. Van Engelen, et al. (2008) RIVM report 320003001/2008, http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

4 Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE), Opinion on the "Assessment of the bioavailability of certain elements in toys", adopted on 22 June 2004, p. 3.

5 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, p. 5.

manufacturing practice should be present. Accordingly, the limits for lead were set in that Directive at 5% of the tolerable daily intake, determined as the migration of lead from toys.

(4) The European Food Safety Authority (EFSA) concluded that for lead, as a toxic metal, there is no threshold below which the exposure to lead has no critical health effects. Even low-level exposure to lead may cause neurotoxicity, namely damage to the nervous system and brain, in particular learning deficits. Therefore, according to that new scientific knowledge published by EFSA, the tolerable daily intake should no longer be used as the toxicological reference value[6].

(5) According to EFSA, the new toxicological reference to be used for establishing lead limits is the $BMDL_{01}$ (benchmark dose limit) relating to neurodevelopmental effects. The $BMDL_{01}$ is the lower confidence limit (95th 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[7]. The $BMDL_{01}$ is equivalent to a lead intake of 0,5 microgram per kilogram body weight per day.

(6) The Committee for Risk Assessment (RAC) established under the European Chemicals Agency (ECHA) agreed with EFSA that the $BMDL_{01}$ is the highest tolerable exposure for lead[8]. Since the current average blood lead levels in European children are up to four times higher than the highest tolerable exposure level, and since no threshold for the neurodevelopmental effects can be established, any additional exposure must be avoided as far as possible[9].

(7) Applying the latest scientific developments to the methodology in the 2008 RIVM report to calculate safe limits for elements in toys and applying the approach of Directive 2009/48/EC in managing the risks of particularly toxic elements such as lead, the limits for lead in toys laid down in Directive 2009/48/EC should be reviewed, and should be set at a 5% allocation of the $BMDL_{01}$ for the protection of children's health.

(8) An erratum to the 2008 RIVM report[10], published in 2015, considered that the amounts of dry and liquid toy material which children are assumed to ingest, amounts upon which the 2008 RIVM report's recommendations for limit values were based, should be expressed as weekly amounts instead of daily amounts. SCHER subsequently contended that the ingestion amounts originally recommended are appropriate and should continue to be expressed as daily amounts rather than weekly amounts[11], thereby confirming that the methodology used in the 2008 RIVM report to calculate safe limits for elements in toys is correct. Accordingly, the methodology used in the 2008 RIVM report should continue to be applied for the purposes of laying down revised limits for lead in toys.

(9) Directive 2009/48/EC should therefore be amended accordingly.

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6 EFSA CONTAM Panel (2013), Scientific Opinion on Lead in Food, p. 5. Applied in: SCHER (2011), Opinion on a Lead Standard in Drinking Water, adopted on 11 January 2011.

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

8 ECHA (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, p. 5.

9 Ibíd.

10 http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

11 Scientific Committee on Health and Environmental Risks (SCHER), Final Opinion on "Estimates of the amount of toy materials ingested by children", adopted on 8 April 2016. http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_170.pdf

(10) The committee established under Article 47 of Directive 2009/48/EC delivered no opinion on the measures provided for in this Directive, the Commission therefore submitted to the Council a proposal relating to those measures and forwarded it to the European Parliament,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In the table under point 13 of part III of Annex II to Directive 2009/48/EC, the entry for lead is replaced by the following:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
'Lead	2,0	0,5	23'

Article 2

1. Member States shall adopt and publish, by […(Fill in date falling 18 months after publication in the OJ)] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from […(Fill in same date as in previous subparagraph)].

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President