Scientific Committee on Health and Environmental Risks

SCHER

Final Opinion on
Estimates of the amount of toy materials ingested by children

The final Opinion was adopted by the SCHER by written procedure on 8 April 2016

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SCHER

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All Declarations of Working Group members and supporting experts are available at the following webpage:
http://ec.europa.eu/health/scientific_committees/environmental_risks/members_committee/index_en.htm

ABSTRACT

The SCHER was asked to review available data on the ingestion of three types of toy material by children in order to evaluate if the current ingestion amounts of 100 mg/d for dry, brittle, powder-like or pliable toy material, 400 mg/d for liquid or sticky toy material, and 8 mg/d for scraped-off toy material are still appropriate, or whether they should be considered to be weekly amounts.

To answer these questions the SCHER has reviewed relevant literature published since 2008.

In this Opinion, the SCHER considers the ingestion amounts mentioned above to be appropriate. Furthermore, the SCHER considers that all ingestion amounts should remain classified as daily rather than weekly.

Keywords: toys, children, ingestion, pliable, liquid, sticky, scraped-off toy material, risk assessment

Opinion to be cited as:

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EXECUTIVE SUMMARY

Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children. The Toy Safety Directive therefore establishes migration limits for 19 elements in toys or components of toys, which may not be exceeded. The migration limits depend on the type of toy material used and are based on a 2008 RIVM report which assumed that 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. However, in another section, the report also noted that the ingestion of 100 mg of dry, brittle, powder-like or pliable toy material and 400 mg of liquid or sticky toy material, although reasonable, may not occur daily, but only once a week, adding that this was a rough estimate that needed further research. An "Erratum" was added to the report in January 2015, which used the assumption of weekly ingestion of the amounts to re-calculate the derived acceptable limits, thus increasing them 7-fold.

The SCHER was asked to review the available data on the ingestion of all three types of toy material by children and to consider whether the ingestion amounts estimated earlier are still appropriate or whether new amounts would be more appropriate.

To answer these questions the SCHER reviewed relevant literature published since 2008. Most papers were found to deal with mouthing frequency and mouthing duration. Some reports focus on transfer rates from different materials (dry, brittle, powder-like or pliable toy material; liquid or sticky) to hands and mouth over a certain period of time. A large study on mouthing behaviour was carried out recently by CEN with 245 children. A total of 1,680 observations were made representing 60 different toys for children aged 0–36 months. This study mainly supports results of existing studies on mouthing behaviour. However, regarding ingestion of the three toy materials by children when playing with different toys, no new data are available.

In addition, the SCHER reviewed default values for mouthing frequency and duration that were given in exposure handbook and fact sheets. Exposure scenarios used in risk assessment for specific chemicals related to toys were compared. Moreover, the SCHER considered information received after a call for information on this topic.

Considering the data base, the SCHER is of the opinion that the current estimated ingestion amounts (100 mg/d of dry, brittle, powder-like or pliable, 400 mg/d of liquid or sticky and 8 mg/d of scraped-off toy material) are still appropriate.

The SCHER does not support the assumption of weekly ingestion of these amounts and recommends not to re-calculate the derived migration limits, thus increasing them 7-fold as proposed by RIVM.

1 BACKGROUND

The Toy Safety Directive 2009/48/EC[1] (TSD) establishes migration limits for 19 elements in toys or components of toys, depending on the type of toy material used: dry, brittle, powder-like or pliable toy material; liquid or sticky toy material; and scraped-off toy material. These migration limits, listed in point 13 of Part III of Annex II of the Toy Safety Directive, may not be exceeded.

The migration limits were based on a 2008 report[2] which assumed that 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.[3] With these assumptions, the report derived tentative limits[4] on which the migration limits of the Toy Safety Directive were based.

However, in another section, the report also noted that the ingestion of 100 mg of dry, brittle, powder-like or pliable toy material and 400 mg of liquid or sticky toy material, although reasonable, may not occur daily, but only once a week[5], adding that this was a rough estimate which needed further research.

An "Erratum"[6] was added to the report in January 2015, which used the assumption of weekly ingestion of the amounts to re-calculate the derived limits, thus increasing them 7-fold.

[1] Directive 2009/48/EC of the European Parliament and of the Council of 18 June2009 on the safety of toys. OJ L 170, 30.06.2009, p. 1.
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20140721&rid=1

[2] RIVM advisory report of 2008, Chemicals in toys. A general methodology for assessment of chemical safety of toys with a focus on elements. http://www.rivm.nl/bibliotheek/rapporten/320003001.pdf

[3]http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2009/april/Chemicals_in_toys_A_general_methodology_for_assessment_of_chemical_safety_of_toys_with_a_focus_on_elements?sp=Y3RsMT1yZXBvcnQ7SU5MSUJSQVJZPXRydWU7U0lURUxBTkdVQUdFPW5sO3NlYXJjaGJhc2U9MDtzZWFyY2hyYW5nZT01MDtzZWFyY2hleHByZXNzaW9uPShjdGwxKSBBTkQgSU5MSUJSQVJZIEFORCBTSVRFTEFOR1VBR0U7c29ydGZpZWxkPXB1Ymxpc2hkYXRlO3NvcnRyZXZlcnNlZD10cnVlOw==&query=&pagenr=1&result=rivmp%3A12983

2 TERMS OF REFERENCE

Taking this new development into consideration, SCHER is asked:

- To review the available data on the ingestion of all three types of toy materials provided for in the Toy Safety Directive 2009/48/EC (dry, brittle, powder-like or pliable toy material; liquid or sticky toy material; and scraped-off toy material) by children;

- To consider, in the light of the review, whether the estimated ingestion amounts (100 mg/d of dry, brittle, powder-like or pliable, 400 mg/d of liquid or sticky and 8 mg/d of scraped-off toy material), which formed the basis for the limits in the Toy Safety Directive, are still appropriate;

- To propose, if the estimated ingestion amounts are no longer considered appropriate, new amounts which would be more appropriate, clearly indicating the data on which they are based.

In this work, SCHER should take account of the Guidance on consumer exposure estimation of the European Chemicals Agency (ECHA), in particular section R.15.2.5.[7]

[7] http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf

3 SCIENTIFIC RATIONALE

3.1 Introduction

Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children (European Directive 2009/48/EC). The directive on the safety of toys applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age. Annex 2 of the directive lists migration limits for several elements which shall not be exceeded in toys or toy components. These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified. The current limit values are based on the report on chemicals in toys by RIVM (RIVM, 2008). They are related to three different toy materials and take into account age specific behaviour and specific exposure scenarios. The amount of toy material that can be ingested is a crucial parameter for estimating exposure to chemicals from ingested toys and hence for determining migration limits.

Children can be exposed to chemicals that are released from toys. Exposure of children to certain elements from toys depends on the toy characteristics like composition of the toy material, its surface, volume and its intended use as well as the playing behaviour and the physiological characteristics of a child which both change with age. Exposure scenarios therefore need to reflect the intended and foreseeable use of a toy and the age of a child.

To determine exposure, several aspects have to be considered i.e. the amount of a chemical released from toys in use, the contact time including the type of contact (skin contact, mouthing of toys, ingestion of toy material). For children under 3 years of age and for toys that are intended to be put in the mouth, oral exposure is an important route of systemic exposure. For example some liquid toys such as finger paint are easily swallowed. Toys that consist of dry, brittle, powder-like or pliable material, such as chalk crayons, plaster or modelling clay may be ingested. In addition, some toys may have a layer of paint or other coating, or textile fibres that may easily be scraped off and swallowed. Ingestion of scraped off material is also relevant for toys which are intended to be placed in the mouth.

Under the age of 3, mouthing behaviour plays an important role regarding contact of children to toy materials (van Engelen *et al*., 2004). Mouthing describes all activities by which hands, fingers or objects are touched by the mouth or put into the mouth. The frequency of object-to-mouth activity is an important variable for exposure assessment, as it determines the chance of ingesting toy material. It has also to be kept in mind that children under 3 years of age may play with toys intended for other age groups.

In order to answer the questions related to appropriate amounts of toy materials taken up by children, the SCHER reviewed the available data and information on the ingestion of three types of toy materials in order to derive appropriate values for ingestion amounts. To support the work of the SCHER, the Commission asked an external company to carry out a literature search, covering the period from January 2008 to June 2015. The search terms were "toys" AND "ingestion" AND "children" AND "behaviour". A search on "whole object ingestion" was added. The number of results specifically

related to toy ingestion by children was very low. A larger number of results were related to ingestion of objects, particularly small magnets (see Annex 1).

Moreover, the Commission published in April 2015 a Call for information[8]. Interested parties were invited to submit any relevant information concerning the ingestion of toy materials by children that could assist the committee in preparation of the Opinion. Toy manufacturers and associations, Commission departments, and universities submitted in total 7 contributions.

3.2 Exposure to chemicals in toys – the RIVM report

In the RIVM report, a risk-based methodology for the assessment of the safety of exposure to chemicals in toys was derived (RIVM, 2008). The focus was on toys intended for children under 36 months and on toys intended to be put in the mouth (children > 36 months). Oral exposure was considered the most relevant route of systemic exposure although dermal and inhalation exposure were also addressed. However, no separate approaches for dermal and inhalation exposure routes were developed, as the proposed migration limits for oral exposure were meant to also cover any exposure *via* the dermal and inhalation routes.

It was recognised that exposure to a chemical can only occur when the chemical is first released from the matrix (bioaccessibility). For elements in toys intended for children < 3 years, migration limits were derived for three different types of toy materials: solid (easily to break or bite off), liquid or sticky material, and for material to be scraped off. For toys intended to be put in the mouth (> 3 years), only the limit for scraped off material was considered relevant, because children of this age display less mouthing behaviour. For elements, it was assumed that when migration limits for oral exposure are derived, they cover both mouthing and ingestion.

The categorisation based on the toy material was chosen for the purpose of determining appropriate migration tests as no other appropriate groups of toys could be identified regarding exposure to elements. Three realistic worst case default values for oral contact were defined. One for dry, pliable or powder-like materials like modelling clay, one for liquid materials like finger paint and one for textile fibres and material that can be scraped off with teeth.

The following aspects were considered by RIVM:

(1) For toys, consisting of dry, brittle, pliable or powder-like material (e.g. chalk crayons, modelling clay and plaster powder), a considerable amount of material may be bitten off or ingested via hand-mouth contact. For chalk crayons, the children's toys fact sheet (TFS) (Bremmer and van Veen, 2002) were firstly considered, which derived a rough default value of 6 mg/min while playing with the crayons as a default, based on studies on ingestion of soil by children. It was further assumed that children play with crayons for 45 minutes. The total amount swallowed during one event was then 6 x 45 = 270 mg. Based on weighing experiments and visual inspection, the default of ingesting 270 mg was considered to be an overestimation. Therefore, a default of 100 mg was proposed, as this default value is also used for ingestion of soil by children in the Dutch Soil

[8] http://ec.europa.eu/health/scientific_committees/consultations/calls/scher_call_info_07_en.htm

Protection Act, although further research was considered warranted. The ingestion of 100 mg by children was considered reasonable, but may not occur daily. For exposure assessment refinement purposes, RIVM proposed to use a frequency of 1/week for this ingestion default when the exposure is compared to a chronic health-based limit value. RIVM also stated: "This is a rough estimate and needs further research."

(2) The amount of liquid toy material that may be ingested *via* hand-to-mouth contact was judged to be considerably higher than for dry material. For finger paint and other products that stick to the skin, the TFS default value of 30 mg/min was used first. It was further assumed that children play with finger paints for 45 minutes. The total amount swallowed was then 30 x 45 = 1350 mg. It was concluded that this default would be too high and the value of 400 mg was proposed by RIVM. For the purpose of an exposure assessment refinement, when comparing exposure to a chronic health-based limit value, RIVM proposed to use a frequency of 1/week as a default, indicating that this is a rough estimate that needs further research.

(3) The amount of toy material scraped off with the teeth while mouthing a solid toy was judged to be considerably lower than the amount of liquid, pliable or sticky toy material that may be ingested. From the TFS, for the first approach, a single ingestion of paint from a toy car was estimated by RIVM based on the volume (0.05 cm^3) and density of paint (2 g/cm^3). This amounts to a total of 0.1 g. However, this value was considered an overestimation. Based on weighting experiments, a default value of 8 mg was therefore recommended for ingested layers of scraped off toy material. In contrast to the previous two defaults for ingested amounts, this default should also apply to toys intended to be mouthed by children over 3 years of age. Furthermore, with regard to frequency, it was assumed that the amount of 8 mg material can be scraped off from a toy every day.

When calculating migration limits for certain elements, however, the RIVM report from 2008 used the amounts for all three toy materials that can be ingested on a daily base instead of a weekly base (see chapter 8). 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. However, no reference was supplied for the new data or additional research.

3.3 Additional information available to the SCHER

Literature reviewed by the SCHER was found to deal with mouthing frequency and mouthing duration, but the authors do not convert this information into estimations about the amount of ingested toy materials or the frequency toy materials are ingested. The reported mouthing frequency and mouthing duration applies to an everyday frequency, based on how the toy is used. But the SCHER is concerned with determining the amount ingested and establishing the frequency of ingestion per toy material.

Some reports focus on transfer rates from different materials (solid, liquid, scraped-off) to hands and mouth over a certain period of time. However, there is no new information available on the amount and frequency children ingest the three toy materials regulated in the TSD when playing with different toys.

The SCHER used available data for mouthing behaviour to estimate the amounts of toy materials taken up by children in a certain time period.

3.3.1 Recent studies on mouthing behaviour and ingestion of toy materials

Infants are born with a sucking reflex for breast feeding, and within a few months, they begin to use sucking or mouthing as a means to explore their surroundings. In early development, sucking provides essential nutrients in the form of breast or bottle feeding, as well as a feeling of well-being and a sense of security (Juberg *et al*., 2001). Sucking also becomes a means of comfort when a child is tired or upset. Mouthing describes all activities by which hands, fingers or objects are touched by the mouth or put into the mouth. Children exhibit large differences in mouthing behaviour (Groot *et al.*, 1998). In addition, teething normally causes substantial mouthing behaviour, sucking or chewing to alleviate discomfort in the gums. Each child is different, and large differences occur between children, even within the same family.

Mouthing behaviour in combination with looking and touching allows children to explore and investigate their environment. Mouthing behaviour develops into an exploratory behaviour in which objects are placed into the mouth for purposes of discovery. During this stage of development, children will put their hands and any object that they come in contact with into their mouths (Ruff, 1984; Ruff and Dubiner, 1987; Davis *et al.,* 1995; Groot *et al.*, 1998).

Teething is another reason that children will mouth fingers and objects. At this stage of development, mouthing alleviates the pain and discomfort associated with teething (Groot *et al.*, 1998). Teething usually begins at 7–8 months, but may start several months earlier or later. As with all childhood behaviour, mouthing activities vary significantly from child to child, and therefore, the impact on exposure will also be highly variable (Cohen Hubal *et al*., 2000). Overall, mouthing activity is positively correlated with teething and negatively correlated with increased mobility (Juberg *et al.*, 2001, Groot *et al*., 1998, Xue *et al*., 2007, Norris and Smith, 2002).

As mouthing is an important component in childhood development, many studies have addressed mouthing behaviour. The frequency and duration of object-to-mouth activity is an important variable for an exposure assessment, as it determines the chance of ingesting toy material (van Engelen *et al*., 2004). Children's mouthing behaviour is studied using both direct observation and videotaping methodologies.

A study on "children's mouthing behaviour in contact with toys" funded by the European Commission and coordinated by European Committee for Standardization (CEN) was carried out between 2013 and 2014 in three European countries (Spain, Germany and France) (CEN, 2014). The objective of the study was to measure and quantify the duration and frequency that children aged 0-36 months introduce toys into their mouth spontaneously. The results of this study will serve as input for the revision of EN 71-12:2013.

The study was carried out with 245 children and 1,680 observations were made representing 60 different specific toys for children aged 0–36 months. However, there is neither data on the parts of toys mouthed nor on the materials of the product mouthed. The only available information is on the percentage of the materials that were rubber or plastic. Arts and craft materials were not included in the study. Additional information on

the type of materials that are mouthed by young children is available from Norris and Smith (2002). In a study with 236 children between 1 month and 5 years, they reported that objects and toys made out of plastic were the most mouthed, followed by fabrics; approximately half of all the toys and other objects mouthed were made of plastic. The study also demonstrated that children mouth many items other than dummies, teethers, and toys expected to be mouthed. Between 6-9 months on average, 26 different items are mouthed per day. The number of toys mouthed decreases with increasing age (Norris and Smith, 2002). The variety of objects mouthed indicates that young children have access to a wide range of non-toy objects.

In the CEN study, parents made observations of their children playing at home for 18 min/d, resulting in 126 minutes of observation per child within one week. In total, 511.8 h of adult observation of children's activities with toys were collected. It was expected that children under 36 months would be awake and not eating for 10 h/d and that they would be in contact with toys for 4.4 h/d in this recent study. Qualitative and quantitative analysis of children's mouthing behaviour was conducted additionally *via* video recording with a total of 16 h of observation. The results confirmed earlier study results from Norris and Smith (2002).

On average children mouthed toys for 14.7% or 75.2 h, (11.7% or 59.9 h, weighted by year) of the total time observed (511.8 h), which gives a mean of 30 min/d, weighted by year. Values for the 95th and 99th percentiles are 50.6% and 60.3% mouthing of the total time observed, respectively. Differences between age groups were significant. The maximum was in the 10-12 month group with 74.8% of the total time observed.

The average mean frequency of children under 36 months mouthing toys was 26 times/h (weighted by year). The values for the 95th and 99th percentiles are 91 and 171 times/h, respectively. The maximum frequency was observed in children aged 3 to 5 months with 228 times mouthing/h. The average number of times children under 12 months mouthed toys (44 times) was significantly different compared with children from 13-36 months (17 times).

The mean duration considering all age groups for toy-to-mouth contacts was 17.3 s (weighted by year). The age group of children under 12 months old (24.9 s) was significantly different from those of 13-24 months old (15.6 s) and 25-36 months old (11.6 s). Maximum duration of toy-to-mouth contact was 106.5 s in the 3-5 month age group. Considerable higher maxima compared to further age groups were also reported for 6-9 month (103.3 s) and 13-18 month (103.0 s). As age increases, mean values for frequency and duration of mouthing decrease.

When analysing the time spent mouthing toys or the frequency of mouthing toys, no significant differences were observed according to gender or period of observation time. No significant differences were observed when analysing the mean values over the age groups for mouthing frequency for the three countries. However, the highest frequency was observed for Spanish babies, aged 3-5 months (106 compared to 62 in France and 44 in Germany) and 6-9 months (68 compared to 37 in France and 29 in Germany). With regard to the duration, Spanish children (10%) spent significantly less time mouthing toys than German (16.3%) and French children (17.8%).

The most frequent type of mouthing behaviour observed in children's contact with toys was lip-touching (average of 21 times/h weighted by year or 9.3% of total mouthing

time, average weighted by year), followed by sucking (16 times or 8.1%) and biting (17 times or 7.6%). Bite marks left on toys were found in average on 10% of mouthed toys, mainly on toys of elastomeric material. Biting behaviour occurred mostly in children aged 6-24 months.

In addition to the different behaviour of children, the degree of salivation while mouthing toys was also evaluated in this study. Sixty percent of mouthing behaviour occurred without salivation, as perceived by parents, 22% with low salivation, 13% with medium salivation, and 4% with high salivation. Children under 12 months exhibited higher levels of salivation than those aged 13 months and over. Three to five months was the only age group where medium levels of salivation were predominant. Toys correlated with higher levels of salivation were usually toys made of elastomeric materials.

In this study, toys were categorised into 13 groups. The frequency and the percentage of time children spent mouthing toys were significantly higher in category 4 (toys for babies, for looking at, grasping and/or squeezing) and in category 10 (sand-water & bath toys).

Another difference was related to the toy material. For elastomeric toys, children showed significantly higher mouthing behaviour than for toys from other materials. Toys with elastomeric materials had a higher frequency (mean 26 times/h weighted by year vs. 22 times/h weighted by year for other toys). If the maximum values are considered, frequency of mouthing an elastomeric toy was 228 times/h, whereas with other toys that were not elastomeric the maximum frequency was 163 times/h. The time spent mouthing elastomeric toys was 12.4% of total time on average, weighted by year, with a maximum of 74.8% of total mouthing time, vs. a mean of 9.7% and a maximum of 53.2% for toys that were not elastomeric. Additionally, a significantly higher duration in individual events of toy-to-mouth contact was observed with elastomeric toys (mean 23 seconds, and a maximum of 120 seconds versus mean 17 seconds and a maximum of 114 seconds for other toys).

When comparing toys intended to be mouthed and toys not intended to be mouthed, significant differences were observed. The time children spent mouthing toys intended to be mouthed was 14% of observed time, weighted by year, whereas it was 11% of observed time, weighted by year, for toys not intended to be mouthed. In addition, significant differences were observed in the frequency children mouthed toys intended to be mouthed (mean 41/h or 33 times/h when weighted by year of, a maximum of 228 times/h) and the toys not intended to be mouthed (mean weighted by year of 22 times/h, a maximum of 172 times/h). The greatest differences were found in older children. At younger ages (under 12 months), children put any toy in their mouth, whether it was intended to be mouthed or not. No significant differences were found in duration of toy-to-mouth contact.

A meta-analysis was conducted on data from seven studies on children's object-to-mouth contacts performed in the US and published between 1999 and 2008 (Xue *et al*., 2010). It should be noted that the objects in these studies were not necessarily toys. The meta-analysis included 438 children between 6 months and 12 years and approximately 1500 h of behaviour observation. Object-to-mouth frequency was significantly greater indoors (2-32 contacts/h) than outdoors (average 1-9 contacts/h). The highest indoor values were reported in 6-12 month old children; the highest outdoor values corresponded to the 1-6 year olds. No significant differences occurred in the age

groups 1–2, 2–3, and 3–6 years. The lowest indoor and outdoor values were reported in the 6-11 year olds. No data were available in any of the studies for infants from birth to 1 month and few were available for 1–3 months old children. For the 3–6 months age group, indoor object-to-mouth frequency data were available for 19 children, but no outdoor object-to-mouth frequency data were available. For the 6–11 years age group, there were only 15 participants for indoor and 29 for outdoor observations. No significant differences in mouthing times were reported between the genders or at different times of the day (Xue *et al*., 2007; Norris and Smith, 2002).

Brittle or pliable toys like chalk, crayons, or carton puzzles can be mouthed for long times as shown in a study to estimate children's exposure to metals in toys (Guney and Zagury, 2012). Due to their structural properties, large amounts of these materials can be directly ingested by children. Some fraction of brittle or pliable toys can also stick to hands, resulting in ingestion after mouthing of hands or uptake *via* dermal exposure.

Based on hospital records, toys were the most frequent cause of medical emergency situations due to aspiration or ingestion of inedible foreign bodies in Greek children, followed by coins and jewellery (Farmakakis *et al.*, 2007).

Guney and Zagury (2012) evaluated the US, Canadian, and European Union (EU) legislations on metals in toys and jewellery and carried out a literature review on content, bioavailability, children's exposure, and testing of metals in toys and low-cost jewellery. They highlighted that children may ingest more material than the amount assumed in the standard EN 71-3 (8 mg). This was also highlighted by Rastogi and Pritzl (1996). For risk assessment of toxic metals in children's toys and jewellery, bioaccessibility was considered together with ingestion (Guney and Zagury, 2014a; Cui *et al.*, 2015). A mass of toys and jewellery ingested of 1 g and 10 g was considered respectively by these authors. Cui *et al.* (2015) estimated that this value is quite reasonable for metallic toys, but might be an overestimation for much lighter toys (such as plastic toy). Guney and Zagury (2014b) argued that to improve risk characterisation results, more information is needed on the quantity of ingested toy/jewellery material and on the frequency of ingestion.

3.3.2 Approaches and default values used by different organisations

US-EPA

The US-EPA Exposure Factors Handbook (EFH) (US-EPA, 2011) recommends hand-to-mouth and object-to-mouth frequencies which are based on data from Xue *et al*. (2007) and Xue *et al*. (2010), respectively. These authors conducted a secondary analysis of data from several studies summarised in the EFH as well as data from an unpublished study. Recommendations for duration of object-to-mouth contacts are based on data from Juberg *et al*. (2001), Greene (2002), and Beamer *et al*. (2008). Recommendations on duration of object-to-mouth contacts pre-dated the US-EPA (2005) guidance on age groups.

Recommended Values, Indoor
EPA Exposure Factor Handbook 2011

Age group	Hand-to-Mouth contacts/hour		Object-to-Mouth contacts/hour		Duration minutes/hour	
	mean	95th percentile	mean	95th percentile	mean	95th percentile
Birth to <1 month	-	-	-	-	-	-
1 to <3 months	-	-	-	-	-	-
3 to <6 months	28	65	11	32	11	26
6 to <12 months	19	52	20	38	9	19
1 to <2 years	20	63	14	34	7	22
2 to <3 years	13	37	9.9	24	10	11
3 to <6 years	15	54	10	39	-	-
6 to <11 years	7	21	1.1	3.2	-	-
11 to <16 years	-	-	-	-	-	-
16 to <21 years	-	-	-	-	-	-

Table 1: Values for hand-to-mouth contacts and object-to-mouth contacts as well as duration of contacts for different age groups as recommended by the US-EPA.

Children's Toys Fact Sheet and ConsExpo

The RIVM computer programme ConsExpo provides mathematical models for the exposure assessment of compounds in consumer products. Fact sheets contain the parameter and default values on which the models are based. The RIVM toys fact sheet (TFS) supplies information on use of children's toys and describes the ways in which children can be exposed. Default parameter values are given (see Table 2) and examples for specific toys were provided (Bremmer and van Veen, 2002).

RIVM
Toys Fact Sheet, 2002

age group	default mouthing time [minutes a day]			
mounth	pacifier	toys for mouthing	other toys	non toys
4.5	285	11	27	8
7.5	82	21	63	23
13.5	52	0	9	26
18	62	0	3	6

Table 2: Default mouthing time for different age groups according to RIVM toys fact sheet.

Defaults given for mouthing are based on the publications from Groot *et al.* (1998) and Juberg *et al*. (2001). For direct ingestion, it is concluded that the most important parameter is the one that indicates the amount of product that is taken in daily. However, no measurement data is available for this parameter and a "single ingestion" scenario was used based on assumptions. The "hand-to-mouth contact" scenario was based on data for the ingestion of soil.

In the TFS different examples are given (see Table 2). For mouthing, the di-iso-nonylphthalate (DINP) exposure from teething rings and dolls was calculated as well as the exposure to dye stuff from wool of a cuddly toy. For direct ingestion, calculations

were made for modelling clay, paint from a toy car and ball pens. For hand-to-mouth contact, chalk, finger paints and face paints were considered.

	Toy	Contact time min	Frequency year			Uptake/event	Frequency	Intake daily average calculated by SCHER
Mouthing				**Area cm^2**	**Leachate $\mu g/cm^2 \times min$**	**mg chemical**		**mg chemical**
	Teething ring	11	365	10	0,244	0,027	daily	0,027
	Cuddly toy	27	365	10	0,036	0,010	daily	0,010
	Plastic doll	63	365	10	0,244	0,154	daily	0,154
Ingestion				**Ingested cm^3**	**Density g/cm^3**	**mg toy material**		**mg toy material**
	Modelling clay	60	52	0,5	2	1000	1/week	143
	Paint from a toy	3	150	0,05	2	100	3/week	43
	Ball pen	30	365	0,2	1,5	300	daily	300
Hand-to-mouth				**Ingestion mg/min**		**mg toy material**		**mg toy material**
	Piece of chalk	45	100	6		270	2/week	77
	Finger paint	45	100	30		1350	2/week	386
	Face paint	480	12	0,44		210	1/month	7

Table 3: Examples of exposure of children to chemicals from toys through mouthing, direct ingestion or hand-to-mouth contact according to the RIVM toys fact sheet. For further details, see Bremmer and van Veen (2002). It should be noted, that not all writing articles are considered as toys[9].

For mouthing, the uptake in Table 3 is calculated for the migrated chemical (DINP from teething ring and a plastic doll, dye from a cuddly toy). The examples for ingestion and hand-to-mouth contact are calculated for the uptake of toy material. The average daily intake (most right-hand column) was calculated by the SCHER based on the assumptions given by RIVM. For some examples (e.g. 143 mg/d for modelling clay which is categorised as a pliable toy material or 43 mg/d for the paint from a toy which is categorised as a solid toy material), the calculated daily average intake exceeds the corresponding daily intake values in the TSD (100 mg for dry, brittle, pliable or powder-like material, 400 mg for liquid toy materials and 8 mg for scrapped-off toy materials).

ECHA

In the ECHA review report on evaluation of new scientific evidence concerning DINP and di-iso-decylphthalate (DIDP) in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006, a mouthing time for DINP and DIDP containing articles of 7.5 min/d was considered in a typical case as well as a duration of 120 min/d in a worst case scenario considered reasonable by ECHA for children up to 18 months (ECHA, 2013). The scenario for mouthing an eraser (rubber) with DINP or DIDP by a 6-year-old child was estimated to be 60 min/d. This approach was supported by the Risk Assessment Committee (RAC) at ECHA (RAC, 2012). In the case of restrictions on lead in jewellery, the RAC supported a mouthing time of one hour per day (RAC, 2011).

[9] EC, 2012, GUIDANCE DOCUMENT No. 15 ON THE APPLICATION OF THE DIRECTIVE ON THE SAFETY OF TOYS

CSTEE

The CSTEE evaluated a risk assessment report on acetyl tributyl citrate (ATBC) as plasticiser used in children's toys (CSTEE, 2004). The committee considered a maximum mouthing duration of 180 min for a child weighing 8.0 kg to estimate the risk.

Danish EPA

The Danish EPA provided a survey and health assessment of preservatives in toys (Danish EPA, 2014). In a worst-case assessment, ingestion was calculated for the following products: finger paint, modelling clay, face paint, make-up, slime and soap bubbles. In Table 4, the assumptions and default values for ingested toy materials are shown. The Danish EPA used TFS from 2002.

Toy	Amount of product used g	Contact time min	Ingested/event g	Frequency y	Frequency	Intake daily average calculated by SCHER mg
Modelling	350	60	1	52	1/week	143
Face paint	1.4	480	0.21	12	1/month	7
Make up	0.36	480	0.054	12	1/month	1.8
						151.8 total for dry, brittle, pliable or powder-like toy materials
Slime	350	45	1	100	2/week	286
Soap bubbles	350	45	1	20	<2/month	67
Finger paint	20	45	1.35	100	2/ week	386
						739 total for liquid toy materials

Table 4: Assumptions and default values used by the Danish EPA in order to evaluate preservatives in toys.

The average daily intake (far right column) in Table 4 was calculated by the SCHER on the base of the assumptions given by the Danish EPA. It should be noted that the calculated daily intake value of 151.8 mg/d for dry, brittle, pliable or powder-like material as well as the calculated daily intake value of 739 mg/d for liquid toy materials exceed the corresponding daily intake values in the TSD of 100 mg/d 400 mg/d, respectively.

3.3.3 Soil

Studies on the ingestion of soil and dust material by infants and toddlers can provide another source of information to estimate the amounts of non-dietary material that can be ingested by children. Non-dietary soil and dust ingestion can be estimated *via* hand-to-mouth contact, hand-to-mouth frequency, hand-surface area mouthed per event, the efficiency of hand-to-mouth transfer and exposure duration. All these parameters depend on material characteristics or personal characteristics and behaviour and thus there can be a huge variability in calculated soil ingestion values. Moya and Phillips (2014) have recently reviewed relevant soil and dust studies for children and have summarised the different types of studies that can be conducted to include tracer

element methods, biokinetic modelling approaches or activity pattern analysis. The tracer element methodology attempts to quantify the amounts of soil ingested by analysing samples of soil from children's residences and from children's excreta (faeces, and sometimes also urine). The soil, faecal, and urine samples are analysed for tracer elements which occur naturally in soils such as aluminium, silicon, titanium and yttrium. Modelling is then used to convert and integrate environmental monitoring data through biokinetic modelling into uptake data. Methods using activity patterns combine information on hand-to-mouth and object-to-mouth activities and time spent at various locations with assumptions about transfer of soil to hands (e.g. soil-to-skin adherence) and from hands to mouth (e.g. saliva removal efficiency) and other exposure factors (e.g. frequency of hand washing) to derive estimates of soil ingestion.

The tracer, biokinetic and activity pattern studies provided mean soil and dust estimates of 26-470, 110 or 10-1000 mg/d, respectively. The EFH recommends the use of 30mg/d as amount of ingested soil for children between 6 weeks and 1 year and 50 mg/d between 1 and 21 years with a 95 upper percentile of 200 mg/d. These values can be used as estimates of non-food materials ingested by children and may be particularly suitable to estimate ingestion of dry and powder-like toy material.

In the RIVM report, reference to soil intake was made when deriving the value of 100 mg for the ingestion of dry, brittle, pliable or powder-like toy materials. RIVM proposes to use this value on a weekly basis, however, the current best estimates of the amount of soil ingested by children (in the range of 10–1000 mg) in Moya and Phillips (2014) is on a daily basis.

3.3.4 Input received from the call for information

As mentioned earlier, the Commission published a call[10] to submit relevant information concerning the ingestion of toy materials by children that could assist the SCHER in preparation of the Opinion. The call for information was open between 30 April and 12 June 2015. Seven submissions were received from the European Commission, from universities and from different toy manufacturers and associations. Some information received was marked confidential.

In evaluating the responses from the call, submitted information has only been considered for the Opinion if:

1. it is directly referring to the questions asked
2. it contains specific information to the issues of the mandate
3. it adds new information to the Opinion of the SCHER.

Each submission that met these criteria has been carefully considered by the Working Group.

In some responses, there was general acceptance that the values proposed in the RIVM report (e.g. for ingestion of dry and powder-like material) overestimate the actual ingestion from toys, but there still remains a degree of uncertainty surrounding these estimates, which does not warrant exposure values to be revised until better data becomes available. Others suggested that more realistic scenarios should be used to estimate exposures, for example the occasional consumption of these amounts

[10] http://ec.europa.eu/health/scientific_committees/consultations/calls/scher_call_info_07_en.htm

(i.e. 100 mg/d or 400 mg/d), should be once per month rather than once a day or week, especially as risk management measures are often in place (e.g. embittering agents in finger paints) which will discourage children from ingesting these products.

The need for further research to improve the estimates (e.g. for some of the ingestion rates) was highlighted and that these (e.g. 100 mg of powder toy or 400 mg ingestion of liquid toy) should be considered an acute dose rather than a dose for chronic toxicity exposure estimates. There was also a suggestion that the model should be refined to reflect more accurately the mouthing behaviour changes with age (e.g. that mouthing behaviour decreases to 6.5% in children 2 years old from a maximum of 36.9% time spent mouthing toys up to 12 months of age).

Several comments were also received that were outside the scope of the Opinion.

3.3.5 Conclusions on amounts of toy materials ingested by children

Literature published after 2008 is mainly related to the mouthing behaviour of children. The information is not sufficient to make a direct estimation of the ingested amounts of toy material or the frequency at which toy material is ingested.

Data from the most recent study on mouthing behaviour carried out by CEN (CEN, 2014) confirm existing data and default values derived. According to this recent study, the average mean frequency children under 36 months mouthed toys was 26 times/h (weighted by year). The values for the 95th and 99th percentiles are 91 and 171 times/h, respectively. Recommended values for object-to-mouth contacts/h in the EFH are slightly lower and lay between 9.9 and 20 times/h (mean) or between 24 and 38 times/h (95th percentile) for different age groups between 3 and 36 month (US-EPA, 2011). Regarding mouthing duration from the CEN study, an average duration of approximately 7 min/h can be derived on a mean-average weighted by age. In the EFH, mean values of 7-11 min/h (mean) and 11-26 min/h (95th percentile) were recommended (US-EPA, 2011). In the TFS (RIVM, 2002) the values for default mouthing time varies between 3 min/d and 285 min/d according to the toy type (pacifier, toy for mouthing, other toy) and the age group (4.5, 7.5, 13.5 or 18 month).

When comparing data on mouthing behaviour, no significant differences were observed related to gender or period of observation time. As age increases, mean values for frequency and duration of mouthing decreases. But data from the CEN study also show that mouthing activities can vary significantly from child to child, and therefore, the impact on exposure may also be highly variable. In addition, mouthing frequency and duration differ in the three countries participating in the CEN study.

It became obvious that infants also frequently suck and bite toys and touch their lips to them. Biting behaviour was observed for 7.6% of mouthing time, mostly in children aged 6 to 24 month. Bite marks were found on 10 % of the toys mouthed. Biting toys can result in the uptake of toy materials.

In the CEN study, toys for babies, for looking at, grasping and/or squeezing and sand-water and bath toys were mouthed significantly more frequently than other toys. The main difference however, was related to toy material. Highest values were observed for elastomeric toys. These findings support the investigations from Norris and Smith (2002), who reported that toys made of plastic were the most mouthed, followed by

fabrics. It has also to be considered that elastomeric toys induce higher salivation when they were mouthed. This can enhance the uptake of chemicals released from such toys.

The CEN study also provides data on differences between toys intended to be mouthed and toys not intended to be mouthed. It has to be noted that toys not intended to be mouthed count for mouthing during 11% of the observed time, while toys intended to be mouthed count for 14%. It is reported that younger age groups in particular use almost everything for mouthing.

Several examples have been provided in the past for the assessment of exposure from toys and risk assessments for different chemicals have been performed considering the exposure of children from toys.

In the TFS (RIVM, 2002), examples for ingestion and for uptake of toy materials *via* hand-to-mouth contact were given. For different toys, the uptake per event was estimated and the frequency of playing events was given (see Table 3). The amounts taken up by a child are relatively high. However, it should be noted that the estimates in the TFS for the amounts of ingested modelling clay and paint from toys were re-evaluated and reduced in the RIVM report of 2006. Therefore, the amounts used in the TFS exceed the amounts currently laid down in the TSD, even if calculated to a daily uptake value. Also in the approach from the Danish EPA of calculating the uptake of preservatives from toys, the amounts estimated to be ingested by children exceed the current amounts laid down in the TSD (see Table 4).

3.4 Knowledge and data gaps

According to RIVM, there is a lack of data to allow for the estimation of realistic risk assessments and there is a need to obtain specific exposure information from toys to allow for a better characterisation of childhood exposures. The ingestion rates are still rough estimates and further research is warranted (RIVM, 2008). The SCHER supports this position.

The SCHER acknowledges the fact that the values currently laid down in the TSD may overestimate the ingestion for a specific toy and the estimated amount ingested per day may be too high. Default values and exposure factors often are highly uncertain. Regarding the ingestion of toy materials by children, further research is required on the amounts of different toy materials ingested and the frequency with which toy material is ingested. Information is needed on how behaviour of children differs by age groups, as well as on mouthing duration for toys intended to be put in the mouth for children over 3 years of age, mouthing amounts and surfaces, playing durations for different types of toys, amounts of dust (and particle size distributions) generated by chalk, plaster and other powder-like toys, leaching rates from toys, dermal absorption and contact surface areas (RIVM, 2008, Philips and Moya, 2014; Guney and Zagury, 2012; Cui *et al*., 2015). This type of information is scarce in the literature, and many parameters still have to be roughly estimated, though recent studies have contributed to fill some of these gaps (e.g. CEN, 2014).

Biomonitoring might be considered to estimate exposure of children to chemicals in toys. The measurement of chemicals or their metabolites in urine, blood or faeces is increasingly used to evaluate exposure to chemicals, e.g. from soil. Sound scientific knowledge on biokinetics is mandatory to allow the estimation of daily intake values based on measured biomarker concentrations. If internal concentrations are related to

information on the daily use of potential sources such as toys, ingestion of chemicals released from toy material might be estimated. However human exposure biomonitoring data of small children are scarcely available. Another difficulty for interpretation is that biomonitoring data integrate exposure from all sources and from different exposure pathways. They are not specific for toys or for exposure by ingestion.

4 OPINION

The SCHER has been asked:

- **To review the available data on the ingestion of all three types of toy materials provided for in the Toy Safety Directive 2009/48/EC (dry, brittle, powder-like or pliable toy material; liquid or sticky toy material; and scraped-off toy material) by children;**

Literature research was carried out to obtain new information on ingestion of toy material by children. Different search strategies were followed (see Annex 1) and recent information on child behaviour in relation to mouthing from reports and peer-reviewed publications has been considered.

The SCHER also consulted guidance documents for calculating indirect ingestion of non-food material by children.

A specific call for information on toy material ingested by children was published on the scientific committees' website between 30 April 2015 and 12 June 2015.

In its Opinion, the SCHER focussed on two aspects: (1) is there new information available on the amount of toy material that is ingested by children and (2) is there new information on the frequency that toy materials are ingested?

The SCHER did not identify new reports or articles that directly addressed the question of the amount of toy material that is ingested. Only one study providing new data on mouthing behaviour related to toys and one meta-analysis on studies before 2009 on object-to-mouth frequency data were published (CEN, 2014 and Xue *et al*., 2010). The amount of non-food material ingested by children is in general derived from studies on ingestion of soil or dust by children. Soil is used as a surrogate to estimate ingestion of dry and powder-like toy material.

The new studies on mouthing behaviour supported the view that mouthing frequency and duration are highly variable between children and depend on (1) the age of the child and (2) the type of toy. Plastic and elastomeric toys were significantly more often mouthed by children than other toys. Toys not intended to be mouthed were mouthed almost as frequently as toys intended to be mouthed.

There is a wide variety of toys available on the market and children may have contact with different toys, including different types of toys and toy materials. Even if children do not play with a certain toy daily or weekly, the contact with the three types of toy materials to be considered occurs frequently. According to the ECHA guidance on information requirements and chemical safety assessment (R.15: Consumer exposure estimation), daily, weekly and monthly consumer exposures can be considered as repeated exposures and assessed against a chronic health-based value. It is to be noted that for products used infrequently, use frequency should not be used to average out exposure over a longer time period. In the first instance, exposure should be calculated for the actual duration of an event (event exposure), and then expressed as that concentration per day (ECHA, 2012).

- **To consider, in the light of the review, whether the estimated ingestion amounts (100 mg/d of dry, brittle, powder-like or pliable, 400 mg/d of liquid or sticky and 8 mg/d of scraped-off toy material), which formed the basis for the limits in the Toy Safety Directive, are still appropriate;**

The SCHER is of the opinion that the current estimated ingestion amounts (100 mg/d of dry, brittle, powder-like or pliable, 400 mg/d of liquid or sticky and 8 mg/d of scraped-off toy material) are still appropriate, taking into account all the information that was evaluated above. The SCHER considers these amounts of ingested toy materials and the daily frequencies of ingestion as appropriate estimates.

The SCHER recommendation takes into account the wide variety of toys, the differences in mouthing behaviour, the high frequency of mouthing toys by young children and the gaps in information.

- **To propose, if the estimated ingestion amounts are no longer considered appropriate, new amounts which would be more appropriate, clearly indicating the data on which they are based.**

The SCHER proposes no new values.

MINORITY OPINION

None.

5 CONSIDERATION OF THE RESPONSES RECEIVED DURING THE CONSULTATION PROCESS

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 a total of eighteen comments concerning 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 cases where the SCHER, after consideration and discussion of the comments, 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 text of the comments received and the response provided by the SCHER is available here:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/followup_cons_toys_en.pdf

6 ABBREVIATIONS AND GLOSSARY OF TERMS

ATBC	acetyl tributyl citrate
CEN	European Committee for Standardization
ConsExpo	Consumer Exposure (software available at http://www.rivm.nl/en/Documents_and_publications/Scientific/Models/Download_page_for_ConsExpo_software)
CSTEE	Scientific Committee on Toxicity, Ecotoxicity, and the Environment
DIDP	di-iso-decyl phthalate
DINP	di-iso-nonyl phthalate
ECHA	European Chemicals Agency
EFH	Exposure Factor Handbook
EPA	Environmental Protection Agency
RIVM	National Institute for Public Health and the Environment, the Netherlands
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
TDI	Tolerable Daily Intake
TSD	Toy Safety Directive
TFS	Children's Toys Fact Sheet
US	United States

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Annex 1

Results of literature search

Method

The search terms to be used were provided in the specification. Preliminary searches were carried out on PubMed to obtain an indication of the numbers of possible papers.

A basic search was carried out using the terms "children" and "ingestion", with a date limit of 1 January 2008 onwards. As used in PubMed, "children" also includes related terms such as child, and ingestion includes related terms such as eating. This produced 8495 hits. Further terms were then used to search within this base search, as below. All terms were ANDed with the basic search.

Term	Number of hits
Exposure OR parameters OR scraped	1052
Toys	116
Exposure factors	289
Default values	3
Behaviour studies	1867*
Behaviour studies AND toys	22

The number of results for the "behavioural studies" term was too large to be dealt with in this work, so the more specific search including toys was used instead. The term "toys" in PubMed includes related terms such as plaything.

The number of results specifically related to the subject of this Opinion was very low. A larger number of results were related to ingestion of objects, particularly small magnets. Following a request from the SCHER Working Group, these results have also been included under the title "Whole object ingestion results".

The types of documents required from these searches are peer reviewed articles, journal entries, book chapters, government funded publications etc. Bibliographic information and abstracts were obtained for the initial search results as above. The abstracts were reviewed to identify documents relevant to the opinion. If there was any uncertainty about the relevance, the document was included in the results.

The specification indicated that the inclusion of guidance and regulatory documents in the results would be useful. No specific guidance documents were located through the PubMed searches but a small number of papers which refer to standard methods for calculating indirect ingestion have been included. Searches of the web using Google were also carried out to try to locate other documents of this type.