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ANEC/BEUC Fact sheet

Chemical requirements in toys ought to be strengthened

→ Background

Lead, phthalates, nitrosamines, volatile organic compounds such as formaldehyde or phenol - a mixture of problematic chemicals, of which some can present risks to children's health and the environment, is contained in all toys: from wooden toys to dolls, rubber ducks to beach toys. Phthalates in soft plastic toys made of PVC can represent up to 30, even 50% of the weight of the toy. All these substances have the potential to migrate or emit out of toys.

Children have increased vulnerability to chemical harms due to their young age. In addition, they have potential exposure to chemicals through play with toys (sucking, biting, chewing, manipulating) as these behaviours can extract chemicals from toys and lead to ingestion, inhalation, entry in contact with the skin, eyes and mucous membranes with a certain amount of the chemicals.

Unfortunately, even if only a small number of emergency room visits for chemical injury related to toys has been reported by hospitals across the EU, this does not necessarily mean that there are effective mechanisms in place to protect children from most acute chemical harms. In addition, uncertainty and data gaps remain about possible non-acute health harms to children from dangerous chemicals used in toys.

There is therefore clearly a need to apply a precautionary approach to children's safety legislation by minimising the use of dangerous chemical substances. In this respect, the Commission's proposal contains many shortcomings. Although it foresees a prohibition of CMRs (substances which are carcinogenic, mutagenic or reprotoxic) it only refers to the accessible parts of toys, with exemptions which would make it easy to get around this prohibition. We also consider that the proposed list of allergens to be prohibited in toys is not exhaustive: it only covers some fragrances, despite the fact that many other substances can also provoke allergies. Finally, it is not acceptable that no measures are foreseen for other problematic substances, such as endocrine disruptors.

→ Our proposal for amendments

CHAPTER I GENERAL PROVISIONS

Article 2 Definitions

(13) “harm” means the physical injury or damage to health, *including long term health effects*;

Justification:

This wording clarifies that the term ‘damage to health’ includes long term health effects such as carcinogenic and endocrine disrupting effects.

ANNEX II PARTICULAR SAFETY REQUIREMENTS

III. CHEMICAL PROPERTIES

1. Toys shall be so designed and constructed that there are no risks of adverse effects on human health or the environment due to exposure to the chemical substances or preparations of which the toys are composed or which they contain, when the toys are used as specified in the first subparagraph of Article 9 (2).

Justification:

Even though the Toy Safety Directive is meant to regulate the safety of toys for children, it should also be stated that toys should not present risks to the environment. One should not forget that a toy generally has a very short lifespan because the child gets tired of it or because the toy is old fashioned or even breaks. Toys therefore generate an enormous amount of waste in the EU every year.

2. Toys shall comply with relevant Community legislation relating to certain categories of products or to the prohibition of use of certain dangerous substances and preparations. Toys that are themselves substances or preparations must comply also with Directives 67/548/EEC and 1999/45/EC25 relating to the classification, packaging and labelling of dangerous substances and dangerous preparations.
3. The use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to Directive 67/548/EEC in individual concentrations equal to or greater than 0.01% shall be prohibited. Where appropriate, a lower limit shall be stipulated for certain CMR substances based upon advice of the relevant Scientific Committee and following a Decision as referred to in Article 45 (2).

Justification:

The concentration limits for CMR substances (i.e. 0,1% for CMR category 1 and 2, 1% for category 3) established in the EU Directive 1999/45/EC on dangerous substances and preparations are too high to be applied in toys. Only very low trace levels of CMR substances should be allowed in toys. In addition, the Comitology

procedure should be introduced in order to allow for a re-evaluation of these concentration limits if necessary to protect children's health.

4. Substances or preparations classified as CMR category 1, 2 and 3 according to Directive 67/548/EEC may be used in one particular toy provided that all the following conditions are met:

Justification:

The precautionary principle needs to be applied when addressing the risks posed by CMR in toys. The same provisions should therefore be foreseen for both CMR 1-2 and CMR 3. Indeed, CMR Category 3 are substances which are suspected from being carcinogenic to man on the basis of available evidence but the evidence is not yet sufficient to classify them in category 2.

- 4.1. use of the substance in this particular toy has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and a Decision as referred to in Article 45 (2) has been taken;
- 4.2. there are no suitable alternative substances or materials available, as documented in an analysis of alternatives,
- 4.3. they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or preparations as soon as safety concerns arise and at the latest every 3 years from the date that a decision in accordance with Article 45 (2) was taken.

Justification:

Considering the fact that only a limited number of CMR substances will be exempted from the prohibition and that new scientific evidence arises almost everyday, three years appears a reasonable period for the SCCP to re-evaluate the safety of the substances.

5. The Commission shall establish a program to systematically and regularly evaluate the occurrence of dangerous substances in toys, other than CMR substances, and including endocrine disruptors, PBT and vPvB, sensitisers other than allergenic fragrances, substances classified e.g. as “very toxic”, “toxic”, “harmful”, “corrosive”, “irritant” or non-classified (or not yet classified) substances which pose health hazards. The program shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders. Appropriate measures shall be taken based upon advice of the relevant Scientific Committee and following a Decision as referred to in Article 45 (2).

Justification:

The precautionary principle needs to be applied in order to allow for quick adaptation of the Toy Safety Directive to new evidence or new risks related to one individual chemical substance. This only will ensure a high level of protection for children.

6. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements provided for in Directive 76/768/EEC.
7. Toys shall not contain the following allergenic fragrances:

- (1) Alanroot (*Inula helenium*)
- (2) Allylthiocyanate
- (3) Benzyl cyanide
- (4) 4 tert-Butylphenol
- (5) Chenopodium oil
- (6) Cyclamen alcohol
- (7) Diethyl maleate
- (8) Dihydrocoumarin
- (9) 2,4-Dihydroxy-3-methylbenzaldehyde
- (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)
- (11) 4,6-Dimethyl-8-tert-butylcoumarin
- (12) Dimethyl citraconate
- (13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one
- (14) 6,10-Dimethyl-3,5,9-undecatrien-2-one
- (15) Diphenylamine
- (16) Ethyl acrylate
- (17) Fig leaf, fresh and preparations
- (18) trans-2-Heptenal
- (19) trans-2-Hexenal diethyl acetal
- (20) trans-2-Hexenal dimethyl acetal
- (21) Hydroabietyl alcohol
- (22) 4-Ethoxy-phenol
- (23) 6-Isopropyl-2-decahydronaphthalenol
- (24) 7-Methoxycoumarin
- (25) 4-Methoxyphenol
- (26) 4-(p-Methoxyphenyl)-3-butene-2-one
- (27) 1-(p-Methoxyphenyl)-1-penten-3-one
- (28) Methyl trans-2-butenate
- (29) 6-Methylcoumarin
- (30) 7-Methylcoumarin
- (31) 5-Methyl-2,3-hexanedione
- (32) Costus root oil (*Saussurea lappa* Clarke)
- (33) 7-Ethoxy-4-methylcoumarin
- (34) Hexahydrocoumarin
- (35) Peru balsam (*Myroxylonpereirae* Klotzsch)

- (36) 2-Pentylidene-cyclohexanone
- (37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one
- (38) Verbana oil (*Lippia citriodora* Kunth).
- (39) Amyl cinnamal
- (40) Amylcinnamyl alcohol
- (41) Anisyl alcohol
- (42) Benzyl alcohol
- (43) Benzyl benzoate
- (44) Benzyl cinnamate
- (45) Benzyl salicylate
- (46) Cinnamal
- (47) Cinnamyl alcohol
- (48) Citral
- (49) Citronellol
- (50) Coumarin
- (51) Eugenol
- (52) Farnesol
- (53) Geraniol
- (54) Hexyl cinnamaldehyde
- (55) Hydroxy-citronellal
- (56) Hydroxy-methylpentylcyclohexenecarboxaldehyde
- (57) Isoeugenol
- (58) Lilial (referred to in the Cosmetics Directive in entry 83 as: 2-(4-tert-Butylbenzyl) propionaldehyde
- (59) d-Limonene
- (60) Linalool
- (61) Methyl heptine carbonate
- (62) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one
- (63) Oakmoss extracts
- (64) Treemoss extracts

However, the presence of traces of these substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice.

Justification:

Fragrances are recognised as one of the leading causes of allergies. As allergies can start at any age but the majority of people develop the first symptoms before the age of ten, the use of fragrances that are recognized as allergenic should be prohibited in toys.

8. The following migration limits, from all parts and components of toys shall not be exceeded:

Element	mg/kg in solid, dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material
Aluminium	5625	1406
Antimony	45	11.3
Arsenic	7.5	1.9
Barium	4500	1125
Boron	1200	300
Cadmium	3.8	0.9
Chromium (III)	37.5	9.4
Chromium (VI)	0.04	0.01
Cobalt	10.5	2.6
Copper	622.5	156
Lead	27	6.8
Manganese	1200	300
Mercury	15	3.8
Nickel	75	18.8
Selenium	37.5	9.4
Strontium	4500	1125
Tin	15000	3750
Organic tin	1.9	0.5
Zinc	3750	938

These limit values do not apply to 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 in the first subparagraph of Article 9 (2).

Justification:

The notion "dry, brittle, powder-like or pliable material" does not necessarily include "solid materials" (see the background study carried out by RIVM and proposing 3 sets of limit values depending on the material). Hence, the headline must be changed to "solid, dry, brittle, powder-like or pliable materials".

9. Specific requirements shall be adopted for toys or parts thereof that are designed to be placed in the mouth, regardless of the age group for which the toy is intended, based on the requirements for packaging for food as laid down in Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and its related specific measures for particular materials. Such requirements shall be taken based upon advice of the relevant Scientific Committee and following a Decision as referred to in Article 45 (2) taking into account the differences between toys and food contact materials (e.g. migration conditions).

Justification:

The Comitology procedure should be used for the establishment of limit values that have a direct impact on children's health and safety. Indeed, setting limit values is a highly political issue which should be solved at political level and not shifted to standardisation bodies. This is particularly true for the establishment of limit values for chemicals, and other limits that are directly linked to the health and safety of children, such as noise or speed limits.

ANNEX IV

TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 20 shall contain, in particular, so far as relevant for assessment:

- a) a detailed description of the design and manufacture, including a list of components and materials used in toys as well as **detailed information on the chemical composition of the toy or the substances used in the manufacture of the toy as well as on the amount of the individual substances used in the toy or parts of it;**

END.