



Results of the public consultation on SCHER's preliminary Opinion on "Estimates of the amount of toys materials ingested by children"

A public consultation on this Opinion was opened on the website of the non-food scientific committees from 21 December 2015 to 14 February 2016. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.

Five organisations provided total of eighteen comments to different chapters and subchapters of the Opinion during public consultation. Among the organisations participating in the consultation were a national public health institute, consumer organisations and industry.

Each contribution was carefully considered by the SCHER and where appropriate, the text of the Opinion has been modified or explanations have been added to take account of relevant comments. The reference list has been accordingly updated with relevant publications. The scientific rationale and the Opinion section were clarified and strengthened. In the cases where the SCHER, after consideration and discussion of the comments, has decided to maintain its initial views, the Opinion (or the section concerned) has remained unchanged.


The SCHER 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 SCHER'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 SCHER preliminary opinion on "Estimates of the amount of toys materials ingested by children".


SUBMISSION					SCHEER response
No	Name of individual/organisation	Table of content to which comment refers	Submission	Additional documents submitted by contributors	SCHER's Response
1	Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands	ABSTRACT	In general, concluding remark: The incentive for the underlying SCHER OPINION is the Erratum on the RIVM report "Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements". The Erratum was written to correct a transcription error made when numbers were transferred from Chapter 3 to Chapter 8. Accidentally mg/week was changed to mg/day. The aim of the Erratum as published in 2015 was to correct this editorial mistake. In general, we are of the opinion that more research is needed to refine the estimates of the amount of toy materials ingested by children. The RIVM report (2008, erratum 2015) mentions in Chapter 3 (3.5.2 Direct ingestion, page 41): "It is emphasized that this default applies to children under 3 years of age only, as these children display most mouthing behaviour. The ingestion of 100 mg by children is considered reasonable, but may not occur daily. For exposure assessment refinement purposes, we propose to use a frequency of 1/week for this ingestion default when the exposure is compared to a chronic health-based limit value. This is a rough estimate and needs further research. More recently, Guney & Zagury (2014b) in their publication conclude: "To improve risk characterization results, more information is needed on the quantity of ingested toy/jewelry material and on the		The SCHER agrees that there are no new data on ingestion of toy materials but more data are available on mouthing of toys. This is explained in the Opinion.


			frequency of ingestion.” More new data are not available, therefore we are of the opinion that scientific reasons to change the assumed defaults from 2006 (reviewed at that time by an Advisory Group, CSTE, DG Enterprise) are absent.		
2	VANDEBERGHE TANIA / ANEC tania.vandenberghe@anec.eu Belgium	EXECUTIVE SUMMARY		 ANEC-CHILD-2016-G-015.pdf	The SCHER would like to thank ANEC for supporting the SCHER opinion.
3	ARASA EDUARDO JOVI S.A. earasa@jovi.es Spain	EXECUTIVE SUMMARY	Page 6, line 5-12 To our knowledge, this paragraph is not adjusted to the actual facts. - When RIVM developed and explained the methodology clearly stated that “For the purpose of an exposure assessment refinement, when comparing exposure to a chronic health-based limit value, we propose to use a frequency of 1/week as a default. This is a rough estimate and needs further research”. - However, when calculating migration limits for certain elements, the RIVM report used the amounts for all three toy materials which can be ingested on a daily base instead of a weekly base. They made a simple mistake that has been admitted with great integrity. In the Erratum from 2015, the migration limits were corrected by applying the same amounts of dry, brittle, pliable or powder-like as well as liquid toy materials ingested but on a weekly base. Therefore, in our opinion, the SCHER document must explicitly recognize that - The Directive was based on the RIVM report. - The RIVM report developed a methodological approach to establish the migration limits. - By an unnoticed and explicitly admitted error, the proposed migration limits were inconsistent with the method assumptions.		The SCHER recognizes that the Toy Safety Directive 2009/48/EC was based on the RIVM report. The question that was asked to SCHER was to review available data and to review if the current amounts estimated for toy materials are still appropriate . The RIVM report and the Erratum, as well as other relevant sources, were taken into consideration in drafting of the Opinion and the final text reflects this. The SCHER is of the opinion that the text already reflects the actual facts. Further details are provided in Chapter 3.2.


			<p>1 Background page 7 line 7-11 As previously exposed, to our knowledge, this paragraph is not adjusted to the actual facts. The methodological assumptions of the RIVM report were that these intakes were weekly. However, by an explicitly admitted error, finally the limits were calculated assuming daily intakes. The following conclusion must be accepted is that the limits established by the Toy Safety Directive were based on an error and should be corrected in the same sense.</p> <p>2 Terms of Reference, P8;L7-10 This is the main question asked to SCHER. To our knowledge, it is not accurate to assert that these daily intakes “formed the basis for the limits in the Toy Safety Directive”. It must be emphasized that - the “basis” for TSD was the RIVM report methodology - Due to the aforementioned error the ingestion amounts used in the estimation of the limits were inconsistent with the proposed methodology Taking this into account, in our opinion, is not suitable to ask whether these inconsistent ingestion amounts are “still” appropriate. The answer can only be that are not appropriate because they are based on an error. Obviously wrongly established limits are so low that it may be optimal from the point of view of safety but of course can not be considered appropriate as being manifestly erroneous.</p>		<p>The background is provided by the Commission as part of the mandate and cannot be changed.</p> <p>The Terms of Reference are provided by the Commission as part of the mandate and cannot be changed.</p>
4	Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands	EXECUTIVE SUMMARY	Chapter 1. Background. Page 7, line 7: For clarification of the chronology of the events: The RIVM report “Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements” was written in 2006 on request of the Commission (DG Enterprise) and was published as RIVM report in 2008, with an Erratum in 2015. Chapter 1. Background. Page 7, Line 12: When following the order in the RIVM report, at first (in Chapter 3) an estimation was		The SCHER recognizes that the Toy Safety Directive 2009/48/EC was based on the RIVM report. The question that was asked to SCHER was to review available data and to review if the current amounts estimated for toy materials are still appropriate . The RIVM report and the Erratum, as well as other relevant sources, were taken into consideration in drafting of the Opinion and

			<p>chosen for the default amount of toy material swallowed. A difference was made in the sort of material, the amount depends on whether the toy is made of dry or liquid, pliable or otherwise sticky material, or whether the ingested material is from scraping off a toy layer. This amount was chosen by expert judgment based on judging pieces of toys and weighing, and set at mg/week. In the transfer of the numbers to Chapter 8 (where calculations for the limits were performed), an editorial error was made in transcription of the unit, changing this by accident from mg/week to mg/day. The Erratum of 2015 corrects this editorial mistake.</p>		<p>the final text reflects this. The SCHER is of the opinion that the text already reflects the actual facts. Further details are provided in Chapter 3.2.</p>
5	<p>ARASA EDUARDO JOVI S.A. earasa@jovi.es Spain</p>	<p>3.2 Exposure to chemicals in toys – the RIVM report</p>	<p>3.2 Page 11;Line 30-33 The last phrase of this paragraph could be understood in the sense that new references or new data would be necessary to justify the correction a previous evident error. In order to correct a mere arithmetical error is only necessary to change it, and even determine your origin, but does not appear logical to require further studies.</p>		<p>The SCHER agrees that no new data are necessary in order to correct the mathematical error that RIVM has addressed in its corrigendum. The text of the Opinion has been changed accordingly.</p>
6	<p>Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands</p>	<p>3.2 Exposure to chemicals in toys – the RIVM report</p>	<p>Chapter 3.2 Exposure to chemicals in toys – the RIVM report. Page 10, line 32-33. “However, no reference was given to new data or further research”. The Erratum was to correct an editorial mistake, and therefore no new references are included. To our knowledge no new studies or data have become available between 2006 (RIVM report written) and 2014 (Guney & Zagury, 2014). As Guney & Zagury (2014b) more recently also remark in their publication: “To improve risk characterization results, more information is needed on the quantity of ingested toy/jewelry material and on the frequency of ingestion.”</p>		<p>The SCHER agrees that no new data are necessary in order to correct the mathematical error, RIVM has addressed in its corrigendum. The text of the Opinion has been changed accordingly. However, the SCHER notes that in the Erratum the selection of daily or weekly intake of the ingested amounts of toy materials was not further justified. The question that was asked to SCHER was to review available data and to review if the current amounts estimated for toy materials are still appropriate.</p>
7	<p>Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl</p>	<p>3.3.1 Recent studies on mouthing behaviour</p>	<p>Chapter 3.3.1. Recent studies on mouthing behavior. Page 12, line 1. Recently, mouthing times were a point of discussion in the Risk Assessment Committee (RAC) at</p>		<p>The SCHER included the relevant information accordingly.</p>


	Netherlands		<p>ECHA. After reviewing several studies, mouthing times in the case of restrictions on phthalates and lead resulted in a conclusion for default values of 2 hr for toys (RAC, 2013; ECHA, 2013) and 1 hr for other articles (non-toys, RAC, 2011). These references should be included in this section or the next section. • ECHA (2013). Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. Reference: ECHA-13-R-07-EN. ISBN: 978-92-9244-001-5 Publ.date: August 2013 http://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715 • RAC (2011). RAC Opinion on an Annex XV dossier proposing restrictions on lead and lead compounds in jewellery. ECHA/RAC/ RES-O-0000001304-85-03/F. Chemicals concerned: Lead and its compounds. Adopted 10 March 2011 http://echa.europa.eu/documents/10162/aa4af911-5dae-4cf2-a337-6bdf81ee7536 • RAC (2013). Opinion on the ECHA’s draft review report on “Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006 (REACH)”. ECHA/RAC/A77-O-0000001412-86-10/F. adopted 8 March 2013 http://echa.europa.eu/documents/10162/13579/rac_opinion_dinp_didp_en.pdf Please, note that ECHA is currently working on the update of the R15 Chapter Consumer Exposure guidance. There was discussion about whether a section on mouthing times had to be included.</p> <p>Chapter 3.3.1 Page 15, line 5-9/ 10-12 and 13-25: This section 3.3.1 is related to mouthing behavior/times. The studies described here refer to possible dermal exposure from sticking to hands (Guney & Zagury, 2012), on ingestion of coins and jewellery (reference Farmakakis et</p>		<p>The title of Chapter 3.1.1. has been changed.</p>
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			al. 2007) and more general risk assessment of chemicals in toys (13-25). This text is better placed in another section.		
8	Pfeffer Heidrun EWIMA (European Writing Instruments Manufacturer's Association) heidrun.pfeffer@ewima-isz.de	3.3.2 Approaches and default values used by different organisations	page 17, line 3, Table 3, "Ingestion", "Ball pen" EWIMA would like to propose to delete the "ball pen" example from Table 3: <ul style="list-style-type: none"> • Ball point pens are generally not considered as toys • Quality of referenced data for ingested material is poor • Technical features of ball point pen refills do not allow a supposed intake of 300 mg material from ball point pens 	 EWIMA_comment_5 CHER_pre-opinion_17	Table 3 cites the examples calculated by RIVM. The SCHER acknowledges that not all writing articles are considered to be toys and has added a reference to the Commission guidance document No. 15 On the application of the Directive on the Safety of toys for clarification.
9	ARASA EDUARDO JOVI S.A. earasa@jovi.es Spain	3.3.2 Approaches and default values used by different organisations	3.3.2 Page 17, Table 3, and Page 18, table 4 The table 3 is based on the Children's Toys Fact Sheet (TFS) reported by RIVM in 2002. Of course, these exposure factors were known by the RIVM scientists responsible of the 2008 report. Explicitly, in RIVM 2008, it was considered that the exposure factors of TFS overestimated the exposure (intake per event and event frequency) and then, on the basis of expert judgements, proposed: - the new lower values for daily (event) intakes: a child would ingest 100 mg/d of dry, brittle, powder-like or pliable toy material, 400 mg/d of liquid or sticky toy material, and 8 mg/d of scraped-off toy material, - weekly event frequency. 3.3.2 Page 18, Table 4 The table 4 is based on Danish EPA report (2014). The classification of toys is different from the previous table 3. However, the exposure factors for similar toy category were identical to those of the RIVM (2002) survey represented in the table 3. Explicitly, in RIVM 2008, these exposure factors were considered excessive, on the basis of expert judgements. Furthermore, Table 4 shows "partial" and "total" daily intakes for some toy types and toy categories. This kind of "partial" and "total" intakes or exposures must be		The SCHER summarized the exposure calculations from RIVM and the Danish EPA in order to give information on different approaches used when dealing with exposure to different chemicals from toys. The SCHER is aware of the fact that these estimations may overestimate the exposure as stated in the Opinion.

			interpreted with caution: if the toys are subdivided in multiple types, but we do not take into account that then it is necessary to decrease the contact time and frequency for each individual toy, probably the total exposure would be overestimated.		
10	Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands	3.3.2 Approaches and default values used by different organisations	<p>Chapter 3.3.2. Page 16, line 4: We would like to remark that RIVM with collaborating partners started in 2015 on the ConsExpo 2015 project. Within this project a webbased version of ConsExpo will be set up, but also within the coming years all the product category Fact Sheets will be updated (. Chapter 3.3.2. Page 17, line 3-4. Please consider deleting (or editing) Table 3. There is no correct unit of the numbers provided. It is mg mentioned, without mentioning that these mg are not amount of toy, but mg DINP (in the case of teething ring 0.244 µg/cm² x min) or acid dye from wool (in the case of the cuddly toy, 0.036 µg/cm² x min) in the row Mouthing. The final column “intake daily average mg calculated by SCHER” is therefore not comparable to each other. It should be noted that the amount of toy ingested for modelling clay and paint for toy (Children’s Toy Fact Sheet, 2002) was re-evaluated in 2006 (RIVM report), and at that time point with the inclusion of weighing experiments and a visual inspection (see also complete description on page 10, this opinion), reviewed by an Advisory Group. Chapter 3.3.2.</p> <p>Page 18, 1-14: The information in the report of the Danish EPA (2014) is based on the assumptions in the Children’s Toys Fact Sheet (2002), which is re-evaluated in the RIVM report (2008). See remark above.</p>		<p>The SCHER acknowledges that some of the assumptions from the toy fact sheets were modified in the RIVM reports 2006 and 2008.</p> <p>The SCHER appreciates the update of the toys fact sheets.</p> <p>Table 3 has been changed in order to make more clear the differences for the leachates and the toy materials.</p> <p>Additional information has been given in the Opinion (Chapters 3.3.2 and 3.3.5).</p>
11	ARASA EDUARDO JOVI S.A. earasa@jovi.es Spain	3.3.4 Input received from the call for information	3.3.4 Page 19, Line 35-39 This is the only reference in the SCHER preliminary opinion to a question that we consider an essential issue. To assess the risk of toxicity (which is trying to establish the study) is essential to consider the	 Sibert and Frude.pdf	This is considered as risk management option. The SCHER acknowledges that exposure of children to toys is reduced by adding embittering agents.

			<p>type of consumer and their behavior. Therefore, just as one considers the mouthing behaviour is essential to assess the inhibitory effect which comprises using an bittering agent. Some toys, finger paints, are formulated, by legal enforcement (EN71-7:2014 Finger paints), with an bittering substance in order to act as an aversive or deterrent agent. The efficiency of this measure to prevent acute exposures to liquid products has been argued (Sibert & Frude, 1991). However, it seems clear, from the published results of several assays, that embittering agents are effective to discourage children from successive mouthing, sucking and intake (Rodgers & Tenenbein, 1993; Friman & Barone, 1986; Berning et al, 1982; Friman & Leibowitz, 1990). Children rapidly learn the association between the product and the very unpleasant taste, reducing the frequency of successive object-to-mouth or hand-to-mouth exposures. Therefore, it seems reasonable to assume that the intake quantity and frequency of the toys formulated with an bittering agent will be lower than the general proposed parameters. In our opinion, the lower potential exposure to these toys must be considered by SCHER and by the EU legislation and directly reflected as specific and more tolerant migration limits.</p>	 Sibert & Frude.pdf	
12	Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands	3.3.4 Input received from the call for information	Chapter 3.3.4. Page 19, 31-39: The SCHER opinion refers to the paper of Moya & Phillips (2014) which provides an overview on dust and soil ingestion studies, resulting in ranges from 10-1000 mg/day (the latter for soil-pica). We are not aware of evidence that the amount of toy material ingested is similar with the amount of dust or soil ingested.		RIVM 2008 report states on pg 41 the following: "For risk assessments within the Dutch Soil Protection Act, a default of 100 mg is now used for ingestion of soil by children (Otte <i>et al.</i> , 2001). It is proposed that this value is used as a default for ingested amount of dry, pliable or powder-like toy materials, although further research is warranted."

13	Schoor Gerlienke RIVM gerlienke.schoor@rivm.nl Netherlands	3.3.5 Amounts of toy materials to be ingested by children	Chapter 3.3.5. Page 20, line 20. Please do not refer to the Children's Toy Fact Sheet (2002) for an overview of the mouthing times (instead of default!), but to the more recent overview in the ECHA report on DINP and DIDP (2013). Chapter 3.3.5 page 21, line 4-10: See remark above. It should be noted that the amount of toy ingested for modelling clay and paint for toy (Children's Toy Fact Sheet, 2002) was re-evaluated in 2006 (RIVM report), and at that time point with the inclusion of weighing experiments and a visual inspection (see also page 10, this opinion), reviewed by an Advisory Group.		The SCHER acknowledges that some of the assumptions from the toy fact sheets were modified in the RIVM reports 2006 and 2008. The SCHER appreciates the update of the toys fact sheets. Additional information was given in the Opinion (Chapters 3.3.2 and 3.3.5).
14	ARASA EDUARDO JOVI S.A. earasa@jovi.es Spain	3.4 Knowledge and data gaps	3.4 Page 21, Line, 12-22 In summary, SCHER admits the lack of new robust exposure data to allow improving the risk assessment reported by RIVM (2008). Following RIVM (2008), a child would ingest 100 mg/d of dry, brittle, powder-like or pliable toy material, 400 mg/d of liquid or sticky toy material, and 8 mg/d of scraped-off toy material. The main point of controversy is about the frequency of these intakes: - RIVM (2008) model considered that these events occur weekly, adding that this was a rough estimate that needed further research. - RIVM (2008) migration limit values were calculated, by error, considering daily frequency. - RIVM (2002) and Danish EPA (2014) consider diverse event frequencies in function of the type of toy (tables 3 and 4): Modelling clay: one per week Finger paint: two per week Piece of chalk: two per week Face paint: one per month Daily frequency was only considered for some toy mouthing events but no for neat toy ingestion events. Therefore, in our opinion, to consider a daily event frequency is not justified and is discordant with the values of frequency recommended in the surveys reviewed in the SCHER opinion (RIVM, 2002 & 2008; Danish EPA 2014).		The question asked to SCHER was to review available data and to review if the current amounts estimated for toy materials are still appropriate. The SCHER does not distinguish between different quality (neat or non-neat) of toys. Every toy which is sold in the EU has to comply with the requirements of TSD.

15	Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands	3.4 Knowledge and data gaps	Chapter 3.4. Page 21, line 17-19: The estimates on amount of toy are not laid down in the TSD, only the calculated limits for certain elements. With the error in the RIVM report corrected, all migration limits were adapted to 7-fold higher values. As the present migration limits are more conservative, we agree with not changing those migration limits.		The SCHER would like to thank RIVM for supporting the SCHER opinion.
16	Kupfer Rosemarie TÜV Rheinland LGA Products GmbH Rosemarie.Kupfer@de.tuv.com Germany	4 OPINION		 SCHER-Public consultation-toy mate	The question asked to SCHER was to review available data and to review if the current amounts estimated for toy materials are still appropriate. New data on mouthing behaviour on toys supported the opinion of the SCHER to keep the current estimates of ingested amounts on daily base.
17	ARASA EDUARDO JOVI S.A. earasa@jovi.es Spain	4 OPINION	4 Opinion Page 23, Line, 5-11 In our opinion, the assumption of a daily event frequency is not justified and is in disagreement with the values recommended in some surveys reviewed in the SCHER opinion (RIVM, 2002 & 2008; Danish EPA 2014). In our opinion, the lower potential intake of the toys formulated with an bittering agent must be considered by SCHER and by the EU legislation, and directly reflected as specific and more tolerant migration limits. Therefore it is clearly justified to take into account the "erratum" and the new values that it proposed and consider as more appropriate (and equally safe) estimate weekly ingestion rather than daily.		New data on mouthing behaviour on toys supported the opinion of the SCHER to keep the current estimates of ingested amounts on daily base. The SCHER acknowledges that exposure of children to toys is reduced by adding embittering agents.
18	Schuur Gerlienke RIVM gerlienke.schuur@rivm.nl Netherlands	4 OPINION	Chapter 4. Page 23, line 1-4. As the background of the Erratum was of an editorial nature, we doubt the relevance for this question. The basis for the limit was supposed to be: 100 mg/week of dry, brittle, powder-like or pliable, 400 mg/week of liquid or sticky and 8 mg/week of scraped-off toy material, as established in the RIVM report (2008) Chapter 3 (so per week, not per day). The question should be if that choice for default amounts is still appropriate.		The questions posed in the Terms of reference are provided by the Commission as part of the mandate and cannot be changed.

