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#### COVER NOTE

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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 25 January 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject: COMMISSION DIRECTIVE (EU) .../... of XXX amending Directive 2009/48/EC of the European Parliament and of the Council as regards specific limit values for aniline in certain toys

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Delegations will find attached document [\[...\]](#)(2020) XXX draft - D 071420/01.

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Encl.: [\[...\]](#)(2020) XXX draft - D 071420/01



Brussels, **XXX**  
[...] (2020) **XXX** draft

**COMMISSION DIRECTIVE (EU) .../...**

**of **XXX****

**amending Directive 2009/48/EC of the European Parliament and of the Council as regards specific limit values for aniline in certain toys**

(Text with EEA relevance)

D071420/01

**Commission Directive (EU) .../...of XXX amending Directive 2009/48/EC of the European Parliament and of the Council as regards specific limit values for aniline in certain toys**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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<sup>1</sup>, and in particular Article 46(2) thereof,

Whereas:

- (1) Directive 2009/48/EC establishes certain requirements for chemical substances that are classified as carcinogenic, mutagenic or toxic for reproduction under Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>2</sup>. Appendix C to Annex II to Directive 2009/48/EC lays down specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.
- (2) Aniline (CAS number 62-53-3) is classified as carcinogenic category 2 and mutagenic category 2 under Regulation (EC) No 1272/2008<sup>3</sup>. According to point 5(a) of Part III of Annex II to Directive 2009/48/EC, carcinogenic substances of category 2, such as aniline, may be used in toys in individual concentrations equal to or smaller than the relevant concentration established in Regulation (EC) No 1272/2008 for the classification of mixtures containing those substances, namely 1 %<sup>4</sup>, which corresponds to 10 000 mg/kg ('content limit'). The same content limit applies to mutagenic substances of category 2<sup>5</sup>.
- (3) The Scientific Committee on Health and Environmental Risks (SCHER) considered, in its opinion of 29 May 2007, that compounds that are carcinogenic, mutagenic or toxic for reproduction (CMR) should not be present in toys<sup>6</sup>. The European Union Risk Assessment Report on aniline<sup>7</sup> concluded that for consumers there is a need for limiting the health risks associated with the use of products containing aniline. That conclusion was based on 'concerns for mutagenicity and carcinogenicity as a

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<sup>1</sup> OJ L 170, 30.6.2009, p. 1.

<sup>2</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>3</sup> Table 3 in Annex VI to Regulation (EC) No 1272/2008.

<sup>4</sup> Table 3.6.2 in Annex I to Regulation (EC) No 1272/2008.

<sup>5</sup> Table 3.5.2 in Annex I to Regulation (EC) No 1272/2008.

<sup>6</sup> Scientific Committee on Health and Environmental Risks (SCHER). CEN's response to the opinion of the CSTEE on the assessment of CEN report on the risk assessment of organic chemicals in toys. Adopted on 29.5.2007.

<sup>7</sup> [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_056.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_o_056.pdf)

European Chemicals Bureau, Institute for Health and Consumer Protection, 2004. EUR 21092 EN. Section 5.2.1.2, p. 180.

[https://echa.europa.eu/documents/10162/6434698/orats\\_final\\_rar\\_aniline\\_en.pdf/0abd36ad-53de-4b0f-b258-10cf90f90493](https://echa.europa.eu/documents/10162/6434698/orats_final_rar_aniline_en.pdf/0abd36ad-53de-4b0f-b258-10cf90f90493)

consequence of exposure arising from use of products containing the substance, as aniline is identified as a non-threshold carcinogen.’ The Committee for Risk Assessment of the European Chemicals Agency (RAC) indicated, in its opinion on restriction of substances in tattoo inks and permanent make-up<sup>8</sup>, that aniline is considered a non-threshold carcinogen. Aniline may therefore cause cancer at even the slightest level of exposure.

- (4) In order to advise the Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety, the Commission has established the Expert Group on Toys Safety. The mission of its subgroup Working group on Chemicals in Toys (subgroup Chemicals) is to provide advice to the Expert Group on Toys Safety with regard to chemical substances which may be used in toys.
- (5) During the meeting of the subgroup Chemicals on 18 February 2015<sup>9</sup>, several of its members indicated that aniline could be found in coloured toy material such as textiles or leather when that material is subjected to the reductive cleavage test provided for in Appendix 10 to Regulation 1907/2006 of the European Parliament and of the Council<sup>10</sup>. The occurrence of aniline in textiles after reductive cleavage testing was confirmed in a study carried out in Sweden<sup>11</sup> as a follow-up to the meeting of the Expert Group on Toys Safety on 8 June 2015. Out of 23 textile samples, aniline was identified in one red textile (4 % of all samples) at 91 mg/kg. The occurrence of aniline in clothing after reductive cleavage testing was confirmed in a study with 153 samples<sup>12</sup>. Aniline was identified in 9 samples (6 % of all samples) at up to 588 mg/kg. Moreover, aniline has been found in a finger paint after reductive cleavage according to a German consumer magazine<sup>13</sup>. The subgroup Chemicals also noted, by written correspondence to the Commission in May 2020, that free aniline could be present in finger paints as an impurity of the colourants in such paints.
- (6) At the meeting of the Expert Group on Toys Safety on 8 June 2015, Germany presented a position paper providing a scientific assessment of the toxicological properties of aniline<sup>14</sup>. According to that assessment, the existing content limit for aniline presents a risk for both the systemic and the cancer effects of that substance.

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<sup>8</sup> Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC), Opinion on an Annex XV dossier proposing restriction on substances used in tattoo inks and permanent make-up. Adopted on 20 November 2018. Appendix 2, section 2, p. 90.

<https://echa.europa.eu/documents/10162/2b4533af-f717-4bff-939b-2320fb43b462>

<sup>9</sup> See Register of Commission Expert Groups, Expert Group on Toys Safety (E01360).

<https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=20916&no=1>

<sup>10</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

<sup>11</sup> Meeting document of the subgroup Chemicals: EXP/WG/2015/027/Ann1, Aniline from azodye cleavage, Results from Sweden.

<sup>12</sup> Brüscheweiler et al., Identification of non-regulated aromatic amines of toxicological concern which can be cleaved from azo dyes used in clothing textiles, Regulatory Toxicology and Pharmacology 69 (2014) 263–272. Cited in: ANEC – Position paper on aniline. April 2016. Presented to the subgroup "Chemicals" meeting on 1 June 2016 (EXP/WG/2016/027).

<sup>13</sup> Ökotest 2/2015, p. 69.

<sup>14</sup> Discussion paper EXP/2015/029/rev1.

The subgroup Chemicals concluded, at its meeting on 26 September 2017<sup>15</sup>, that a restriction for aniline in toys should target toys and toy components of textile and leather, and finger paints, since too little information was available so far on the need for an aniline restriction in toys or toy materials other than textile, leather and finger paints. The subgroup also indicated that the limit value should be 30 mg/kg after reductive cleavage. That value is the lowest concentration that the reductive cleavage test can reliably identify. As regards finger paints, the subgroup indicated that a limit of 10 mg/kg for free aniline should be set since that is the lowest concentration that can reliably be checked in routine tests of finger paints.

- (7) The Expert Group on Toys Safety, at its meeting on 19 December 2017<sup>16</sup>, examined the setting of limit values of 30 mg/kg for aniline after reductive cleavage in toy materials of textile and leather; of 30 mg/kg for aniline after reductive cleavage in finger paints; and of 10 mg/kg for free aniline in finger paints, as indicated earlier by the subgroup Chemicals.
- (8) Pursuant to Article 46(2) of Directive 2009/48/EC, the packaging requirements for food laid down in Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>17</sup> are to be taken into account when adopting specific limit values for chemicals in Appendix C to that Directive. The basic assumptions behind the migration test methods referred to in Article 11(4) of Commission Regulation (EU) No 10/2011<sup>18</sup>, which is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004 and which establishes specific requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with food, are however different from the basic assumptions behind the content limits for aniline in certain toys in Directive 2009/48/EC. In addition, it is impossible to compare migration limits with content limits. Therefore, further to these conclusions there is no way to take account of the packaging requirements for food when setting content limits for aniline in certain toys.
- (9) In light of the classification of aniline as a CMR substance, the European Union Risk Assessment Report on aniline, the opinion of RAC and SCHER and the opinions of the Expert Group in Toys Safety and its subgroup Chemicals as well as the studies on the presence of aniline in textiles, it is necessary to set a limit for aniline in textile toy material and leather toy material of 30 mg/kg after reductive cleavage and a limit for aniline in finger paints of 10 mg/kg as free aniline and 30 mg/kg after reductive cleavage.
- (10) Directive 2009/48/EC should therefore be amended accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Toy Safety Committee,

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<sup>15</sup> Register of Commission Expert Groups, Expert Group on Toys Safety (E01360). <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=4151>.

<sup>16</sup> Register of Commission Expert Groups, Expert Group on Toys Safety (E01360), tab 'Meetings'. <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=1485>.

<sup>17</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).

<sup>18</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 012 15.1.2011, p. 1).

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

In Appendix C to Annex II to Directive 2009/48/EC, the following entry is added:

Substance	CAS No	Limit value
'Aniline	62-53-3	30 mg/kg after reductive cleavage in textile toy material and leather toy material
		10 mg/kg as free aniline in finger paints
		30 mg/kg after reductive cleavage in finger paints'

*Article 2*

1. Member States shall adopt and publish, by [*Insert here the date 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 [*Insert here the date 18 months + 1 day after publication in the OJ.*].

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 Commission*  
*The President*  
Ursula von der Leyen