



Guidance Document on the interpretation of the concept

“which can be placed in the mouth” as laid down in the Annex to the 22nd amendment of Council Directive 76/769/EEC

Introduction

In order to ensure as far as possible a common understanding among the Member States as well as between the Member States and the competent services of the Commission, the Commission services may issue guidance dealing with specific matters related to the practical implementation and application of Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous preparations (hereafter called the Directive).

The present guidance document does not provide a legally binding interpretation of the Directive. It is not legally binding and it does not modify or amend the Directive in any way.

The guidance document will be primarily of interest and use to those involved in giving effect to the Directive 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 guidance.

The guidance may be further elaborated, amended or withdrawn by the same procedure leading to its issue.

The Commission declaration to Council and Parliament

This specific guidance document has been drawn up following a request from the Council and the European Parliament. At the occasion of the adoption of the Directive 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 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 guidance document therefore only is 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 does therefore not address the likelihood that a toy or childcare article will be mouthed.

Definitions and scope

The definition of toys in Directive 88/378/EEC on the Safety of Toys applies also to Directive 2005/84/EC.

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 Directive 2005/84/EC 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 Directive. Sleeping bags are designed to facilitate sleep, and should therefore fall under the Directive.

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 Directive.

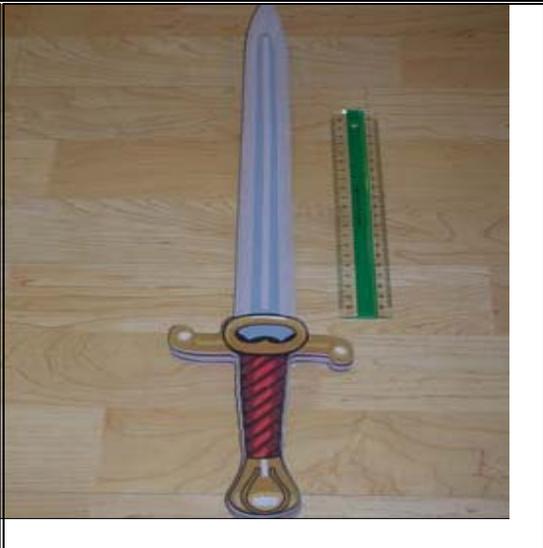
“Placing in the mouth” means that the article or parts of an article can actually be brought to the mouth and kept in the mouth by children so that it can be sucked and chewed. If the object can just be licked, it can not be regarded as “placed in the mouth”.

- 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 part 1 point 3.1 and “detachable components” in point 3.32 (as amended) can be used as decision-making criteria. 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 toy.
- 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 guidance 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:

| Name & Description | Picture | Can | Can not |
|---|--|---|---|
| | TOYS according to Directive 88/378 EEC | | |
| <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 <5cm 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> |

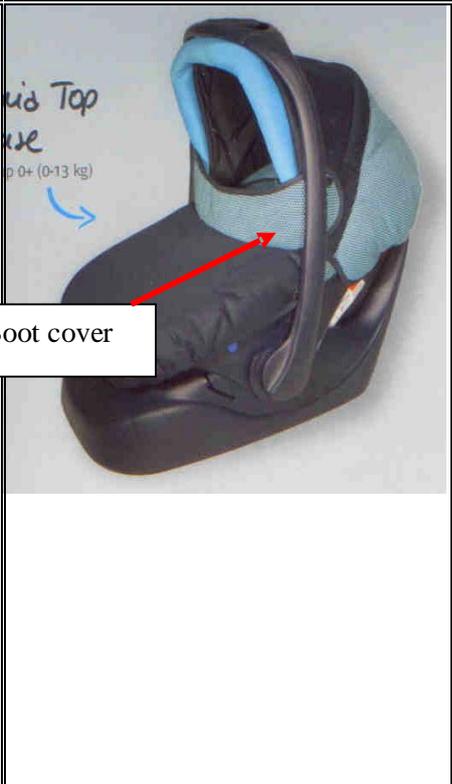
| | | | |
|-----------------------------------|---|--|--|
| <p>Dolls for older children</p> |  | <p>External parts if < 5 cm in one dimension</p> | |
| <p>Mannequin doll</p> |  | <p>External parts if < 5 cm in one dimension</p> | |
| <p>Child-sized Kitchen Center</p> |  | <p>Utensils, food items, protruding 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 ¹ | 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. |

¹ 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. A teething rail is attached to the side rail, and the baby's mouth is resting on it. The cot has a light-colored mattress and a white sheet. There are some toys hanging from the cot.</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 changing table pillow with a pattern of colorful suns, butterflies, and other designs. It is lying on a light-colored surface.</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> |

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|--|--|---|------------------|
| <p>Car seats</p> <p>Side of backrest above lap level</p> |  | <p>See above</p> <p>cover of headrest</p> <p>Sides headhugger/reducer</p> | <p>See above</p> |
| <p>Car seats</p> |  | <p>See above</p> <p>Reducer/ support pillow</p> <p>Belt pads and harness straps</p> | <p>See above</p> |