Commission Directive (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council for the purpose of adopting specific limit values for chemicals used in certain toys, as regards formaldehyde (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2019/1929

of 19 November 2019

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(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[(1)], 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[(2)]. Appendix C to Annex II to the Directive 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) Formaldehyde (CAS number 50-00-0) is currently not listed in Appendix C to Annex II to Directive 2009/48/EC. It is classified as carcinogenic category 1B under Regulation (EC) No 1272/2008. Pursuant to point 4(a) of Part III of Annex II to Directive 2009/48/EC, formaldehyde may be used up to a concentration of 0,1 %, which corresponds to 1 000 mg/kg (content limit).

(3) 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[(3)]. 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.

(4) Formaldehyde is used as a monomer in the manufacture of polymeric materials. Polymeric materials are often used in toys. Children may therefore ingest formaldehyde when mouthing toys containing polymeric materials. The tolerable daily intake (TDI) for formaldehyde was set by the World Health Organisation (WHO)[(4)] and has been confirmed by the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) of the European Food Safety Authority[(5)]. The TDI is 0,15 mg/kg bodyweight per day. With an allocation of 10 % of the TDI to the

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intake of formaldehyde from toys[6]; a child with a bodyweight of 10 kg should therefore not take in more than 0,15 mg formaldehyde per day. Assuming a daily ingestion of 100 ml of mouthing saliva, the subgroup Chemicals recommended, at its meeting on 26 September 2017[7], a formaldehyde migration limit of 1,5 mg/l in polymeric materials when the migration of formaldehyde is determined in accordance with the test method in standards EN 71-10:2005[8] and EN 71-11:2005[9].

(5) Formaldehyde is also used in the manufacture of resin-bonded wood products such as particle board, oriented-strand board (OSB), high-density fibre board (HDF), medium density fibre board (MDF) and plywood. Formaldehyde resins include phenol-formaldehyde (PF), urea-formaldehyde (UF), melamine-formaldehyde (MF) and polyacetal (polyoxymethylene — POM) resins. POM tends to be used only for small internal components and not in whole toys. The subgroup Chemicals recommended, at its meeting on 26 September 2017, a formaldehyde emission limit of 0,1 ml/m^3 when the emission of formaldehyde is determined in such materials in accordance with the test chamber method in standard EN 717-1:2004[10]. That limit corresponds to the indoor air limit value that the WHO has established to prevent sensory irritation in the general population and to prevent cancer[11].

(6) Formaldehyde may also be present in textile toy material due to its use during the manufacture of textiles. According to a report from the Organisation for Economic Cooperation and Development (OECD) published in 2002, the lowest threshold concentration for allergic contact dermatitis from formaldehyde is 30 mg/kg[12]. On that basis and in order to protect also the most sensitised individuals, the subgroup Chemicals recommended, at its meeting on 26 September 2017, a formaldehyde content limit of 30 mg/kg when the content of formaldehyde is determined in accordance with the water extraction method in standard EN ISO 14184-1:2011[13].

(7) Formaldehyde may be present in leather toy material due to its use during the manufacture of leather. Since leather toy material may lead to an exposure similar to textile toy material the subgroup Chemicals recommended, at its meeting on 26 September 2017, a formaldehyde content limit of 30 mg/kg when the content of formaldehyde is determined in accordance with standard EN ISO 17226-1:2008[14].

(8) Formaldehyde in paper toy material should have a content limit of 30 mg/kg according to the recommendation of the subgroup Chemicals at its meeting on 26 September 2017, when determined in accordance with the water extraction method in standard EN 645:1993[15] and with standard EN 1541:2001[16]. That conclusion was based on the consideration that paper toy material may lead to an exposure similar to textile and leather toy material.

(9) Formaldehyde may be present in water-based toy material due to its function as a preservative. It could be used in water-based toy materials such as soap bubbles or inks in felt-tip pens, and also in dry materials intended to be mixed with water prior to use. In light of the opinion of the Scientific Committee on Health and Environmental Risks (SCHER) that CMR compounds should not be present in toys[17], the subgroup Chemicals recommended, at its meeting on 3 May 2018[18], a formaldehyde limit of 10 mg/kg in water-based toy material when the content of formaldehyde is determined