

Last Name	First name	Organisation/company	E-mail	Country	Table of contents	Please indicate the line numbers of the text on which you comment, if appropriate	SCHEER response
Craen	Hans	EPBA - European Portable Battery Association	epba@kellencompany.com	Belgium	SUMMARY	Page 7, line 9 Cobalt is indeed used in various types of batteries such as Lithium-Ion and certain cylindrical Alkaline batteries. The use of Cobalt in portable batteries has a specific function and can be present for the Lithium-Ion segment in composite electrodes, consisting of active materials (e.g. LiCoO2), conductive additives, and polymeric binder. For certain Alkaline cylindrical cells, cobalt is used on the inner side of the can to reduce corrosion during long term storage.	Thank you for the information.
Craen	Hans	EPBA - European Portable Battery Association	epba@kellencompany.com	Belgium	OPINION or CONCLUSIONS	Page 16 Line 17 The 2009 Toy Safety Directive requires that the compartments of small batteries for toys are not accessible by children. This is an essential safety requirement to ensure that children having a normal and foreseeable use of toys cannot have access to the battery  Line 18 The presence of Cobalt is always inside a portable battery. We are not aware that cobalt is used in the contacts of portable batteries. A battery is considered an article under the REACH legislation which does not release the substances during normal and foreseeable use.  Line 19 We do not agree that destroying a toy is to be considered as a normal and foreseeable use of the product. It is unclear what scientific evidence can underbuilt such a statement. If the destruction of a toy is considered as normal use, the current applicable legislation should be strengthened to avoid destruction rather than regulating products, such as batteries, which do not fall within the scope of the toys legislation. The REACH legislation and the revision of the batteries legislation provide Instruments to have a comprehensive review of the use of substances in batteries. The SCHEER evaluation is based on assumptions  Line 22 The reference to the US Poison Control Centre only show the number of reported ingestion incidents of button cells. The data do not conclude nor imply that these demonstrate [...] a realistic source for exposure to cobalt.	With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user. The SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR, agreed with the mandating DG, has been included in the Opinion in 5.3
Craen	Hans	EPBA - European Portable Battery Association	epba@kellencompany.com	Belgium	OPINION or CONCLUSIONS	Page 13, Line 55 Batteries should not be included in the scope of the evaluation. It is the only product covered by an exposure scenario which is not a toy. As mentioned above, batteries are regulated by a separate product-specific legislation. Any discussion on substances used in batteries should be covered via REACH or the soon to be adopted new batteries legislation. Small batteries are not accessible in products which comply with the Toy Safety Directive.	With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user. The SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR , agreed with the mandating DG, has been included in the Opinion in 5.3

Craen	Hans	EPBA - European Portable Battery Association	epba@kellenccompany.com	Belgium	SUMMARY	<p>Page 9, line 14:  <input type="checkbox"/> Batteries cannot be considered as 'other metal toys'. Batteries are products which sole purpose is to power devices. It is not intended and should not be used as a toy.  <input type="checkbox"/> On EU level, batteries are regulated by the batteries legislation and not by the Toy Safety Directive.  <input type="checkbox"/></p>	<p>With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user.  The SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR, agreed with the mandating DG, has been included in the Opinion in 5.3</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	REFERENCES	<p>Page 45 line 44:  Incorrect reference. Should be: Heim KE, Danzeisen R, Verougstraete V, Gaidou F, Brouwers T, Oller AR. 2020. Bioaccessibility of nickel and cobalt in synthetic gastric and lung fluids and its potential use in alloy classification. Regul Toxicol Pharmacol 110: 104549. Incorrect reference. Should be: Heim KE, Danzeisen R, Verougstraete V, Gaidou F, Brouwers T, Oller AR. 2020. Bioaccessibility of nickel and cobalt in synthetic gastric and lung fluids and its potential use in alloy classification. Regul Toxicol Pharmacol 110: 104549.</p>	<p>Thanks for highlighting it. The correct reference is included in the final opinion</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.6 Risk Assessment	<p>Page 42 lines 40-41:  There is no restriction for cobalt in textiles. There is a final opinion by RAC and SEAC included the Registry of Intentions. The RAC/SEAC propose a total content limit of 70mg/kg Co in textiles and 15mg/kg Co in leather.</p>	<p>This is indeed a proposal, not yet a formal restriction. The text has been changed accordingly.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.6 Risk Assessment	<p>Page 42 lines 9-25:  The calculation is incorrect. The limits are 100 times lower than they should be. The equation is the same as RIVM (2008). For example, using 8mg toy material:  <input type="checkbox"/> <math>(10 * 0.0016 \text{ mg/kg bw/day} * 7.5\text{kg}) / (8\text{mg} * 100) * 106 = 150\text{mg/kg toy material}</math>  <input type="checkbox"/> <math>X\% \text{TDI}(\text{mg/kg bw/day}) * \text{Body weight (kg)} / \text{Amount of toy ingested (mg/day)}</math>  <input type="checkbox"/> The existing limits in the TSD are calculated based on a TDI of 1.4ug/kg bw/day. By adopting the threshold TDI of 1.6 ug/kg bw/day are SCHEER proposing that the migration limits need to increase? <input type="checkbox"/>  <input type="checkbox"/> Limit values using 1.6ug/kg bw/day  Scraped off 150mg/kg (TSD 130 mg/kg)  Dry, powder like 12 mg/kg (TSD 10.5 mg/kg)  Liquid 3 mg/kg (TSD 2.6 mg/kg)  <input type="checkbox"/>  Page 42 line 19:  Should be 10 to the power of 6 not 106</p>	<p>Thank you. The opinion has been changed accordingly.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.5.2.6 Toys containing batteries	<p>Page 39 lines 34-36:  The TSD indicates that toys shall be assessed when they are used as intended or in a foreseeable way taken into account the behaviour of children. Account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user. Destroying a toy and exploring its interior has however never been considered as a foreseeable way of use. In normal use, cobalt in a lithium-ion (LCO) battery will not be released – meaning there is a very low risk of exposure. If the battery were to be completely destroyed, and the enclosed lithium-ion battery pouch or cylinder subsequently pierced, the immediate concern is likely to be thermal runaway and fire, rather than the toxicity of the chemicals within. With ingestion of batteries, particularly coin cell types, the immediate concern is most likely rapid tissue necrosis (internal burn injuries) resulting from the current produced by the battery. SCHEER is asked to delete that part as it is not a realistic scenario. <input type="checkbox"/>  <input type="checkbox"/>  Page 39 line 38:  Button cells and coin cells that are lithium based are primary cells that do not have cobalt cathodes.</p>	<p>With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user.  The SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR has been agreed with the mandating DG at the very beginning and included in the Opinion in 5.3</p>

Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.5.2.5 Cobalt-containing paintings, inks and coatings used for toys and toys made of leather or textiles	<p>Page 39 line 23: A quantitative assessment has been performed by the Cobalt REACH Consortium. The dossier contains exposure scenarios under REACH that address consumer exposure (accidental ingestion of painted toy material by children) that may be of relevance to SCHEER. The long term systemic oral exposure to cobalt bis(2-ethylhexanoate) in this scenario was 0.61 µg/ kg bw/day with a corresponding RCR &lt; 0.01.</p> <p>Page 39 lines 25-27: See comments on terms of reference page 11 related to elemental cobalt versus cobalt-based pigments/colourants.</p> <p>Page 39 line 28: It is not understood why suffocation is relevant</p>	<p>The SCHEER agrees with the comment regarding the possible relevance of the accidental ingestion of painted toy material by children: the information is now added in the opinion.</p> <p>The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion in 5.3.</p> <p>The SCHEER agrees that suffocation does not pertain to cobalt content in toys. Suffocation has, therefore, been removed from the text.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.5.2.4 Exposure scenario for 3-D pens and toy printers	<p>Page 39 lines 7-17:☐ This study suggests that cobalt may be released by emission in the air when PLA is melted. It is quite unclear whether the release is related to elemental cobalt or most probably from cobalt-based pigments/colourants – See also comments on terms of reference page 11.</p>	<p>The SCHEER agrees with the comment. However, it is not relevant to the exposure assessment followed and does not affect it. No changes are needed in the text. The SCHEER is asked to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). Therefore the SCHEER included the different forms of cobalt that could be present in any toy material as a source of foreseeable exposure for children, and does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. Please see interpretation of the ToR in 5.3 in the final Opinion, which was agreed with the mandating DG.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.5.2.3 Exposure scenarios for kids' cosmetics: cobalt in toy make up sets	<p>Page 36 line 36:☐ See comment for page 24 Table 3. Cobalt chloride was not identified. ☐ ☐ Page 38 lines 23-25:☐ This is incorrect. Data are provided the Corrazza study referenced by SCHEER in this draft opinion. This study provides evidence that the content of cobalt in lip products is &lt; 1ppm.</p>	<p>In table 3 CoCl<sub>2</sub> as been replaced by Co, as reported in the cited paper. However the paper reported: "Cobalt was present in amounts over 5 ppm in 5/52 (9.6%) samples. Powdery toy make-up (eye shadows) had the highest levels of metals, and "creamy" toy make-up (lip gloss and lipsticks) the lowest": since the levels in lipstick were low, only eyeshadows have been mentioned.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.5.2.2 Cobalt-containing metals that serve a function other than electrical conductance	<p>Page 36 lines 8-10: The Wennervaldt paper cited does not make reference to the alloying of cobalt in jewellery. Could SCHEER clarify the statement?</p> <p>Page 36 line 13: Information is available in the literature that suggests the occurrence of cobalt in jewellery is limited. In a survey of jewellery on the Danish market, cobalt release was found in 4 (1,1%) of 354 items. All these had a dark appearance. SEM/EDS was performed on the four dark appearing items which showed tin-cobalt plating on these. (Thyssen et al (2010) Cobalt release from inexpensive jewellery: has the use of cobalt replaced nickel following regulatory intervention? Contact Dermatitis; 63 (2); 70-76). Two studies related to the German market identified the presence of cobalt, but primarily in earrings and piercing posts. (Uter, W., Schmid, M., Schmidt, O., Bock, C. &amp; Wolter, J. Cobalt release from earrings and piercing jewellery - Analytical results of a German survey. Contact Dermatitis 70, 369-375 (2014). Uter, W. &amp; Wolter, J. Nickel and cobalt release from earrings and piercing jewellery – analytical results of a German survey in 2014. Contact Dermatitis 78, 321-328 (2018).) Toy jewellery would be highly unlikely to include items for pierced ears or piercing posts. It is not clear why SCHEER is recommending a survey when data does in fact exist. Furthermore, SCHEER on Page 42, Line 35 of the Draft Opinion conclude that dermal exposure is in any case likely to be minimal. See also comment page 9 line 14 on the toy/non-toy classification of jewellery kits.</p>	<p>Thank you for spotting this editing error; the correct Wennervaldt paper on cobalt has now been cited. Thank you for pointing out the other literature, which was known to the SCHEER. Inexpensive jewellery is indeed not primarily a toy. The recommendation regarding a survey has been removed.</p> <p>The SCHEER has changed the final opinion in order to clarify that only 'toy jewellery' complying with the description as indicated in the Explanatory Guidance Document on the Toy safety Directive is addressed. This is now explained in chapter 5.3 in which the SCHEER interpretation of the ToR agreed with the mandating DG is given.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.5.2.1 Cobalt-containing metals included to allow conduction of electric current	<p>Page 34 line 36: The SCHER in 2012 did not question TIE's exposure estimation of 3 hours (Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys). Could SCHEER provide further argumentation to support a 7 hours exposure?</p>	<p>Electric toys that require setting up and preparation have become more widespread. They also keep children's interest for longer. Therefore, in the judgement of SCHEER, playing with such toys for only 3 hours in a week is too little time. The Opinion does not need to be changed.</p>

Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.4.1. Health Effects to humans	<p>Page 29 line 26.</p> <p>The medical devices sector recently published a suite of papers that included a risk assessment for both carcinogenicity and reproductive toxicity associated with cobalt-containing alloys (Eichenbaum et al. 2021, Kovochich et al. 2021, Monnot et al. 2021 and Zhang et al. 2021).</p> <p>In an analysis of the carcinogenic hazard of cobalt-containing alloys (CoCA), 33 in vivo studies in animals with exposures relevant to medical implants were analysed. It was shown that there was no significant increase in local or systemic tumours from implant-like exposures in these studies, indicating that medical devices would unlikely be a carcinogenic hazard in humans (Kovochich et al. 2021). In support, a review of 20 publications on patients with orthopaedic implants concluded that there was no association between exposure to a CoCA implant and overall cancer risk, nor was there a difference in cancer risk when comparing patients with CoCA implants and non-metal implants (Zhang et al. 2021).</p> <p>Regarding the potential hazard of reproductive toxicity, the authors compared the systemic doses following a maximally tolerated intake of cobalt via the oral or inhalation route, compared with a maximally achievable systemic dose generated by cobalt release from a CoCA medical device. It is concluded that cobalt exerts reproductive toxicity only at extremely high doses, in combination with other toxicity, and not as a primary effect. Therefore, cobalt metal should only be considered as a category 2 reproductive toxicant ("suspected human reproductive toxicant"). Implanted CoCA, from which a systemic dose sufficient to cause reproductive toxicity is extremely unlikely to occur, should not be considered as a reproductive hazard (Monnot et al. 2021).</p> <p>Eichenbaum G, Wilsey JT, Fessel G, Qiu QQ, Perkins L, Hasgall P, Monnot A, More SL, Egnot N, Sague J et al. 2021. An</p>	<p>Thank you for this comment. However, the routes of exposure for toys are different than those relevant to medical devices. It is clear from the papers cited that the route of exposure plays a significant role in the final effect. Exposure to cobalt from medical devices has been added to the chapter regarding other sources.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.4. Toxicity and health effects	<p>Page 27 line 27:☐</p> <p>Instead of Lyson et al. (2018) this should be titled Lison et al. (2018). The remainder of the reference was correct in the SCHEER document.</p>	<p>The reference has been corrected in the Opinion.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.4. Toxicity and health effects	<p>page 27 line 20: second continuation of our comments (not enough space available)☐</p> <p>Van den Brule, S., Iboursaaten, S., Brombin, L., Lison, D., 2022. A tiered approach to investigate the inhalation toxicity of cobalt substances. Tier 2 a: grouping cobalt compounds based on their capacity to stabilize HIF-1α in human alveolar epithelial cells in vitro. Reg Pharm Tox Vol 130. <a href="https://www.sciencedirect.com/science/article/pii/S0273230022000083">https://www.sciencedirect.com/science/article/pii/S0273230022000083</a> ☐</p> <p>Verougstraete, V., Danzeisen, R., Viegas, V., Marsh, P., Oller, A., 2022. A Tiered Approach to Investigate the Inhalation Toxicity of Cobalt Substances. Tier 1: Bioaccessibility Testing. Regul. Toxicol. Pharmacol. Vol 129. ☐ <a href="https://www.sciencedirect.com/science/article/pii/S0273230022000113">https://www.sciencedirect.com/science/article/pii/S0273230022000113</a> ☐</p> <p>Viegas, V., Burzlaaf, A., Brock III, T.O., Danzeisen, R., 2022. A tiered approach to investigate the inhalation toxicity of cobalt substances. Tier 3: inflammatory response following acute inhalation exposure correlates with lower tier data. Regul. Toxicol. Pharmacol. Vol 130. <a href="https://www.sciencedirect.com/science/article/pii/S0273230022000149">https://www.sciencedirect.com/science/article/pii/S0273230022000149</a> ☐</p>	<p>Thank you for the additional references related to inhalation toxicity and bioaccessibility. The bioaccessibility information has been added to the appropriate chapter. However the part on toxicity in the opinion was considered not to be amended, since the additional testing proposal is still under evaluation by ECHA</p>

Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.4. Toxicity and health effects	<p>Page 27, line 20 (continuation of our previous comment as not enough available space):  Based on the legal text of the CLP regulation, as there is no conclusive evidence of carcinogenicity (or lack thereof) via other routes of exposure, an H350 hazard phrase ('carcinogen via all routes of exposure') was applied to cobalt metal. In 2020, Cobalt Institute and Nickel Institute (NI) submitted a formal request to generate data via the oral route. A testing proposal was submitted to ECHA under the REACH regulation, to conduct a combined oral chronic/carcinogenicity study in rats with cobalt dichloride (i.e. highly bioavailable cobalt substance). This testing proposal is awaiting a draft final decision from ECHA as of 2nd September 2022.</p> <p>Genotoxicity  The 'nuclear anomalies' (i.e. apoptotic effects) in the GI tract have been discussed in in the Kirkland et al. (2015) paper. In comments submitted into the public consultation Professor Kirkland writes, "The CLH document also focuses on the nuclear anomalies (NA) seen in the intestines of rats in the same study. It is not clear how this is viewed by the authors of the CLH document, but as discussed in Kirkland et al (2015), the biological relevance of these unconventional markers is unclear and is not considered evidence of genotoxicity".  Recent, state-of-the-art genotoxicity tests (ToxTracker) were conducted for cobalt and cobalt substances with inorganic ligands. These tests supported the overall genotoxicity database that cobalt is an indirect (i.e. non-mutagenic) genotoxicant.</p> <p>Burzlaff, A., Creutzenberg, O., Schaudien, D., Viegas, V., Danzeisen, R., Warheit, D., 2022. A tiered approach to investigate the inhalation toxicity of cobalt substances. Tier 4: effects from a 28-day inhalation toxicity study with tricobalt tetraoxide in rats.</p>	The changing of the CLH Opinion adopted by RAC (2017) CLH-O-0000001412-86-172/F is not under the remit of the SCHEER. The additional testing proposal is still under evaluation by ECHA.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.4. Toxicity and health effects	<p>Page 27, line 20 (continuation of our previous comment as not enough available space):  The ECHA CLH opinion (2017) and ECHA Restriction Opinion (2020) evaluated the carcinogenicity of cobalt and cobalt substances (5 soluble Co salts). □  The Cobalt Institute (CI) states that there is enough data existing in the public domain (contributed heavily from the advent of the REACH regulation) to demonstrate that carcinogenicity induced by the cobalt ion has a threshold dose-relationship (i.e. safe level at which no cancer is predicted to occur). This is due to the preceding events in the mode-of-action for 'reactive' cobalt substances, which consists of oxidative stress, hypoxia, cytotoxicity and inflammation, all of which are known threshold events. The CI has published a series of papers in a special edition issue on the carcinogenicity and genotoxicity of cobalt and certain cobalt substances (available open access; Burzlaff et al., 2022, Danzeisen et al. 2022a, Danzeisen et al. 2022b, Derr et al. 2022, van den Brule et al., 2022, Verougstraete et al. 2022 and Viegas et al. 2022). These papers outline a read-across approach for cobalt substances for the endpoints of carcinogenicity and longer-term inhalation toxicity. ECHA has stated it is difficult to determine a numerical threshold from the empirical data available. Due to this lack of a numerical threshold, ECHA and the Committee for Risk Assessment (RAC) derived a non-threshold relationship (i.e. cancer risk at every exposure), with a 'breakpoint' implemented at 1 µg Co/m3 (i.e. exposure level at which cancer risk is reduced by 10-fold). The CI has used high quality, recent epidemiological workplace evidence alongside the NTP carcinogenicity studies for cobalt metal and cobalt sulphate in a weight-of-evidence approach to present a combined dose-response relationship. At the workplace exposures studied, no increase in cancer risk relating to cobalt exposure was observed. In the NTP rodent studies, with both cobalt metal and cobalt sulphate, lung cancer occurred at all exposure levels. The workplace exposures are considered to be at the level of the workplace exposures studied in the NTP rodent studies.</p>	The paragraph of the mode of action has been amended accordingly, however the overall assessment of the SCHEER has not been changed.

Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.4. Toxicity and health effects	<p>Page 20 line 19: For bioavailable cobalt substances (including cobalt metal and the 5 soluble cobalt salts ), exposure via the oral route led to identification of an increase in erythrocytosis as the most sensitive leading effect (i.e. effect seen at the lowest dose). This effect has been observed in OECD- and GLP-compliant studies, and the majority of older, published studies, as occurring before reproductive toxicity and/or lung toxicity.</p> <p>A plausible mode-of-action for reproductive toxicity (male rodents, testes effects) commonly begins with the release of the cobalt ion above a certain threshold, resulting in the induction of hypoxia under normoxic conditions. As a consequence of this hypoxic-effect and observed in humans and in OECD- and GLP-compliant studies conducted under REACH, an increase in erythropoiesis is observed. In a sub-chronic oral repeated dose toxicity study conducted under REACH, no reproductive toxicity effects were observed at any dose (Danzeisen et al., 2020). Instead, at maximum tolerated dose (achieved at high dose), significant increases in polycythaemia / erythrocytosis were observed along with significant decreases in body weight.</p> <p>Also outlined in the Danzeisen et al. (2020) paper is a read-across and grouping strategy that defined two groups of cobalt substances:</p> <ol style="list-style-type: none"> <li>1. Highly bioavailable/bioaccessible (based on bioelution) cobalt substances (cobalt metal, five cobalt salts, cobalt monoxide, cobalt dihydroxide, cobalt lithium dioxide, cobalt propionate, cobalt octoate, cobalt borate octoate, cobalt acetyl acetonate and cobalt oxalate) and</li> <li>2. Poorly bioavailable/bioaccessible cobalt substances (tricobalt tetraoxide, cobalt sulphide and cobalt hydroxide oxide).</li> </ol> <p>In addition, based on repeated-dose oral toxicity data generated under REACH (i.e. OECD 422 RDT oral studies with reproductive/developmental toxicity screening), a third group is</p>	<p>Thank you for the interesting discussion. Relevant points have been included in the Opinion (toxic effects and bioaccessibility).</p> <p>The SCHEER assessment was not changed.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.3.1. Possible alternatives to cobalt for use in toys	<p>Page 25 line 9: TIE only provided information on alternatives for the defined scope of the document where cobalt metal was identified as an impurity. The industry does not use or intend to use cobalt or cobalt compounds in other applications since in many cases cobalt compounds are classified as CMR which restricts/bans their use. In addition, the requirement to meet migration limits for cobalt necessarily limits the applications where cobalt/cobalt compounds could be used.</p> <p>Page 25 line 12: While batteries may be used in toys, these do not fall within the definition of a toy. Therefore, this was not addressed in the analysis of alternatives. Furthermore, alternative batteries such as LiMn2O4 still contain hazardous substances.</p> <p>Page 26 line 5: Could SCHEER provide evidence that SmCo magnets are used in toys. Most toy manufacturers where a magnet is required use neodymium-based technology. Furthermore, access to magnets in toys is already limited in EN71-1. In neodymium magnets, cobalt is not easily separated from the other elements in the magnet, and it is coated by a thick protective layer of zinc plating. The current soluble content test is already sufficient to ensure that there is not a risk to the consumer or the environment</p> <p>Reference is made to very rare metals such as samarium and neodymium which do not have full REACH registration dossier/any higher tier data to truly compare toxicities against cobalt and cobalt substances.</p> <p>Page 26 line 9: This is already the case.</p>	<p>Thank you for the clarification. However, the mandate to SCHEER included the examination of all alternatives.</p> <p>With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user.</p> <p>The SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR, agreed with the mandating DG, has been included in the Opinion in 5.3</p> <p>It is not the responsibility of SCHEER to provide any such evidence. A simple search on the internet can provide various pages of magnet suppliers and manufacturers that claim SmCo magnets are used in toys. The SCHEER does not find it appropriate to cite commercial sites.</p>
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.3. Presence of cobalt in toys	<p>Page 25 line 3: TIE would disagree that the weight of evidence for the qualitative presence of cobalt in toys is strong based on our critique of the references in Table 3. Further, since 2005 there have only been two Safety Gate notifications for cobalt migration from toys. These notifications were about a modelling clay and a finger paint for which the migrated amount of cobalt (not due to the presence of elemental cobalt but cobalt-based pigments/colourants) exceeded the legal values set by the TSD. Industry experience shows that cobalt failures are extremely rare and in most cases, cobalt is not detected according to the EN71-3 method.</p>	<p>The SCHEER made use of relevant available scientific literature for its evaluation of possible sources for cobalt. The market surveillance is an instrument of enforcement control for regulation. There is no representative testing for all types of toys. Only results exceeding limit values are published. Data from market surveillance can therefore not be used by the SCHEER to identify possible sources for cobalt. No change of Opinion is needed.</p>

Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.3. Presence of cobalt in toys	Page 25 Table 3: <input type="checkbox"/> Alkyd resin paints are only likely to contain 0.02–0.06 wt.-% Co in solvent-borne paints. Boer, Johannes & Wesenhausen, Philana & Wenker, Erica & Maaijen, Karin & Gol, Franjo & Gibbs, Hugh & Hage, Ronald. (2013). The Quest for Cobalt-Free Alkyd Paint Driers. European Journal of Inorganic Chemistry. 2013. 3581-3591	Thank you. The reference list has been updated accordingly.
Billeret	Dominique	Toy industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.3. Presence of cobalt in toys	Page 24 table 3: <input type="checkbox"/> Cobalt acetate is not included in the Aurisano study (see comment related to page 23). Can SCHEER provide a different reference to support this statement? <input type="checkbox"/> <input type="checkbox"/> Cobalt chloride is not included in the Corrazza et al study. Cobalt was quantified in some toy cosmetic samples but at low levels. More data from this paper should be presented. In the study 24/29 eye shadows contained < 5ppm cobalt and all samples of lipsticks, lipbalm, nail polish and lip pencils contained < 1ppm cobalt. These limited results suggest impurities rather than intentional use. A typical frame formulation for a lipstick would include about 5% pigment w/w. Toys that are cosmetics also have to comply with the Cosmetics Products Regulation which prohibits the use of many cobalt colourants in Annex II, with the exception of CI 77346 Cobalt Aluminum Oxide which is a permitted colourant in Annex IV of the CFR.	Thank you. Table 3 has been updated and the reference to the Aurisano study was deleted. In table 3 CoCl <sub>2</sub> as been replaced by Co, as reported in the cited paper from Corrazza et al. However the paper reported: 'Cobalt was present in amounts over 5 ppm in 5/52 (9.6%) samples. Powdery toy make-up (eye shadows) had the highest levels of metals, and "creamy" toy make-up (lip gloss and lipsticks) the lowest'. since the levels in lipstick were low, only eyeshadows have been mentioned. The Opinion has been changed accordingly
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.3. Presence of cobalt in toys	Page 24 lines 3-10: <input type="checkbox"/> Lithium-ion batteries have built in short circuit protection and toys also have to comply with the strict requirements of EN62115 for electric toys in terms of short circuit performance. While TIE agree that such an event cannot be excluded, the probability of occurrence is likely to be negligible and not relevant for exposure assessment. Ingestion of batteries, particularly coin and button cells, does occur mainly from non-toy products that do not need to meet the strict EN 62115 toy requirements regarding accessibility to button batteries and coin cells (or from unsafe illegal toys). However these are primary lithium cells and should not be confused with lithium ion secondary cell technology where cobalt is present in the cathode.	The SCHEER disagrees. There are various rechargeable button or coin batteries in the market that are lithium ion batteries and contain cobalt (e.g., <a href="https://ufdcimages.uflib.ufl.edu/UF/E0/04/34/92/00001/erol_s.pdf">https://ufdcimages.uflib.ufl.edu/UF/E0/04/34/92/00001/erol_s.pdf</a> ). It is not appropriate for the SCHEER to cite here battery manufacturers' web sites.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	6.3. Presence of cobalt in toys	Page 23 lines 27-29: <input type="checkbox"/> The Aurisano paper referenced by SCHEER does not adequately support the statement that all toys may contain cobalt derivatives. The authors include cobalt as a substance that could not be characterised in the study, in other words it was included in regulatory lists but without exposure or toxicity estimates. The inclusion of cobalt in the Aurisano paper is based on evidence from a single study in the Lebanon (Korfali, S.I., Sabra, R., Jurdi, M. et al. Assessment of Toxic Metals and Phthalates in Children's Toys and Clays. Arch Environ Contam Toxicol 65, 368–381 (2013)). The Korfali study analysed metal content in plastics using hand held energy dispersive X-ray fluorescence (EDXRF) techniques and reported the concentration of cobalt in plastics ranging from ND to 10 ug/g with a mean of 0.85 ug/g. The relevance of this data is open to question since the study was conducted in a non-EU country and the analysis preceded the July 2013 date for the introduction of limits for cobalt in toys in the TSD.	Thank you. Table 3 has been updated and the reference to the Aurisano study has been deleted.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	OPINION or CONCLUSIONS	Page 18 line 44: <input type="checkbox"/> The limit values are calculated incorrectly. See comment related to page 42	Thank you. The opinion has been changed accordingly.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	OPINION or CONCLUSIONS	Page 17 lines 4-6: <input type="checkbox"/> See comments page 11 and comment page 25 line 9. The analysis of alternatives provided by TIE concerns only residual presence of elemental cobalt in toy metallic material as agreed with the European Commission for a potential TSD Appendix A derogation targeting these toy materials.	Thank you for the comment. However, the mandate to SCHEER included the examination of all alternatives.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	OPINION or CONCLUSIONS	Page 16 line 12: It is not understood why suffocation is relevant	The SCHEER agrees that suffocation does not pertain to cobalt content in toys. Suffocation has, therefore, been removed from the text.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	OPINION or CONCLUSIONS	Page 14 lines 29-30: See comment page 34 line 36	Thank you for this comment. However, the routes of exposure for toys are different than those relevant to medical devices. It is clear from the papers cited that the route of exposure plays a significant role in the final effect. Exposure to cobalt from medical devices has been added to the chapter regarding other sources.

Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	SUMMARY	Page 9 - lines 42-46: See comment page 42 line 40	This is indeed a proposal, not yet a formal restriction. The text has been changed accordingly.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	SUMMARY	Page 9 lines 21-27:□ The limit values are calculated incorrectly. See comment related to page 42	Thank you. The opinion has been changed accordingly.
Billeret	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	SUMMARY	page 9 line 14: □ It is unclear what is meant by "kids cheap jewellery". The word "cheap" seems to refer to illegal/unsafe products placed on the EU market whilst a scientific opinion should refer to products placed on the EU market which are compliant with all the applicable EU rules. It is also unclear whether "kids cheap jewellery" refers to products classified as toys. They need to have a play value to actually be classified as such. The European Commission has published on its website several guidance documents that help to distinguish between toys and children's products. Guidance N°13 related to crafts: <a href="https://ec.europa.eu/docsroom/documents/4624/attachments/1/translations">https://ec.europa.eu/docsroom/documents/4624/attachments/1/translations</a> □ Indicates in its pages 3 and 4:□ "However, some creative kits have only an educational purpose (for example knitting, sewing, embroidering, etc.). The kits are not child appealing, and the end product is not a toy. The purpose of the kit is not play, but learning and mastering a technique (knitting, mosaic, etc.). Therefore, they cannot be qualified as toys. They have to comply with the general safety requirement set out in the General product safety Directive 2001/95/EC (GPSD)." An example of such products is a jewellery set.□	The SCHEER has changed the final opinion in order to clarify that only 'toy jewellery' complying with the description as indicated in the Explanatory Guidance Document on the Toy safety Directive is addressed.  This is now explained in chapter 5.3 in which the SCHEER interpretation of the ToR agreed with the mandating DG is given.
BILLERET	Dominique	Toy Industries of Europe	dominique.billeret@toyindustries.eu	Belgium	MANDATE FROM THE EU COMMISSION SERVICES	The European Commission's mandate asked SCHEER to assess the presence of elemental cobalt in toy metallic materials in light of its classification as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B. The Toy Safety Directive indicates that, when substances and mixtures classified as CMR by the CLP Regulation (EC) No 1272/2008 are contained in individual concentrations exceeding the CLP thresholds for their classification, a decision in accordance with Article 46(3) can be taken to permit a substance and its use via TSD Appendix A. The SCHEER preliminary opinion should make it clearer in its content that it refers to the presence of CLP classified elemental cobalt in concentration slightly exceeding 0.1% in toy metallic materials. Other cobalt derivatives (such as cobalt ions inside cobalt-based pigments/colorants) potentially used in toy materials were not requested to be assessed.  Furthermore, SCHEER should consider that at the REACH Committee meeting on the 27-28th April, the European Commission officially announced that the REACH restriction process for the 5 cobalt salts was to be stopped and instead the eventual legal implementation of an EU-wide binding occupational exposure limit value (OELV) was to be started for cobalt and inorganic cobalt compounds.	The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion in 5.3.
PUNZANO	Florence	BEUC - the European Consumer Organisation	fpu@beuc.eu	Belgium	SUMMARY	BEUC - the European Consumer Organisation, welcomes the preliminary opinion of SCHEER on the use of cobalt in toys and supports its findings and recommendations. □ Exposure to cobalt through toys needs to be minimised and wherever possible be avoided as it is harmful for children's health (Cobalt has been classified as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B). □ We agree therefore with the SCHEER recommendation that for powder-like toy materials only cobalt free pigments should be used and that dermal exposure should be reduced through applying existing ECHA restrictions on cobalt in textiles and leather also to toys□	Thank you.
Melissano	Marino	ANEC	marinomelissano@hotmail.com	Italy	6.2. Physico-Chemical characterisation of cobalt compounds	The greatest Italian consumer association, Altroconsumo, found, in his tests, cobalt beyond the limits, along with traces of nickel and arsenic, in pencils, which, unfortunately, are not considered toys, but are very used by children. We would like to extend the toys Directive to all products commonly used by children.	Thank you for the comment. However, pencils are not considered toys and the extension of the TSD is outside the remit of the SCHEER.

Vandenbergh	Tania	ANEC	tania.vandenbergh@anec.eu	Belgium	SUMMARY	ANEC, the European consumer voice in standardisation, welcomes the SCHEER opinion on the use of cobalt in toys and supports its findings and recommendations. □ □ We agree with the SCHEER recommendation that cobalt-free pigments should be used in toys. □	Thank you for your comment.
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	SUMMARY	A General Comment on the Preliminary Opinion: The European Commission's mandate asked SCHEER to assess the presence of elemental cobalt in toy metallic materials considering its classification as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B. □ The Toy Safety Directive indicates that, when substances and mixtures classified as CMR by the CLP Regulation (EC) No 1272/2008 are contained in individual concentrations exceeding the CLP thresholds for their classification, a decision in accordance with Article 46(3) can be taken to permit a substance and its use via TSD Appendix A. □ The SCHEER preliminary opinion should make it clearer in its content that it refers to the presence of CLP classified elemental cobalt in concentration slightly exceeding 0.1% in toy metallic materials. Other cobalt derivatives (such as cobalt ions inside cobalt-based pigments/colorants) potentially used in toy materials were not requested to be assessed. □	The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion in 5.3.
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.6 Risk Assessment	Page 42 - Line 9-25: The calculation is incorrect. The limits are 100 times lower than they should be. The equation is the same as RIVM (2008). For example, using 8mg toy material: □ □ (10 * 0.0016 mg/kg bw/day * 7.5kg) / (8mg * 100) * 106 = 150mg/kg toy material □ □ The existing limits in the TSD are calculated based on a TDI of 1.4ug/kg bw/day. By adopting the threshold TDI of 1.6 ug/kg-bw/day are SCHEER proposing that the migration limits need to increase? □ □ Limit values using 1.6ug/kg-bw/day □ Scraped off 150mg/kg (TSD 130 mg/kg) □ Dry, powder like 12 mg/kg (TSD 10.5 mg/kg) □ Liquid 3 mg/kg (TSD 2.6 mg/kg) □ □ Page 42 - Line 19: Should reduce the size of number 6, currently reads 106. □ □ Page 42 - Line 40: There is no restriction for cobalt in textiles. There is a final opinion by RAC and SEAC included the Registry of Intentions. The RAC/SEAC propose a total content limit of 70mg/kg Co in textiles and 15mg/kg Co in leather. □	This is indeed a proposal, not yet a formal restriction. The text has been changed accordingly.
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.5.2.6 Toys containing batteries	Page 39 - Line 34-36: The TSD indicates that toys shall be assessed when they are used as intended or in a foreseeable way taken into account the behavior of children. Account has to be taken of the behavior of children, who normally do not show the same care as an average adult user. Destroying a toy and exploring its interior has however never been considered as a foreseeable way of use. SCHEER is asked to delete that part as it is not a realistic scenario. □ □ Page 39 - Line 38: Button cells and coin cells that are lithium based are primary cells that do not have cobalt cathodes.	With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user. The SCHEER is aware of the Toy Safety Directive's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR, agreed with the mandating DG, has been included in the Opinion in 5.3
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.5.2.5 Cobalt-containing paintings, inks and coatings used for toys and toys made of leather or textiles	Page 39 - Line 25-27: See general comments related to elemental cobalt versus cobalt-based pigments/colorants. □ Page 39 - Line 28: It is not understood why suffocation is relevant	The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion. The SCHEER agrees that suffocation does not pertain to cobalt content in toys and has, therefore, suffocation removed from the text.
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.5.2.4 Exposure scenario for 3-D pens and toy printers	Page 39 - Line 7-17: This study suggests that cobalt may be released by emission in the air when PLA is melted. It is quite unclear whether the release is related to elemental cobalt or most probably from cobalt-based pigments/colorants – See also general comments.	The SCHEER agrees with the comment. However, it is not relevant to the exposure assessment followed and does not affect it. No changes are needed in the text.

Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.5.2.3 Exposure scenarios for kids' cosmetics: cobalt in toy make up sets	<p>Page 36 - Line 36: See comment for page 24 Table 3 in The Toy Association comments. Cobalt chloride was not identified. □</p> <p>Page 38 - Line 23-25: This is incorrect. Data are provided the Corazza study referenced by SCHEER in this draft opinion. This study provides evidence that the content of cobalt in lip products is <math>\leq</math> 1ppm. □</p>	<p>In table 3 CoCl<sub>2</sub> as been replaced by Co, as reported in the cited paper from Corazza et al. However the paper reported: 'Cobalt was present in amounts over 5 ppm in 5/52 (9.6%) samples. Powdery toy make-up (eye shadows) had the highest levels of metals, and "creamy" toy make-up (lip gloss and lipsticks) the lowest'; since the levels in lipstick were low, only eyeshadows have been mentioned. The Opinion has been changed accordingly</p>
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.5.2.2 Cobalt-containing metals that serve a function other than electrical conductance	<p>Page 36 - Line 8-10: The Wennervaldt paper cited does not reference the alloying of cobalt in jewelry. Could SCHEER clarify the statement. □</p> <p>Page 36 - Line 13: Information is available in the literature that suggests the occurrence of cobalt in jewelry is limited. In a survey of jewelry on the Danish market, cobalt release was found in 4 (1.1%) of 354 items. All these had a dark appearance. SEM/EDS was performed on the four dark appearing items which showed tin-cobalt plating on these. (Thyssen et al (2010) Cobalt release from inexpensive jewelry; has the use of cobalt replaced nickel following regulatory intervention? Contact Dermatitis; 63 (2); 70-76). Two studies related to the German market identified the presence of cobalt, but primarily in earrings and piercing posts. (Uter, W., Schmid, M., Schmidt, O., Bock, C. &amp; Wolter, J. Cobalt release from earrings and piercing jewelry - Analytical results of a German survey. Contact Dermatitis 70, 369-375 (2014). Uter, W. &amp; Wolter, J. Nickel and cobalt release from earrings and piercing jewelry - analytical results of a German survey in 2014. Contact Dermatitis 78, 321-328 (2018).) Toy jewelry would be highly unlikely to include items for pierced ears or piercing posts. It is not clear why SCHEER is recommending a survey when data does in fact exist. Furthermore, SCHEER on Page 42, Line 35 of the Draft Opinion conclude that dermal exposure is in any case likely to be minimal. □</p> <p>See also comment page 9 line 14 on the toy/non-toy classification of jewelry kits. □</p>	<p>Thanks for spotting this editing error; the correct Wennervaldt paper on cobalt has now been cited. Indeed jewelry for pierced ears is not present in toy kits. Thank you for pointing out this literature, which was considered by the SCHEER. The recommendation regarding a survey has been removed. The SCHEER has changed the final opinion in order to clarify that only 'toy jewellery' complying with the description as indicated in the Explanatory Guidance Document on the Toy safety Directive is addressed.</p> <p>This is now explained in chapter 5.3 in which the SCHEER interpretation of the ToR agreed with the mandating DG is given.</p>
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.5.2.1 Cobalt-containing metals included to allow conduction of electric current	<p>Page 34 - Line 36: TA understands that SCHEER in 2012 did not question TIE's exposure estimation of 3 hours (Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys). Could SCHEER provide further argumentation to support a 7-hour exposure? □</p>	<p>Electric toys that require setting up and preparation have become more widespread. They also keep children's interest for longer. Therefore, in the judgement SCHEER, playing with such toys for only 3 hours in a week is too little time. The Opinion does not need to be changed.</p>
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.3.1. Possible alternatives to cobalt for use in toys	<p>Page 25 - Line 9: The TA understands that TIE only provided information on alternatives for the defined scope of the document where cobalt metal was identified as an impurity. The industry does not intentionally use cobalt or cobalt compounds in other applications since in many cases cobalt compounds are classified as CMR which restricts/bans their use. In addition, the requirement to meet TSD migration limits for cobalt necessarily protects against situations where cobalt/cobalt compounds could be present as an unintentional contaminant.</p> <p>Page 25 line 12: Batteries are not toys, but integral part of toys. Children may be exposed to them under a realistic scenario. The SCHEER suggests that alternatives need to be evaluated for potential risks before they are used.</p> <p>Page 25 - Line 12: While batteries may be used in toys, these do not fall within the definition of a toy. Therefore, this was not addressed in the analysis of alternatives.</p> <p>Page 26 - Line 5: Could SCHEER provide evidence that Sm-Co magnets are used in toys. Most toy manufacturers where a magnet is required use neodymium-based technology. Furthermore, access to magnets in toys is already limited in EN71-1.</p> <p>Page 26 - Line 9: This is already the case</p>	<p>Thank you for the clarification. However, the mandate to SCHEER included the assessment of all possible exposures.</p> <p>With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user.</p> <p>The SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR, agreed with the mandating DG, has been included in the Opinion in 5.3</p> <p>It is not the responsibility of SCHEER to provide any such evidence. A simple search on the internet can provide various pages of magnet suppliers and manufacturers that claim SmCo magnets are used in toys. The SCHEER does not find it appropriate to cite commercial sites.</p>

Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.3. Presence of cobalt in toys	<p>Page 25 - Table 3: Alkyd resin paints are only likely to contain 0.02–0.06 wt.-% Co in solvent-borne paints. Boer, Johannes &amp; Wesenhagen, Philana &amp; Wenker, Erica &amp; Maaijen, Karin &amp; Gol, Franjo &amp; Gibbs, Hugh &amp; Hage, Ronald. (2013). The Quest for Cobalt-Free Alkyd Paint Driers. European Journal of Inorganic Chemistry. 2013. 3581-3591. □</p> <p>Page 25 Table 3: TA disagrees that the weight of evidence for the qualitative presence of cobalt in toys is strong based on our critique of the references in Table 3. Further, since 2005 there have only been two Safety Gate notifications for cobalt migration from toys. These notifications were about a modelling clay and a finger paint for which the migrated amount of cobalt (not due to the presence of elemental cobalt but cobalt-based pigments/colourants) exceeded the legal limit values set by the TSD. Industry experience shows that cobalt failures are extremely rare and in most cases cobalt is not detected according to the EN71-3 method. □</p>	<p>New reference has been added to table 3. The SCHEER made use of relevant available scientific literature for its evaluation of possible sources for cobalt. The market surveillance is an instrument of enforcement control for regulation. There is no representative testing for all types of toys. Only results exceeding limit values are published. Data from market surveillance can therefore not be used by the SCHEER to identify possible sources for cobalt. No change of Opinion is needed.</p>
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	6.3. Presence of cobalt in toys	<p>Page 23 - Line 27-29: The Aurisano paper referenced by SCHEER does not adequately support the statement that all toys may contain cobalt derivatives. The authors include cobalt as a substance that could not be characterized in the study, in other words it was included in regulatory lists but without exposure or toxicity estimates. The inclusion of cobalt in the Aurisano paper is based on evidence from a single study in the Lebanon (Korfali, S.I., Sabra, R., Jardi, M. et al. Assessment of Toxic Metals and Phthalates in Children's Toys and Clays. Arch Environ Contam. Toxicol 65, 368–381 (2013)). The Korfali study analyzed metal content in plastics using hand held energy dispersive X-ray fluorescence (EDXRF) techniques and reported the concentration of cobalt in plastics ranging from ND to 10 ug/g with a mean of 0.85 ug/g. The relevance of this data is open to question since the study was conducted in a non-EU country and the analysis preceded the July 2013 date for the introduction of limits for cobalt in toys in the TSD. □</p> <p>Page 24 - Line 3-10: Lithium-ion batteries have built in short circuit protection and toys also must comply with the strict requirements of EN62115 for electric toys in terms of short circuit performance. While TA agree that such an event cannot be excluded, the probability of occurrence is likely to be negligible and not relevant for exposure assessment. Ingestion of batteries, particularly coin and button cells, does occur mainly from non- toy products that do not need to meet the strict EN 62115 toy requirements regarding accessibility to button batteries and coin cells (or from unsafe illegal toys). However, these are primary lithium cells and should not be confused with lithium-ion secondary cell technology where cobalt is present in the cathode. □</p> <p>Page 24 - Line 16 Table 3: Cobalt acetate is not included in the Aurisano study (see above). Can SCHEER provide a different</p>	<p>Regarding the Aurisano paper, SCHEER agrees that it is not a single paper which can justify the statement that toys may contain Co and cobalt derivatives and for this reason reference to the entire Table 3 has been introduced in the text. The reference to the Aurisano paper which can be questionable has been deleted since the information is supported by many other references.</p> <p>Thank you for the clarification. The SCHEER is aware of the Toy Safety Directive 's requirement that theThe SCHEER is aware of the Toy Safety Directive 's requirement that the compartments of small batteries for toys are not accessible by children, however, the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries as within the ToR of this opinion. The interpretation of the ToR, agreed with the mandating DG, has been included in the Opinion in 5.3</p>
Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	OPINION or CONCLUSIONS	<p>Page 14 - Line 42-46: Please see comment page 34 - line 36 in from the Toy Association. □</p> <p>Page 16 - Line 12: It is not understood why suffocation is relevant. □</p> <p>Page 17 - Line 4-6: See General comments and comment page 25 line 9 from the Toy Association. The analysis of alternatives provided by the toy industry through the Toy Industries of Europe (TIE) concerns only residual presence of elemental cobalt in toy metallic material as agreed with the European Commission for a potential TSD Appendix A derogation targeting these toy materials. □</p> <p>Page 18 - Line 44: The limit values are calculated incorrectly. See comment page 42 from the Toy Association.</p>	<p>The SCHEER agrees that suffocation does not pertain to cobalt content in toys and has, therefore, suffocation removed from the text.</p> <p>The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Refence in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion, please see 5.3.</p> <p>The limit values have been corrected. Thanks for highlighting the mistake.</p>

Kaufman	Alan	The Toy Association	akaufman@toyassociation.org	United States of America	SUMMARY	<p>Page 9 - Line 14: It is unclear what is meant by "kids cheap jewelry". The word "cheap" seems to refer to illegal/unsafe products placed on the EU market whilst a scientific opinion should refer to products placed on the EU market which are compliant with all the applicable EU rules. It is also unclear whether "kids cheap jewelry" refers to products classified as toys. They need to have a play value to actually be classified as such. The European Commission has published on its website several guidance documents that help to distinguish between toys and children's products. Guidance N°13 related to crafts: <a href="https://ec.europa.eu/docsroom/documents/4624/attachments/1/translations">https://ec.europa.eu/docsroom/documents/4624/attachments/1/translations</a>.</p> <p>Indicates in its pages 3 and 4: □</p> <p>"However, some creative kits have only an educational purpose (for example knitting, sewing, embroidering, etc.). The kits are not child appealing, and the end product is not a toy. The purpose of the kit is not play, but learning and mastering a technique (knitting, mosaic, etc.); therefore, they cannot be classified as toys. They are required to comply with the general safety requirement set out in the General Product Safety Directive 2001/95/EC (GPSD)." □</p> <p>An example of such products is a jewelry set. □</p> <p>□</p> <p>Page 9 - Line: 21-27: The limit values are calculated incorrectly. See comment page 42 from the Toy Association. □</p> <p>□</p> <p>Page 9 - Line 42-46: See comment page 42-line 40 from the Toy Association.</p>	<p>The SCHEER has changed the final opinion in order to clarify that only 'toy jewellery' complying with the description as indicated in the Explanatory Guidance Document on the Toy safety Directive is addressed. This is now explained in chapter 5.3 in which the SCHEER interpretation of the ToR agreed with the mandating DG is given.</p> <p>The limit values have been corrected. Thanks for highlighting the mistake.</p>
Waechter	Johannes	Chemical and Veterinary Analytical Institute □ Muensterland-Emscher-Lippe (CVUA-MEL)	johannes.waechter@cvua-mel.de	Germany	SUMMARY	<p>We appreciate this draft opinion of SCHEER and we hope it will contribute to higher safety of toys for children. □</p> <p>SCHEER emphasized that the inhalative exposure to cobalt from powder-like materials is a potential risk for the users of toys. However, toys like chalks and chalk bombs (the latter are expected to produce dust and should therefore have a high risk of inhalative exposure) are not mentioned specifically, only kids' cosmetics and creative art toys. □</p> <p>In addition, chalks and chalk bombs are not mentioned as a relevant exposure scenario in terms of oral exposure. Nevertheless, the new calculated limit (0.12 mg cobalt per kg toy material) could be exceeded for those toys, taking into account our own (limited) examinations of cobalt release from chalk and chalk bombs (according to EN 71-3, category I) in the past. Due to this, chalks and chalk bombs can be seen as relevant for oral exposure to cobalt from toys in our opinion. □</p> <p>□</p> <p>Therefore, we would like the following to be added in the SCHEER opinion: □</p> <p>page 7, line 24-38: in our opinion toys like chalks and chalk bombs are missing as scenarios relevant for exposure assessment; □</p> <p>page 8, line 30-32: in our opinion toys like chalks and chalk bombs should be mentioned as well in terms of potential risk for inhalation exposure; □</p> <p>page 9, line 10-19: in our opinion toys like chalks and chalk bombs should be mentioned as well in terms of relevant risk for oral exposure. □</p> <p>□</p>	<p>The SCHEER thanks for the useful comments: chalks and chalk bombs are now mentioned in the text among the relevant source for inhalation and oral exposures.</p>

Brendel	Martin	Verband der Mineralfarbenindustrie e.V. (VdMI)	brendel@vdmi.vci.de	Germany	ABSTRACT	<p>The Verband der Mineralfarbenindustrie e.V. (VdMI) request / advocates: <input type="checkbox"/></p> <p><input type="checkbox"/></p> <ul style="list-style-type: none"> <li>•No general exclusion of cobalt-containing colourants in toys. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•No general reduction of limit values for cobalt-containing colourants to the detection limit. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•Colouring agents containing cobalt which do not pose a risk according to the risk assessment carried out <input type="checkbox"/></li> <li style="padding-left: 20px;">should not be generally excluded or limited to the limit of detection. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>because <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•There is no scientific justification for equating all cobalt compounds with metallic cobalt. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•CMR classified substances are already banned in toys. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•Therefore, for all colourants / pigments that contain cobalt and that are not CMR classified, a general <input type="checkbox"/></li> <li style="padding-left: 20px;">exclusion or a general limitation to the detection limit for all colourants with cobalt is neither justified, nor <input type="checkbox"/></li> <li style="padding-left: 20px;">expedient or proportionate. <input type="checkbox"/></li> <li><input type="checkbox"/></li> </ul> <p>The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e.g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e.g. silica), carbon black, ceramic and glass colours, food colorants, artists and school paints, masterbatches and products for applied photocatalysis <input type="checkbox"/></p>	The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion.
Brendel	Martin	Verband der Mineralfarbenindustrie e.V. (VdMI)	brendel@vdmi.vci.de	Germany	6.5.2.5 Cobalt-containing paintings, inks and coatings used for toys and toys made of leather or textiles	<p>The Verband der Mineralfarbenindustrie e.V. (VdMI) request / advocates: <input type="checkbox"/></p> <p><input type="checkbox"/></p> <ul style="list-style-type: none"> <li>•No general exclusion of cobalt-containing colourants in toys. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•No general reduction of limit values for cobalt-containing colourants to the detection limit. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•Colouring agents containing cobalt which do not pose a risk according to the risk assessment carried out <input type="checkbox"/></li> <li style="padding-left: 20px;">should not be generally excluded or limited to the limit of detection. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>because <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•There is no scientific justification for equating all cobalt compounds with metallic cobalt. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•CMR classified substances are already banned in toys. <input type="checkbox"/></li> <li><input type="checkbox"/></li> <li>•Therefore, for all colourants / pigments that contain cobalt and that are not CMR classified, a general <input type="checkbox"/></li> <li style="padding-left: 20px;">exclusion or a general limitation to the detection limit for all colourants with cobalt is neither justified, nor <input type="checkbox"/></li> <li style="padding-left: 20px;">expedient or proportionate. <input type="checkbox"/></li> <li><input type="checkbox"/></li> </ul> <p>The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e.g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e.g. silica), carbon black, ceramic and glass colours, food colorants, artists and school paints, masterbatches and products for applied photocatalysis <input type="checkbox"/></p>	The European Commission's mandate asked the SCHEER to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Reference in the Mandate). The SCHEER therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials. The SCHEER added an interpretation of the ToR in its opinion, see 5.3.
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	REFERENCES	<p>Not all references cited in the draft opinion have been included in the reference list. Please check for completeness.</p>	The Opinion has been updated accordingly.

Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.6 Risk Assessment	<p>p.40, lines 26-30 SCHEER concluded that there is a potential (risk) for inhalation exposure for kids cosmetics and toys containing Co-based pigments/colourants. Inhalation exposure has however not been addressed in the respective sections 6.5.2.3 and 6.5.2.5. Please add.</p> <p>p.41, line 22 Please specify what the population exposure to cobalt is (not given in e.g. section 6.5.2.7).</p> <p>p.41, lines 31 and 41 It is noted that a slot car magnet scenario has not been described in the draft opinion (in 6.5.2.2 it is a scenario for a stainless-steel ball bearing).</p> <p>p.41, lines 31-37 For transparency, it is proposed to add an annex with the details of the risk assessment performed by TIE. For this risk assessment, TIE apparently used a TDI of 1.5 µg/kg bw/d. Should that have been 1.6 µg/kg bw/d, or did TIE derive its own TDI? And what was the basis for the DNEL of 29.8 µg/kg bw/d?</p> <p>p.41, lines 44-46 Plus 3-D pens. Given the low exposures estimated for this scenario (0.00010-0.00018 ng/kg bw/d, according to Annex 2), this scenario in itself would not present an oral risk.</p> <p>p.42, lines 9-25 The calculation of the migration limits is not correct. E.g. for scraped off toy materials the migration limit = <math>[(10 * 1.6 * 7.5) / (8 * 100)] * 10E6 = 150 \text{ mg/kg}</math>. The migration limits should thus be 150, 12 and 3 mg/kg, respectively, so almost identical to the ones now.</p>	<p>The possibility for a relevant inhalation exposure has been included also in the cited sections to be consistent with the indication previously given in the text, as suggested.</p> <p>The opinion is on toys and the target population is specifically identified in children of different age, therefore the SCHEER see no reason for addressing the exposure of the general population. The slot car magnet was used in the TIE assessment for the oral exposure scenario after ingestion. The SCHEER explained and cited the exposure scenarios given in the TIE report. It is not within the remit of the SCHEER to publish reports from TIE. The limit values have been corrected. Thank you for highlighting this mistake.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.5.2.4 Exposure scenario for 3-D pens and toy printers	<p>p.38, lines 32-33 RIVM uses the term 'modelling clay' rather than 'play dough' in its report 612810012/2002 – suppose this source is meant (please include a reference to this report at the end of the sentence). □</p> <p>p.39, lines 9-10 It is noted that the Co concentrations presented (0.043 and 0.086 ng/m3) are different from the ones mentioned in Annex 2 (0.15 and 0.29 ng/m3), where apparently the air change rate was taken into account. Please make consistent. In addition, Annex 2 mentions an age group of 6.5-12.5 years instead of 6-11 years. □</p>	<p>This is the term that the authors of the report had used. It was not introduced by the SCHEER. However a clarification has been added, together with the original reference</p> <p>The text in the Opinion has been amended for clarification.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.5.2.3 Exposure scenarios for kids' cosmetics: cobalt in toy make up sets	<p>p.37, line 33 It would be nice to refer here to the OECD document 'Considerations when assessing children's exposure to chemicals from products' from 2019: <a href="https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JMM/MONO(2019)29&amp;docLanguage=en">https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JMM/MONO(2019)29&amp;docLanguage=en</a> □</p> <p>p.37, line 35 The reference to the SCHER 2010 opinion on migration limits is missing in the reference list. □</p> <p>p.38, lines 23-25 How about the concentrations reported in Corazza et al. 2009? Can't these be used? □</p>	<p>The reference to the OECD document and the missing references have been added to the Opinion.</p> <p>In table 3 CoCl<sub>2</sub> as been replaced by Co, as reported in the cited paper from Corazza et al. However the paper reported: 'Cobalt was present in amounts over 5 ppm in 5/52 (9.6%) samples. Powdery toy make-up (eye shadows) had the highest levels of metals, and "creamy" toy make-up (lip gloss and lipsticks) the lowest': since the levels in lipstick were low, only eyeshadows have been mentioned. The Opinion has been changed accordingly</p>

Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.5.2.2 Cobalt-containing metals that serve a function other than electrical conductance	<p>p.35, line 3- Please insert inhalation before exposure ("Based on the negligible inhalation exposure related to...")<input type="checkbox"/></p> <p>p.35, lines 8-9<input type="checkbox"/> Please present the slot car magnet scenario, as this is the scenario on which TIE presented its risk assessment.<input type="checkbox"/></p> <p>p.35, lines 17-24 and 28-30<input type="checkbox"/> Please add frequency (once in a life) to the list of exposure determinants used by TIE. Since body weight and absorption percentage are also exposure determinants, it would be more logical to have these also added to the list.<input type="checkbox"/></p> <p>p.35, line 34<input type="checkbox"/> What is considered worst-case then?<input type="checkbox"/></p> <p>p.35, line 39 and p.36, lines 2-3<input type="checkbox"/> The reference to the SCHER 2016 Final Opinion on Estimates of the amount of toy materials ingested by children is missing in the reference list, as well as the reference to the RIVM 2008 report.<input type="checkbox"/></p> <p>p.36, lines 4-6<input type="checkbox"/> For the toys tested by Jensen et al. 2014 and Ahlström et al. 2018, the detection limit of 8 ppm could possibly be used as worst-case Co release for the quantitative exposure assessment.<input type="checkbox"/></p> <p>p.36, lines 18-19<input type="checkbox"/> Please include watches in the list of jewelry items mentioned in between brackets. At least the watch's case (and depending on the material also the watch band) present a relative large surface area for potential contact with metal alloys.<input type="checkbox"/></p>	<p>1) Inhalation was added in the final Opinion 2,3.4) The slot car magnet scenario was amended as well as exposure determinants regarding frequency, bodyweight and absorption rate. Based on the information available, the SCHEER considers the ingestion of cobalt containing toys and toy materials as the worst case. In addition aggregate exposure has to be considered when assessing possible health risks for children. 5) Reference to SCHER 2016 and RIVM 2008 is added to the final Opinion. Thank you for your comment. Watches have been added.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.5.2.1 Cobalt-containing metals included to allow conduction of electric current	<p>p.33, line 37 The reference to the SCHER 2012 opinion on Ni is missing in the reference list.</p> <p>p.34, lines 1-6 The reference to the Jensen et al. 2014 study might be more appropriate for scenario 2 (unless all selected toys had metal components included to allow conduction of electric current, but that is probably not the case).</p> <p>p.34, line 25 There seems to be a mistake in the TIE calculation of the release of Ni per day as <math>0.637 \times 3/40</math> is not 0.0073 but 0.048.</p> <p>p.34, lines 32-37 SCHEER agrees with the exposure assessment by TIE, aside from the play time. However, shouldn't the calculation of the cobalt exposure have been done on the basis of the cobalt content of the alloy (0.26%) rather than on the nickel content (13%)? In combination with a play time of 7 h/week as suggested by SCHEER (and assuming that is 1h/day), the worst case cobalt intake would be <math>4.23 \times 10^{-5} \mu\text{g/d}</math> (<math>0.013 \times 24/40 \times 1/24 \times 0.13</math>) rather than 0.028 <math>\mu\text{g/d}</math>. Please explain the origin of the suggested play time of 7h/wk. Is this based on expert judgement and an assumption of 1 h/day? And is it considered worst-case, or 'realistic worst case'? We are aware that values for duration from toy contact scenarios are scarce, but therefore the origin of those postulated must be described clearly as such values tend to take on a life of their own.</p>	<p>1) Thank you for your comment, the SCHER opinion on Nickel (2012) was added to the final Opinion. 2) The SCHEER considers the publication by Jensen et al (2014) as a correct reference for Exposure Scenario 1: "...dermal exposure to cobalt when handling model rail track and model rail track joiners during play or assembly"; for oral exposure, migration to gastric juice surrogate should be considered. 3) indeed the calculation is not correct and has been changed in the final Opinion. 4) TIE assessment is based on a measured mass loss of 4.9 mg silver-nickel alloy during 40 hours (nickel content of 13% and estimated respective cobalt content of 0.26%). Electric toys that require setting up and preparation have become more widespread. They also keep children's interest for longer. Therefore, in the judgement of SCHEER, playing with such toys for only 3 hours in a week is too little time.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.5.2. Exposure scenarios for children playing with cobalt-containing toys	<p>p.33, lines 11-12 Earlier on in the report (e.g. on p.23) it is stated that SCHEER also identified some plastic materials as possible source of exposure to cobalt. Given this, what was the reason not to include a scenario for plastic toys?</p>	<p>Plastic materials have been deleted due to insufficient evidence.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.4.2. Immunological effects: sensitisation	<p>p.30, lines 12-19 and 20-21<input type="checkbox"/> Please note that the ECHA restriction opinion on skin sensitisers (from 2020, not 2019) proposes concentration limits of 70 mg/kg w/w in textile and 15 mg/kg w/w in leather, hides and furs, as also correctly noted in line 21. It is further to be noted that the formula to come from the elicitation threshold to the concentration limits involves more parameters than just the migration factor.</p>	<p>The SCHEER agrees with this comment. Indeed for textiles and clothes exposure parameters such as skin contact surface and frequency/duration were taken into account. Nevertheless, the SCHEER considers the concentration limits as sufficiently protective. The text has been adjusted.</p>

Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.4. Toxicity and health effects	<p>p.27, lines 12-13 Repr. 1B is missing. □</p> <p>p.28, lines 6-11 Here, and elsewhere in 6.4, reference is made to several ECHA documents and opinions. The most recent one, the 2022 scientific report for evaluation of limit values for cobalt and inorganic cobalt compounds at the workplace (8946312e-f910-72bf-7d47-444c9ba37bc2 (europa.eu)) is however missing and could be added. More importantly, this latter report builds on the conclusions from the 2020 ECHA cobalt restriction opinion, in particular on the MoA and the PoD. Please note that in lines 8-11 the ECHA conclusions have been cited incorrectly, as ECHA uses a PoD of 0.067 mg/m3 and a sublinear approach, and not a PoD of 0.414 mg/m3 and linear extrapolation approach based on a T25. □</p> <p>p.28, line 17 Please insert 'For chronic duration,' before 'EFSA (2012) considered....' □</p> <p>□</p> <p>p.28, line 40 Please insert the route (inhalation) before bioavailability ("The inhalation bioavailability of....")□</p>	<p>Category 1B (H350) is already mentioned in the Opinion;</p> <p>Thank you for your comment. The PoD in the Opinion has been modified accordingly.</p> <p>"Intermediate duration" included in the Opinion refers to the reference values derived by ATSDR in 2004; the EFSA TDI was derived starting from the ATSDR data and indeed a uncertainty factor was used to account for the shorter duration of the study. There is no need for changes in the Opinion</p> <p>The relation to the inhalation is already mentioned in the paragraph.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.3. Presence of cobalt in toys	<p>p.24, Table 3 For presence of cobalt in toys, reference is made to a.o. Ahlström et al. 2018 and Aurisano et al. 2020 (NB: should be 2021). But in these studies cobalt appeared not detectable.</p>	<p>The following references have been added Boer, Johannes &amp; Wesenhagen, Philana &amp; Wenker, Erica &amp; Maaijen, Karin &amp; Gol, Franjo &amp; Gibbs, Hugh &amp; Hage, Ronald. (2013). The Quest for Cobalt-Free Alkyd Paint Driers. European Journal of Inorganic Chemistry, 2013, 3581-3591 and <a href="https://www.oki.com/en/eco/procurement/pdf/E_S.pdf">https://www.oki.com/en/eco/procurement/pdf/E_S.pdf</a>. The reference to the Aurisano paper has been deleted.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.2. Physico-Chemical characterisation of cobalt compounds	<p>p.21, line 6 It is stated that the International Chemical Safety Cards are reproduced at the end of this document, but these cannot be found.</p>	<p>A footnote has been added to the appropriate source, and the reference to copies of the cards at the end of the document was deleted (<a href="https://www.cdc.gov/niosh/ipcs/default.html">https://www.cdc.gov/niosh/ipcs/default.html</a>)</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	6.1. Introduction	<p>p.20, line 36 It is suggested to add an explanation why local effects after inhalation exposure, despite the respiratory sensitising potential of cobalt, were not considered in the opinion.</p>	<p>Thank you for the suggestion. The SCHEER did not consider local effects following inhalation, i.e. respiratory sensitisation. Although Cobalt can cause asthma, and while it is still a matter of debate whether it is based on allergy, exposures are relatively high in the context of industrial settings. Text has been added, in the Opinion.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	5.2. Methodologies	<p>p.20, lines 9 and 17 Since ECHA is referred to at several places in section 6, it would be good to add ECHA to the parts in between brackets.</p>	<p>Thank you, the reference to ECHA will be added accordingly.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	OPINION or CONCLUSIONS	<p>p.16/line 34 It would be informative to explain the specific behaviours by young children: "...certain behaviours of children (e.g. crawling on the floor, hand-mouth contact, ingestion of dust and soil) can also..."</p>	<p>The behaviour of children has been described in the relevant sections within the Opinion.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	ABSTRACT	<p>Please note that some comments made on section 6 of the draft opinion also apply to the abstract (see e.g. the comment in section 6.6 on the newly calculated migration limits).</p>	<p>Noted. Thank you.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	OPINION or CONCLUSIONS	<p>Please note that several comments made on section 6 of the draft opinion also apply to the opinion/conclusions section.</p>	<p>Noted. Thank you.</p>
Pronk	Marja	National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	marja.pronk@rivm.nl	Netherlands	SUMMARY	<p>Please note that several comments made on section 6 of the draft opinion also apply to the summary.</p>	<p>Noted. Thank you.</p>