

**Request for an opinion on the safety of cobalt in toys
with regard to a possible derogation from its prohibition**

1. Background

The Toy Safety Directive 2009/48/EC¹ prohibits the use of substances in toys if those substances are classified as carcinogenic, mutagenic or toxic for reproduction (CMR)^{2,3}. Under certain conditions, however, the use of such substances may be permitted.

To permit the use of a CMR substance of category 1B, the substance has to be evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure. An additional condition is that there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives. Finally, the substance must not be prohibited for use in consumer articles under REACH^{4,5}.

Cobalt (CAS number 7440-48-4) has been classified as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B, among others^{6,7}. The toy industry has

¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.06.2009, p. 1.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589882074178&uri=CELEX:02009L0048-20191118>

² Annex II, Part III, point 3 of the Toy Safety Directive.

³ 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.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589288952589&uri=CELEX:32008R1272>

⁴ Annex II, Part III, point 4 (c) of the Toy Safety Directive.

⁵ REACH: 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.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589281141090&uri=CELEX:32006R1907>

⁶ Committee for Risk Assessment (RAC), Opinion proposing harmonised classification and labelling at EU level of cobalt. 22.9.2017.

https://echa.europa.eu/documents/10162/23665416/clh_opinion_cobalt_6858_en.pdf/b7316b11-ae65-1dd0-2e64-bb6ad3efbd82

⁷ Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation. OJ L 44, 18.2.2020, p. 1.

signalled the presence of cobalt in toys and toy materials, as an impurity in nickel and in alloys that contain nickel, up to slightly exceeding 0.3% for example in toy materials intended to conduct an electric current not made of stainless steel⁸. TIE has also undertaken an analysis of alternatives⁹.

Cobalt was further found in consumer products other than toys, when they were made of or with leather¹⁰. A study on the bioaccessibility of (nickel and) cobalt in stainless steel, alloys and artificial sweat has been made available¹¹.

2. Terms of reference

SCHEER is asked:

1. to review the available data on the presence of cobalt in particular in toys and toy materials;
2. to assess whether the use of cobalt in toys and toy materials can lead to exposure;
3. to assess whether the TIE analysis of alternatives referred to in the background above can be considered sufficiently complete for the safety evaluation requested in point 4 below;
4. to evaluate whether the presence of cobalt in toys and toy materials can be considered to be safe in light of the exposure identified, and in light of the classification of cobalt as outlined in the background above. Safe toys and toy materials should be indicated.

Timeline:

Preliminary opinion – autumn 2021

Final opinion – by the end of 2021

Annexes: 1. Toy Industries of Europe (TIE), Background document ... [on the] uses of cobalt (EC N° 231-158-0, CAS N° 7440-48-4) in certain toy materials. 8 July 2020.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.044.01.0001.01.ENG&toc=OJ:L:2020:044:TOC

⁸ Toy Industries of Europe (TIE), Background document ... [on the] uses of cobalt (EC N° 231-158-0, CAS N° 7440-48-4) in certain toy materials. 8 July 2020. See annex 1 to this mandate.

⁹ Toy Industries of Europe (TIE), Cobalt in certain toy materials - Analysis of alternatives as required by the Toy Safety Directive in the framework of a request for an Appendix A derogation for CMR 1A and 1B substances. 5 May 2020. See annex 2 to this mandate.

¹⁰ Swedish Chemicals Agency, Enforcement project on Co and CrVI. 2019. See annex 3 to this mandate.

¹¹ X. Wang, et al. (2019) Bioaccessibility of nickel and cobalt in powders and massive forms of stainless steel, nickel- or cobalt-based alloys, and nickel and cobalt metals in artificial sweat. Regulatory Toxicol. and Pharmacol. 106:15-26. See Annex 4 to this mandate.

2. Toy Industries of Europe (TIE), Cobalt in certain toy materials - Analysis of alternatives as required by the Toy Safety Directive in the framework of a request for an Appendix A derogation for CMR 1A and 1B substances. 5 May 2020.
3. Swedish Chemicals Agency: Enforcement project on Co and CrVI. 2019.
4. X. Wang, et al. (2019) Bioaccessibility of nickel and cobalt in powders and massive forms of stainless steel, nickel- or cobalt-based alloys, and nickel and cobalt metals in artificial sweat. *Regulatory Toxicol. and Pharmacol.* 106:15-26; and its Supplemental Material.