EUROPEAN
COMMISSION

Brussels, XXX
[…](2025) XXX draft

COMMISSION DIRECTIVE (EU) .../…

of XXX

amending Appendix A of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards cobalt

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION DIRECTIVE (EU) .../…

of XXX

amending Appendix A of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards cobalt

(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(3) thereof,

(1) Directive 2009/48/EC establishes general requirements for substances which are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2]. CMR substances of category 1A, 1B or 2 are not to be used in toys, in components of toys or in micro-structurally distinct parts of toys, except if those substances are contained in individual concentrations equal to or smaller than the relevant concentrations established in Regulation (EC) No 1272/2008 for the classification of mixtures containing them as CMRs, they are inaccessible to children or their use has been permitted. The Commission may permit the use of CMR substances category 1A, 1B or 2 in toys if the use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, the substance is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3] and in addition for CMR substances category 1A and 1B, that there are no suitable alternative substances or mixtures. Appendix A of Annex II to Directive 2009/48/EC contains the list of CMR substances and their permitted uses.

(2) In its opinion[4] adopted on 16 December 2022 and corrected on 9 March 2023 the Scientific Committee on Health, Environmental and Emerging Risks ('SCHEER') identified that cobalt may be present in toys and toy materials as an impurity in nickel and in alloys that contain nickel. These materials have a number of applications in toys including the use of nickel plating, electro-conductive coatings and in alloys such as

---

1 OJ L 170, 30.6.2009, p. 1, ELI: http://data.europa.eu/eli/dir/2009/48/oj.

2 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

3 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, ELI: http://data.europa.eu/eli/reg/2006/1907/2014-04-10).

4 SCHEER - Scientific Opinion on the safety of the presence of cobalt in toys - European Commission (europa.eu).

nickel silver and stainless-steel. Furthermore, in the same opinion SCHEER identified that cobalt may be intentionally added to toys, as for example in the case of cobalt-based pigments or colourants, specific hard metals, batteries and materials for 3-D pens and 3-D printing.

(3) Cobalt, in its metallic form, but also several cobalt salts, such as cobalt sulfate, cobalt di(acetate), cobalt dinitrate, cobalt dichloride and cobalt carbonate, are classified under Regulation (EC) No 1272/2008 as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B, among other hazard classes. The classifications apply as of 1 October 2021 for the metallic cobalt and as of 1 December 2019 for other cobalt ionic forms.

(4) The highest percentage of cobalt as a contaminant of nickel has been estimated by the toy industry to slightly exceed 0,1% in stainless steel and 0,3% in metallic toy materials intended to conduct an electric current not made of stainless-steel. This is higher than the relevant concentration for carcinogens of category 1B provided for in Regulation (EC) No 1272/2008, which is 0,1% according to table 3.6.2 of that Regulation. The related derogation from the prohibition of CMR substances in toys, laid down in Part III, point 4(a), of Annex II to Directive 2009/48/EC therefore cannot be applied.

(5) Furthermore, cobalt in toys can be accessible to children during play, such as when touching metallic toy materials containing metallic cobalt or when coming into contact with cobalt salts containing pigments or colourants such as in powder-like kids cosmetics. The derogation from the prohibition of CMR substances in toys referring to inaccessibility, laid down in Part III, point 4(b), of Annex II to Directive 2009/48/EC therefore, to the extent cobalt and cobalt salts containing materials are concerned, cannot be applied either.

(6) In light of the above, the Commission mandated SCHEER to evaluate the use of cobalt in toys, in particular in view of exposure, with a view to possibly permit those uses in toys that have been evaluated to be safe.

(7) In its opinion adopted on 16 December 2022 the SCHEER considered 6 scenarios (each including one or more exposure mode: inhalation, oral and dermal) as relevant for the exposure assessment and possibly identifying safe uses for which a derogation could be granted.

(8) In scenario 1 cobalt-containing metals are included to allow conduction of electric current. In its opinion mentioned above the SCHEER considered that the risk due to cobalt inhalation associated with the use of cobalt-containing metals can be considered negligible and therefore unlikely to be associated with an increased risk for children playing with such toys. This is why the presence of cobalt in metals intended to conduct the electric current can be considered as safe via inhalation exposure. The SCHEER is of the opinion that dermal exposure to cobalt can be considered negligible, when handling model rail track and model rail track joiners during play or assembly. The SCHEER agrees that no direct oral exposure is expected to occur through intended use of these products, as it is unlikely that metal parts will be ingested from these toy types. Mouthing is considered not to be of concern for the age group of users most likely to play with model railways with metal track. Scrape off during mouthing would not be relevant because of the hardness of the material. However, a possible indirect route of exposure may occur through ingestion of dust present on hands or settling on nearby objects, particularly by children's hand-to-mouth contact.

(9) In scenario 2 cobalt-containing metals serve a function other than electrical conductance like for metal toys, toy jewellery, fidget spinners and magnets. Based on the negligible inhalation exposure related to the use of these toys, the inhalation pathway for cobalt is associated with negligible risk and also exposure to cobalt via the dermal route for these toy types is negligible and unlikely to be associated with increased risk. As concerns oral exposure, although it is the most relevant as to the risk of ingestion of cobalt containing metallic toys, due to data gaps the SCHEER could not perform a quantitative exposure assessment for all these toys since only data for a stainless-steel ball bearing and a slot car magnet was provided.

(10) In relation to metal toys, the analysis of a stainless-steel ball bearing does not appropriately address all possible oral exposure sources from other metallic toys falling under this scenario. However, based on available toxicological reference values for oral exposure, the SCHEER calculated new migration limits for cobalt in toys. In its opinion SCHEER states that compliance with those migration limits should prevent risks associated with oral exposure. Given that scenario 2 covers toys and toy components made of stainless steel, their use should be permitted.

(11) However, due to the uncertainties regarding the carcinogenic properties of cobalt after oral exposure, the SCHEER recommended reducing migration limits to the lowest technically achievable levels.

(12) In relation to magnets, the analysis was based on the data provided for a slot car magnet. The SCHEER supports the view that exposure to cobalt via the dermal route for a slot car magnet is negligible and unlikely to be associated with increased risk. The SCHEER considers the oral exposure as most relevant and recommends migration analysis for oral exposure. Moreover SCHEER recommends using neodymium-based magnets ('NdFeB magnets') in toys as an alternative to Samarium-cobalt (SmCo) magnets.

(13) As NdFeB magnets contain metallic cobalt in quantities exceeding the relevant concentration for carcinogens of category 1B provided for in Regulation (EC) No 1272/2008, their use would be prohibited. Therefore, the use of such magnets should be permitted where those magnets cannot be swallowed or inhaled, i.e. those magnets, toys and their components containing magnets which are not small parts according to the relevant harmonised standard.

(14) In scenario 3 cobalt is used in kids make-up. No or scant data are available on the amount of cobalt (as impurity or part of a colourant) in such toys. Therefore the SCHEER could not provide a quantitative exposure assessment on a representative sample nor conclude on safe uses of cobalt that should be permitted under Directive 2009/48/EC.

(15) In scenario 4 cobalt is used in 3-D pens, materials for toy printers and printed toys. The SCHEER considered that specific attention should be given to inhalation exposure from the emerging use of cobalt-containing materials in 3D pens and 3-D printers. According to the SCHEER opinion cobalt-containing materials should therefore be avoided for 3-D printing. No safe use for cobalt-containing materials in 3D pens and 3-D printers can thus be identified.

(16) In scenario 5 cobalt is used in paintings, inks and coatings used for toys, chalks and chalk bombs and toys made of leather or textiles. The SCHEER is of the opinion that the possibility of ingestion and mouthing needs to be taken into account when assessing the exposure of children to cobalt from those toys. Due to data gaps the

SCHEER could however not perform a quantitative exposure assessment. A potential risk could be associated for inhalation exposure to cobalt from chalks and chalk bombs as well as from powder-like toy materials, containing cobalt-based pigments or colourants in scenario 5. For such toys, the SCHEER recommended that cobalt-free pigments should be used. Accordingly, for this scenario the SCHEER did not identify any safe uses that should be permitted under Directive 2009/48/EC.

(17) In scenario 6 cobalt is used in batteries. The SCHEER is of the opinion that exposure to cobalt from batteries cannot be excluded and that batteries (especially the small button ones) are a realistic source for possible exposure to cobalt, although no quantitative exposure scenario could be provided. Although not specifically concluding on any safe uses that should be permitted under Directive 2009/48/EC, in its above mentioned opinion, the SCHEER acknowledges that the relevant harmonised standard supporting Directive 2009/48/EC requires that small batteries, i.e. batteries that fit wholly within the small parts cylinder, as specified in point 8.2 of EN 71:2014+A1:2018, are not to be removable without the aid of a tool (EN IEC 62115 :2020/A11:2020, clause 13.4.1).

(18) In conclusion, from the SCHEER opinion it appears that cobalt-containing metal toy components intended to conduct electric current, can be permitted as chemically safe. In addition, cobalt can also be permitted in toys and toy components made of stainless steel and in NdFeB magnets used in toys if those magnets cannot be swallowed or inhaled.

(19) The analysis of alternatives carried out by the toy industry in accordance with Part III, point 4(c)(ii), of Annex II to Directive 2009/48/EC, was considered as incomplete by the SCHEER because the analysis did not cover all relevant scenarios. However, as regards metallic cobalt contained in metal toy components intended to conduct electric current, in toys and toy component made of stainless steel, which contain cobalt as an impurity in nickel, and in NdFeB magnets the assessment was complete and did not identify any suitable alternative substances or mixtures available.

(20) In accordance with Part III, points 4(c)(iii) and 5(c)(ii), of Annex II to Directive 2009/48/EC, the use of CMR substances of category 1A, 1B and 2 cannot be permitted if the substance is prohibited for use in consumer articles under Regulation (EC) No 1907/2006. Entries 28 and 30 of Annex XVII to that Regulation only restrict the placing on the market and use of, inter alia, cobalt as a substance or in mixtures for supply to the general public, but not in consumer articles. Entry 75 of Annex XVII to that Regulation only restricts the placing on the market and use of, inter alia, cobalt in mixtures for tattooing purposes, but not in consumer articles. Entry 3 of Annex XVII to that Regulation only restricts the placing on the market and use of liquid substances, including cobalt, in ornamental articles intended to produce light or colour effects, tricks, jokes, games for one or more participants, and articles intended to be used as such games, as well as the placing on the market of lamp oils and grill lighter fuels. The restriction of entry 3 of Annex XVII to Regulation (EC) No 1907/2006, because it applies to cobalt in liquid form, is not considered to amount to a prohibition of use of that substance in consumer articles for the purpose of this derogation as the stainless steel containing cobalt is not expected to be in liquid form. Therefore, the amendment to Directive 2009/48/EC, as set out in this Directive, does not affect the application of entry 3 to toys covered by that entry.

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

(22) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Appendix A of Annex II to Directive 2009/48/EC, the following row is added:

'Cobalt	CMR 1B	In toys and toy components made of stainless steel, as an impurity in the nickel contained in the stainless steel. In toy components which are intended to conduct an electric current. In neodymium-based magnets used in toys if those magnets cannot be swallowed or inhaled.

Article 2

1. Member States shall adopt and publish, by *[Insert here the date 6 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 7 months 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