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Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006

Introduction

The present document aims at providing guideline concerning the interpretation of the concept "which can be placed in the mouth"¹, as laid down in the entry 52 of the Annex XVII of the Regulation (EC) 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

The guideline does not necessarily represent an official position of the European Commission and it must not be interpreted as such. Final judgements concerning the interpretation of the Regulation can only be made by the European Court of Justice. The guideline document will be primarily of interest and use to those involved in giving effect to the provisions of Entry 52 to annex XVII to REACH ("the entry in Annex XVII") from a technical and administrative standpoint. It is understood that a final assessment has to be made on a case-by-case basis, taking into account the criteria established by this guideline.

The guideline may be further elaborated, amended or withdrawn by the same procedure leading to its issue.

The Commission declaration to Council and Parliament

This specific guideline document has been initially drawn up following a request from the Council and the European Parliament. At the occasion of the adoption of Directive 2005/84/EC on phthalates in toys and childcare articles by the European Parliament on 5 July 2005, the Commission repeated the following declaration, which it had made already at the Competitiveness Council on 24 September 2004:

As soon as the Directive relating to restrictions on the marketing and use of phthalates in toys and childcare articles (22nd amendment of Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous preparations) is adopted, the Commission, in consultation with Member States' experts responsible for the

¹ "which can be placed in the mouth" should not be confused with "intended to be placed in the mouth" as mentioned in the Toy Safety Directive

*management of Directive 76/769/EEC and stakeholders, will prepare a guidance document in order to facilitate the implementation of the Directive. The document will address in particular the provisions on restrictions of certain substances in toys and childcare articles intended for children insofar as they concern the condition "**which can be placed in the mouth**" as specified in the annex to the Directive.*

In the context of this work, the aspects related to "accessible" plasticised material and "handheld" toys will be examined.

This guideline document therefore is only aimed at providing some criteria and examples to help identifying those toys and childcare articles or parts of toys and childcare articles which can and those which can not be placed in the mouth by children. It therefore does not address the likelihood that a toy or childcare article will be mouthed.

Definitions and scope

The definition of toys in Directive 2009/48/EC on the Safety of Toys applies also to the Regulation.

Childcare articles are defined as “any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children”. It is the Commission’s interpretation that the entry in Annex XVII covers the accessible parts of articles such as push chairs, car seats and bike seats which are intended to facilitate sleep and relaxation during transport.

The main purpose of pyjamas is to dress children when sleeping and not to facilitate sleep. Pyjamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the entry in Annex XVII. Sleeping bags are designed to facilitate sleep, and should therefore fall under the entry in Annex XVII.

From 16 January 2007, the phthalates DINP, DIDP and DNOP are only allowed for use in articles which can not be placed in the mouth.

Therefore DINP, DIDP and DNOP shall not be used in plasticised toys or childcare articles or plasticised parts of toys and childcare articles which can be placed in the mouth by children.

Articles which can and can not be placed in the mouth

The following explanations can be used to assess if toys and childcare articles or parts therefore can be placed in the mouth by children and thus fall under the scope of the entry in Annex XVII of the Regulation.

“Placing in the mouth” means that the article or parts of an article can actually be brought to the mouth and kept in the mouth by children so that it can be sucked and chewed. If the object can just be licked, it can not be regarded as “placed in the mouth”.




- Articles which exceed a size of 5 cm in all three dimensions can as a starting point not be placed in the mouth by children. If an article or a part of an article in one dimension is smaller than 5 cm, it can be taken into the mouth. However, the shape of the article, e.g. the existence of detachable or protruding parts and its resistance to compression or deformation also needs to be given consideration.
- Inaccessible parts of articles can also not be taken into the month. Articles or parts of articles should be considered inaccessible if, during proper use or reasonably foreseeable improper use by children, they can not be reached. The definitions of “accessible” in EN 71 (European Standard on the safety of toys) can be used as decision-




making criteria. The proper use or reasonably foreseeable improper use by children can be tested by looking for detachable parts when the relevant various foreseeable use tests are applied. Inaccessible plastic material, such as cables in toys, can not be taken into the mouth under normal, foreseeable conditions. Cables made from plasticised material containing DINP, DIDP or DNOP should be safely enclosed inside the toy².


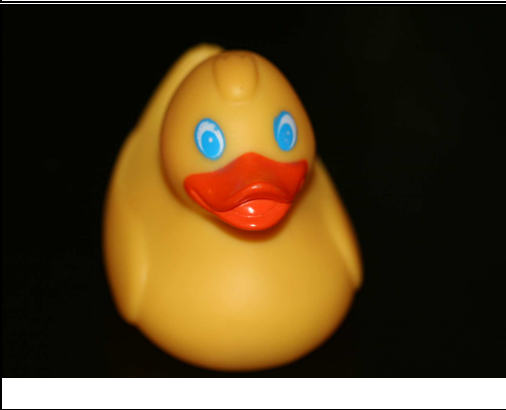


- Handheld toys are more likely to be placed into the mouth, but it can not be excluded that toys which are not handheld also can be placed into the mouth. The guideline therefore also includes toys which are not handheld, but which can be taken into the mouth.
- Inflatable articles should be considered in an empty state. The mouthpiece, which is intended to be placed in the mouth, should not contain DINP, DIDP or DNOP.

The following pictures are examples in order to better indicate which toys and childcare articles or parts of them can be taken into the mouth:

² Please note that the restriction of entry 51 of annex XVII of REACH applies to all the components of the toys and childcare articles, whether these components are accessible or not.



Name & Description	Picture	Can	Can not
	TOYS according to Directive 2009/48/EC		
<p>Childs soft playmat Child can lie or sit on playmat and play with attached toys</p>		<p>All parts can be accessed by child and could be mouthed</p>	<p>None</p>
<p>TOY MOWER</p>		<p>Green handle, orange key (if <5 cm in one dimension)</p>	<p>The main body and wheels (if > 5 cm in all dimensions).</p>
<p>Soft Bodied Doll</p>		<p>Hands and feet Other body parts if < 5 cm in one dimension</p>	<p>Head and other body parts if > 5 cm in all three dimensions</p>




<p>Dolls for older children</p>		<p>External parts if < 5 cm in one dimension</p>	
<p>Mannequin doll</p>		<p>External parts if < 5 cm in one dimension</p>	
<p>Child-sized Kitchen Center</p>		<p>Utensils, food items, protruding parts (eg handles)</p>	<p>Housing components, large trays</p>



<p>Plastic sword</p>		<p>External parts if < 5 cm in one dimension</p>	
<p>Plastic duck</p>		<p>External parts if < 5 cm in one dimension</p>	
<p>Bath book</p>		<p>External parts if < 5 cm in one dimension</p>	
<p>Inflatable soft plastic aquatic toy</p>		<p>External parts if < 5 cm in one dimension and not inflated</p>	

	CHILDCARE ARTICLES (see also Directive 2001/95/EC Art. 2 a)	Can	Can not
HIGH CHAIRS		Upper surface of side arms, uppermost part of sides and straps and front edge of the tray can be mouthed.	Other parts such as footrest, legs end caps, seat back are not accessible to mouthing.
PUSHCHAIRS		Surfaces of bumper bar, seat sides and braces, straps or belts can be mouthed ³	Handlebar, wheels, seat back, shopping tray and bags (on back), foot rest, and endcaps are not mouthed under normal and foreseeable conditions and are not accessible to child in pushchair.

³ This does not mean that the European Commission wants manufacturers to produce pushchairs or high chairs without safety restraints. There is a sufficient offer of other plasticisers and materials on the market which can replace DINP, DIDP and DNOP.

<p>COTS, CRIBS AND MATTRESSES</p>	 <p>The image shows a baby lying in a cot. The cot has a wooden frame and a white mattress. A teething rail is attached to the side rail, and a mobile with toys is hanging above the baby. The cot is positioned against a wall.</p>	<p>Top of side and end rails (teething rail) can be mouthed for long periods</p>	<p><u>Mattress cover.</u> Cover is not directly mouthable in normal & foreseeable use conditions. The edges and corner are not accessible for mouthing by the child – by design (the mattress must fit snugly in the cot to avoid entrapment risks). The mattress is covered with a sheet in normal use and the surface is sufficiently taut (by design – to avoid suffocation risks) to prevent pvc from being mouthed through the sheet.</p>
<p>Changing table pillow.</p>	 <p>The image shows a blue rectangular pillow with a pattern of colorful suns, butterflies, and flowers. The pillow is placed on a light-colored surface, possibly a changing table.</p>	<p>Edges can be taken into the mouth</p>	<p>Backside</p>

<p>Carrying sling with parts of plastic</p>		<p>Accessible parts on the upper side can be mouthed</p>	<p>Unaccessible and parts on the lower side can not be mouthed under normal and foreseeable conditions</p>
<p>Breast-feeding pillow</p>		<p>External surface can be taken into the mouth due to the softness of the pillow</p>	
<p>Car seats</p>		<p>The inside / upper surface of the sides along the backrest (above lap level) can be mouthed.</p> <p>Mid section of the backrest above lap level (or above shoulder height of smallest child = above lowest harness slots) can be mouthed.</p> <p>Cover of headrests can be mouthed.</p> <p>Accessories like footmuffs and boot covers can be mouthed.</p> <p>Belt pads and harness straps can be mouthed.</p>	<p>Sides of seat cover below hip level can not be mouthed under normal and foreseeable use conditions nor the mid section of the seating surface (below lowest harness slots/shoulder height)</p>

<p>Car seats</p> <div data-bbox="129 271 419 392" style="border: 1px solid black; padding: 5px;"> <p>Side of backrest above lap level</p> </div>		<p>See above</p> <div data-bbox="804 224 999 344" style="border: 1px solid black; padding: 5px;"> <p>cover of headrest</p> </div> <div data-bbox="783 367 1094 488" style="border: 1px solid black; padding: 5px;"> <p>Sides headhugger/reducer</p> </div>	<p>See above</p>
<p>Car seats</p>		<p>See above</p> <div data-bbox="828 1012 1094 1133" style="border: 1px solid black; padding: 5px;"> <p>Reducer/ support pillow</p> </div> <div data-bbox="828 1256 1120 1377" style="border: 1px solid black; padding: 5px;"> <p>Belt pads and harness straps</p> </div>	<p>See above</p>