



Results of the public consultation on SCHEER's preliminary Opinion on "Tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys"

A public consultation on this Opinion was opened on the website of the non-food scientific committees from 7 July to 10 September 2017. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.

Nine contributors from industry and public institutes participated in the public consultation, providing input to different chapters and subchapters of the Opinion. Ten comments in total were submitted.

Each submission was carefully considered by the SCHEER, but the SCHEER did not feel that any of them indicated a necessity for making changes to the final Opinion.

The SCHEER thanks all contributors for their comments and for the references provided during the public consultation.

The table below shows all comments received on different chapters of the Opinion and SCHEER's response to them. It is also indicated if the comment resulted in a change of the Opinion.



Comments received during the public consultation on the SCHEER preliminary opinion on "Tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys"

No	Name of individual/organisation	Table of contents	Submission	SCHEER's response
1	Bazan, Ewa, TREFL S.A., e.bazan@treffl.com, Poland	5.1. Introduction and RIVM approach	There is no doubt that when estimating the total exposure of infants and children to aluminium, it is important to take into account all significant sources of exposure, especially dietary exposure, which is the main and difficult to reduce the source. The SHEER preliminary opinion and analysis confirms, that the uptake of aluminium from other voluntary sources should therefore be minimised. However, to advise on a tolerable intake level for aluminium that could be used to adapt the migration limits for aluminium in the Toy Safety Directive 2009/48/EC, there additional analyses and data needed (such as determination share of toys in other voluntary aluminium sources, assessment of the impacts and benefits of reduce aluminium sources and economic justification). Final opinion should take these aspects into account - so that the possible change is reflected in reality and has contributed to the real improvement of children's health and safety.	Thank you for your comments. The implementation of the SCHEER's Opinion is outside of the SCHEER's mandate. Considering additional voluntary sources would not change the overall outcome of the Opinion. There is no need to change the Opinion.
2	Czarnecla-Partyka, Monika, J.S.Hamilton Poland SA, mpartyka@hamilton.com.pl, Poland	5.2. Evaluation of aluminium health effects by other regulatory	There is no doubt that when estimating the total exposure of infants and children to aluminium, it is important to take into account all significant sources of exposure, especially dietary exposure, which is the main and	Please see the reply to comment 1.

		bodies	difficult to reduce the source. The SHEER preliminary opinion and analysis confirms, that the uptake of aluminium from other voluntary sources should therefore be minimised. However, to advise on a tolerable intake level for aluminium that could be used to adapt the migration limits for aluminium in the Toy Safety Directive 2009/48/EC, there additional analysis and data needed (such as determination share of toys in other voluntary aluminium sources, assessment of the impacts and benefits of reduce aluminium sources and economic justification). Final opinion should take these aspects into account - so that the possible change has contributed to the real improvement of children's health and safety.	
3	ZIRA, EVANGELIA, MINISTRY OF ECONOMY AND DEVELOPMENT/ GENERAL SECRETARIAT FOR INDUSTRY, zirae@ggb.gr, Greece	5.2. Evaluation of aluminium health effects by other regulatory bodies	At future, new light materials and alloys should be used for toys production, based on less harmful metals, such as magnesium, magnalium etc., which are better intaken from human (children) organisms	Thank you for your comment. This issue has already been mentioned in the preliminary Opinion. There is no need to change the Opinion.
4	Lenzner, Ariane, German Federal Institute for Risk Assessment, ariane.lenzner@bfr.bund.de, Germany	5.2. Evaluation of aluminium health effects by other regulatory bodies	In 2008 EFSA derived a TWI value of 1 mg/kg bw based on studies in mice which resulted in a LOAEL of 50 mg/kg bw/day and a NOAEL of 10 mg/kg bw/day, respectively (EFSA, 2008). EFSA's evaluation included various animal species, i.e. mouse, rat and dog. Although all of these studies had certain limitations, the different animal species exhibited different sensitivities to the effects of Al, with the mouse appearing to be the most sensitive species.	This is not entirely correct: the EFSA NOAEL was an overall NOAEL, not only based on a mouse study. The limitations of the studies considered by EFSA were described in the EFSA Opinion, as well as in the JECFA report. For this specific reason, a study performed using TG methodologies and

			<p>Therefore the EFSA used the mice study for deriving the TWI value.</p> <p>In 2011 a lege artis conducted study in rats was published, which resulted in a NOAEL of 30 mg/kg bw/day (Poirier, 2011), substantially higher than that in mice, and led to a PTWI of 2 mg/kg bw/day derived by JECFA. But only rats and no other (potentially more sensitive) species were used by Poirier, which is a limitation of that study. In its preliminary opinion on "Tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys", SCHEER identified the rat study of Poirier as a key study and used this study for deriving a TDI of 0.3 mg/kg bw/d. However, a reasoning why the results of the rat study were superior to those in mice could neither be found in the opinion by JECFA nor in the preliminary opinion by SCHEER. Besides the structure of the study design also the selection of the most sensitive animal species is an important factor. A discussion of the different sensitivities of various species by SCHEER is missing and should be included in the opinion. Finally it might be useful to derive an additional uncertainty factor to account for the apparent variability of the sensitivity between animal species.</p>	<p>compliant to quality criteria was indicated as a research need. And indeed JECFA re-evaluated AI as soon as the study became available.</p> <p>The quality of the study is the rationale behind the SCHEER's choice, as already explained in the preliminary Opinion.</p> <p>On a closer examination of the database, the varying degrees of sensitivity between species is not striking, therefore it is not considered a relevant point to be included in the final Opinion.</p> <p>There is no need to change the Opinion.</p>
5	Lenzner, Ariane, German Federal Institute for Risk Assessment, ariane.lenzner@bfr.bund.de,	5.4. Sources of exposure to Aluminium	As EFSA already pointed out in 2008, both the TWI of 1 mg/kg bw as well as the PTWI of 2 mg/kg bw are already exceeded by a substantial part of the population regarding	As the dietary uptake level already exceeds the PTWI, the SCHEER's recommendation has to be to lower as far as possible the contribution from toys.

	Germany		<p>diet alone. Hereby, the proportion of children (EFSA, 2008) is particularly high. SCHEER also emphasizes this fact in its preliminary opinion, and thus, recommends minimizing the exposure of aluminium from all other sources, including toys.</p> <p>In its opinion of 2010, SCHER recommends that the allocation factor for deriving migration limit values for toys should not exceed 10% (maximum value) and underlines that background exposure must also be taken into account. However, in SCHEER's preliminary opinion on aluminium, a discussion and a specific proposal as to which allocation factor is appropriate due to the high background load to meet the requirement to minimize the intake of all sources, including toys, is lacking. It is questionable whether an allocation factor of 10 % is suitable to minimize the aluminium exposure of children by toys. Thus, BfR recommends reviewing the allocation factor of 10% of the TDI by toys and, if necessary, reducing it due to aluminium's high background load.</p>	There is no need to change the Opinion.
6	Lenzner, Ariane, German Federal Institute for Risk Assessment, ariane.lenzner@bfr.bund.de, Germany	5.7. Overall conclusion regarding aluminium exposure in children	In 2008 EFSA derived a TWI value of 1 mg/kg bw based on studies in mice which resulted in a LOAEL of 50 mg/kg bw/day and a NOAEL of 10 mg/kg bw/day, respectively (EFSA, 2008). EFSA's evaluation included various animal species, i.e. mouse, rat and dog. Although all of these studies had certain limitations, the different animal species exhibited different	Please see the reply to comment 4.

sensitivities to the effects of Al, with the mouse appearing to be the most sensitive species. Therefore the EFSA used the mice study for deriving the TWI value.

In 2011 a lege artis conducted study in rats was published, which resulted in a NOAEL of 30 mg/kg bw/day (Poirier, 2011), substantially higher than that in mice, and led to a PTWI of 2 mg/kg bw/day derived by JECFA. But only rats and no other (potentially more sensitive) species were used by Poirier, which is a limitation of that study. In its preliminary opinion on "Tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys", SCHEER identified the rat study of Poirier as a key study and used this study for deriving a TDI of 0.3 mg/kg bw/d.

However, a reasoning why the results of the rat study were superior to those in mice could neither be found in the opinion by JECFA nor in the preliminary opinion by SCHEER. Besides the structure of the study design also the selection of the most sensitive animal species is an important factor. A discussion of the different sensitivities of various species by SCHEER is missing and should be included in the opinion. Finally it might be useful to derive an additional uncertainty factor to account for the apparent variability of the sensitivity between animal species.

7	<p>Dr. Wächter, Herbert , Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit, Eggenreuther Weg 43, 91058 Erlangen, Herbert.Waechter@lgl.bayer n.de, Germany</p>	<p>5.7. Overall conclusion regarding aluminium exposure in children</p>	<p>In den letzten Monaten wurden am Bayerischen Landesamt für Gesundheit und Lebensmittelsicherheit einige Proben Spielzeug-Knetmasse, Straßenmalkreide und Fingeralfarben gemäß der Norm EN 71 „Sicherheit von Spielzeug, Teil 3: Migration bestimmter Elemente“ auf die Lässigkeit verschiedener Elemente, darunter Aluminium, untersucht. Die zusammengefassten Erkenntnisse möchten wir der EU-Kommission und SCHEER im Rahmen der Konsultation zur Verfügung stellen:</p> <p>Für die Lässigkeit von Aluminium wurden bei den uns vorliegenden Proben, in denen Aluminium bestimmbar war, folgende Mengen ermittelt:</p> <table data-bbox="842 774 1464 1181"> <thead> <tr> <th>Spielzeug</th> <th>Aluminium-Lässigkeit</th> </tr> <tr> <th>(mg/kg)</th> <th>tägliche Aufnahmemenge</th> </tr> </thead> <tbody> <tr> <td>Knetmassen</td> <td>100 - 400</td> </tr> <tr> <td>10 - 40 µg (Verzehr 100 mg)</td> <td></td> </tr> <tr> <td>Straßenmalkreide</td> <td>100 - 200</td> </tr> <tr> <td>10 - 20 µg (Verzehr 100 mg)</td> <td></td> </tr> <tr> <td>Fingeralfarbe</td> <td>140</td> </tr> <tr> <td>56 µg (Verzehr 400 mg)</td> <td></td> </tr> </tbody> </table> <p>In der SCHEER-Stellungnahme ist die tolerierbare tägliche Aufnahmemenge an Aluminium mit 0,3 mg pro kg Körpergewicht</p>	Spielzeug	Aluminium-Lässigkeit	(mg/kg)	tägliche Aufnahmemenge	Knetmassen	100 - 400	10 - 40 µg (Verzehr 100 mg)		Straßenmalkreide	100 - 200	10 - 20 µg (Verzehr 100 mg)		Fingeralfarbe	140	56 µg (Verzehr 400 mg)		<p>Thank you for your comment and your support of the SCHEER preliminary Opinion. There is no need to change the Opinion.</p>
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			<p>angegeben. Bei einer Allokation für Spielzeug von 10 % wäre für ein Kind mit 10 kg Körpergewicht eine Aluminiumaufnahme von 300 µg als tolerierbar anzusetzen. Bei den uns vorliegenden Proben ist dieses Limit eingehalten.</p>	
8	"No agreement to disclose personal data"	5.7. Overall conclusion regarding aluminium exposure in children	<p>"Dietary aluminium intake alone in some cases already exceeds the reference values established by EFSA [...] the uptake of aluminium from other voluntary sources - such as toys - should therefore be minimised".</p> <p>Just reading this comment, I think the most urgent thing is too minimize aluminium intake from food!</p> <p>Why is aluminium tolerated in some food additives and food colors and leading to massive exposure to aluminium and should be exempted from toys while its presence is already massively restricted?</p> <p>This perfectly lacks of common sense!</p>	Thank you for your comment; dietary aluminium intake is out of the SCHEER's mandate.
9	Affourtit, Femke, National Institute for Public Health and the Environment (RIVM), femke.affourtit@rivm.nl, Netherlands	5.7. Overall conclusion regarding aluminium exposure in children	<p>Page 14, line 3-47.</p> <p>The SCHEER opinion selects a NOAEL of 30 mg Al/kg bw/day from the Poirier study, with alterations in neuromuscular measurements (hind-limb and fore-limb grip strength) in both males and females being the critical toxic effect. Indeed, based on the neurotoxic endpoint, you may argue that the NOAEL should be at 30 mg/kg bw/day assuming that</p>	Since the end-point for the neurodevelopment was considered much more relevant for children using toys than the renal effect from the all-life-long chronic exposure - it was chosen as the critical end-point. The rationale for choosing 30 mg/kg bw per day is already

			<p>the toxic effects induced during the pregnancy/lactation is reversible.</p> <p>Please add reasoning why the renal toxicity (the formation of urinary calculi as observed postmortem in the period from PND 22-PND 364) is not selected as the critical toxic effect?</p> <p>In case the renal toxicity is selected as critical effect the lowering in the treatment dose noted in adult pups is relevant. After weaning (PND 22) offspring was exposed via the drinking water up to PND 364 (same levels of aluminum as the dams). By week 9, mean dosage of low-dose males and females had fallen to 15.4 and 17.4 mg Al/kg bw/day, respectively. Between weeks 15 and 49 post-weaning, dosage for males fell from 10.7 to 5.0 mg Al/kg bw/day. For females, dosage fell from 13.5 to 10.0 mg Al/kg bw/day during this same period. For the induction of urinary tract pathology in offspring which postnatally have been exposed to Al, a dose level of 30 mg Al/kg bw/day cannot be considered as a NOAEL. Here a NOAEL of 5 mg Al/kg bw/day appears more appropriate. Applying a safety factor of 100 on this NOAEL then leads to a TWI of 0.35 mg Al/kg bw/week for the exposure of infants, toddlers and young children to Al.</p>	<p>indicated in the preliminary Opinion.</p> <p>There is no need to change the Opinion.</p>
10	Affourtit, Femke, National Institute for Public Health and the Environment (RIVM),	5.7. Overall conclusion regarding aluminium	<p>Page 11, line 4-5.</p> <p>The calculation uses default amounts for the ingestion of toy material (Section 5.1, page 10,</p>	<p>Thank you for your comment. Default values for the amount of toy materials</p>

	femke.affourtit@rivm.nl, Netherlands	exposure in children	<p>line 3-6 and 12) as proposed in the RIVM "Chemicals in Toys"-report from 2008. However in 2015, RIVM published an Erratum on these amounts, having made a mistake in ingested amount per day and per week. The SCHER considered this Erratum and decided in 2016 in their opinion to not adopt the Erratum, but to keep the defaults and use those per day (SCHER opinion, 2016).</p> <p>As this choice results in the fact that (older and newly calculated) migration limits are more conservative, we agree. However, for transparency reasons, please, add correct references for the support and argumentation for these choices to this calculation and the opinion.</p>	<p>ingested by children are outside the scope of this mandate. The RIVM Erratum and the amount of toy materials ingested by children were evaluated by the SCHER in 2016. There is no need to change the Opinion.</p>
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