REVISION OF THE TOY SAFETY DIRECTIVE: HOW COULD WE MAKE TOYS SAFER?

Contact: Laura Degallaix (BEUC) – environment@beuc.eu
Tania Vandenberghe (ANEC) – tva@anec.eu
Ref.: X/017/2008 - 25/03/08
ANEC-CHILD-2008-G-010final

BEUC, the European Consumers' Organisation
36 avenue de Tervueren, 1040 Bruxelles - +32 2 743 15 90
Find out more information on the extranet via www.beuc.eu

ANEC - European Association for the Co-ordination of Consumer Representation in Standardisation, AISBL
Av. de Tervueren 32, box 27 – B-1040 Brussels, Belgium - +32-2-743 24 70
internet: www.anec.eu

Table of Contents

Summary

Council Directive 1988/378/EEC[1] regulates the safety of toys in Europe. The Directive is a New Approach Directive setting essential safety requirements. European Standards Organisations are responsible for developing standards to support these essential requirements: EN 71, EN 50088 and IEC 62115 are the most relevant.

The European Commission adopted a proposal for a revision of the existing EU Directive on toy safety on 25 January 2008. This proposal will now be subject to a co-decision procedure.

Discussions on the revision of the Toy Directive already started within the European Commission in 2001. As consumer organisations, we have been calling during these discussions for the Directive to be updated to reflect development in the design and manufacture of toys over the past twenty years and the increased knowledge of risks presented by them. Despite all these years of discussion, the proposal for a revised Directive falls short of what is needed to protect our children.

The aspects we consider of utmost importance are the following:

1. Introduction of the precautionary principle

↘ *Our concerns:*
We are concerned that the precautionary principle[2] has not been included as a basic principle of the directive. We consider it essential in this area.

↗ *Our demands:*
Given that there is not sufficient data on the risks posed to children, and that children are part of the most vulnerable population, the only acceptable solution is to introduce the precautionary principle as a legal basis into the directive.

2. Introduction of a Comitology procedure

↘ *Our concerns:*
We are concerned that more flexibility has not been foreseen in the proposed revised directive in order to make it possible to adapt it quickly to emerging risks.

↗ *Our demands:*
We ask for the introduction of a comitology procedure to be applicable to all provisions in the directive that support the essential safety requirements. It is the only procedure which would allow the directive to be adapted quickly to new developments, so avoiding a long co-decision process or a standardisation procedure.

[1] Directive 88/378/EEC of 3 May 1988 concerning the safety of toys.

[2] According to which a product can be removed from the market if there are suspicions that it could be dangerous

3. More stringent and clear chemical properties

↘ *Our concerns:*

On the issue of dangerous chemical substances, although the proposal contains a prohibition of CMRs (substances which are carcinogenic, mutagenic or reprotoxic) it only refers to the accessible parts of toys, and foresees exemptions which would make it easy to get around this prohibition. Furthermore, there are no measures foreseen for other problematic substances, such as endocrine disruptors. We find it unacceptable that a toy can contain dangerous chemical substances.

Moreover, we 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.

↗ *Our demands:*

We ask for a total ban on CMR and other chemicals of very high concern. We also call for a total ban of allergens and sensitizing chemicals.

4. An obligatory EC-type examination for certain types of toy

↘ *Our concerns:*

We emphasize once again our concerns regarding CE Marking, which consumers wrongly believe to be a safety label. We believe that the CE Marking should not appear on the toys themselves, but solely on the technical documentation. The current system of CE Marking (affixed by producers without any independent third-party check) on toys is not a guarantee of safety, even though the majority of parents think of it as such.

In this context, we very much regret that the proposed revised toy directive does not foresee obligatory EC-type examination (independent third-party testing) for some toys.

↗ *Our demands:*

Third-party conformity assessment should be obligatory for certain types of toys: for example those for children younger than three years, toys that present an element of risk which cannot be eliminated (e.g. toy irons which are intended to become hot), or toys that have previously caused serious accidents (such as toys containing magnets).

5. Specific requirements for warnings

↘ *Our concerns:*

We are worried about the increasing use of warnings and labels as substitutes for requiring a manufacturer to put safe toys on the market. We believe that warning and labels should only be complementary to strict safety measures.

↗ *Our demands:*

To be meaningful, warnings should catch the buyer's attention, and be present on both the toy itself and its packaging. In particular, the most important warnings (e.g. this toy is not suitable for children under three) should be visible before purchase. Moreover, we consider that warnings should always give information on both the inherent hazard of the toy and the risks related to its use.

6. Requirements for toys in food

↘ *Our concerns:*

In many countries, including the United States, it is forbidden to put toys in boxes of cereal or in chocolate eggs. We find it unacceptable that European children keep being exposed to such avoidable risks.

Consumer organisations have long been calling for requirements for toys in food products to be introduced in the legislation. Although the revised directive includes new requirements for toys in food, it does not go far enough. In particular, it does not address all risks related to toys in food.

↗ *Our demands:*

We ask for the proposed requirements to be strengthened in order to cover all risks arising from the combination of toys and food products. In particular, we ask for the requirements for the packaging of these toys to cover all foreseeable hazards , including internal airway obstruction. In addition, specific warnings should be affixed on such products.

In this paper, ANEC and BEUC highlight and further describe the major issues that should be taken into account in order to ensure the highest level of protection possible for our children.

1. Introduction of the precautionary principle (not only in a recital)

The **precautionary principle needs to be introduced** in the revised toy safety directive. This is of particular importance with respect to exposure to chemicals but also relevant to other hazards.

In many cases it is not possible to base risk reduction measures or product specifications on clear scientific evidence of harm considering the lack of scientific data or accident statistics. As children are a vulnerable consumer group, the introduction of the precautionary principle is justified.

The absence of an accident history, a small number of accidents or a low severity of accidents with a certain toy or product must not be taken as a presumption of a low level of risk. This caveat should be added to the text of the Directive.

2. Introduction of a Comitology procedure

We call for the **introduction of a Committee Procedure (Comitology) with scrutiny** in order to allow for easy and flexible modification and updating of the Toys Directive to market changes (e.g. new toys) or new risks. The use of this procedure would avoid a long co-decision process or to rely exclusively on standardisation procedures. The latter are often slow, with unbalanced representation of stakeholders, and European standards do not always provide an adequate level of protection. Moreover, standardisation should not be used to resolve highly political issues, e.g. the setting of limit values for chemicals, noise or speed. The comitology procedure would therefore serve as an alternative to standardisation in certain cases. It should always be decided on a case-by-case basis whether safety requirements should be set at political level (i.e. through comitology or even co-decision) or could be deferred to standards bodies.

In this context, we warmly welcomed the recent Resolution of the European Parliament[3] calling on the Commission to "follow an approach in which specific implementing measures for the key requirements are to be adopted in comitology by means of the regulatory procedure with scrutiny". The need for an extension of the comitology procedure to key safety requirements of the Directive was also part of the recommendations of the recent EP study on safety and liability issues relating to toys[4].

Although we welcome that the Comitology procedure with scrutiny has been introduced into the proposal, it remains limited to *inter alia* the approval of CMR substances and to the addition of allergenic fragrances. The use of the comitology procedure should not be restricted to certain chapters of the annexes but should be extended to all provisions in the directive that support the essential safety requirements. Therefore the comitology procedure ought to be applicable to all listings in the annexes to the directive.

In practice, it would mean that the comitology procedure could be used for example:

[3] "Dangerous toys made in China", European Parliament resolution of 26 September 2007 on the safety of products and particularly toys.

[4] Study on safety and liability issues relating to toys, Policy Department, Economic and Scientific Policy, January 2008.

- to determine the products that fall inside or outside the scope of the Directive (Annex I) in order to avoid non-regulated borderline products on the market;
- to identify toys for which an EC type examination (third-party testing) is necessary e.g. toys which, for functional reasons, cannot be designed to eliminate all risks;
- to establish specifications to complement the essential requirements such as product or substance bans, limit values for chemicals, noise or speed of toys which are not self-propelled and so forth. More detailed specifications on e.g. how to measure these limit values could be left to the standards bodies.

Finally, it is essential to allow major stakeholders to participate in the comitology procedure. At the moment, consumers are represented in the Commission's Toy Safety Experts' Group[5] alongside industry. However, this group is informal and is not embodied in the Directive. Hence, the Committee Procedure, which allows only participation of representatives of Member States and at a later stage of Members of the European Parliament, needs to be complemented by a Consultative Committee which includes the representatives of interest groups (CEN[6], CENELEC[7], ANEC, BEUC, TIE[8], etc.). The EU Directive on Eco-design of Energy-Using Products (2005/32/EC) may serve as a model.

3. More stringent and clear chemical properties

Lead, phthalates, nitrosamines, volatile organic compounds such as formaldehyde or phenyl - a mixture of 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. In our view, the Commission proposal for chemicals in toys has fundamental deficiencies.

In a comprehensive study published in 2006[9], the World Health Organisation (WHO) demonstrated that children's exposure to chemicals may be the origin of cancer, heart disease and chronic respiratory disease later in life. The report highlighted the special susceptibilities of children relative to adults during the various life stages, organ systems, and exposure scenarios. The report states that the period of a child's development when exposure occurs may be as important as the magnitude of the exposure. For instance, a child's lungs are not yet fully developed at the age of eight, and the lung maturation may be altered by chemical substances that induce acute respiratory effects in childhood and may be the origin of chronic respiratory disease in adulthood. This study confirms the need to apply a precautionary approach to children's safety legislation by banning the use of dangerous chemical substances.

[5] Expert Group on the implementation of Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys

[6] CEN: Comité Européen de Normalisation – European Committee for Standardisation

[7] CENELEC : Comité Européen de Normalisation Electrique – European Committee for Electrotechnical Standardisation

[8] TIE : Toy Industries of Europe, an Action Group for the European Toy Industry

[9] Principles for evaluating health risks in children associated with exposure to chemicals, World Health Organization, 2006. http://whqlibdoc.who.int/publications/2006/924157237X_eng.pdf

3.1 CMR substances

In principle, **CMR substances[10], including category 3, should be prohibited in all parts of toys**, whether accessible or not. Children need special protection and the precautionary principle should be applied. It is therefore urgent that chemicals which may have serious health implications are prohibited in toys even if the adverse effects have not yet been fully scientifically proven.

Further, it should be noted that the provisions of the existing Cosmetics Directive[11] exclude CMR chemicals (Article 4b):

> *"The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited."*

Even though the recent Commission proposal to recast the Cosmetics Directive into a Regulation has introduced exemptions to the ban of CMR, it goes far beyond the protection offered through the revised toy safety directive. This is not acceptable and there is no reason why less stringent rules should apply to toys.

Finally, the EU legislation on dangerous substances and preparations[12] implies that no account needs to be taken of CMR substances if they are present in very small amounts (i.e. 0,1% for CMR category 1 and 2, 1% for category 3). The Commission's proposal requires applying these CMR concentration limits in toys. In our view, these limits are too high as only very low trace levels of CMR substances should be found in toys. It is common that highly potent carcinogens are assigned a specific concentration limit even lower than 0.01% when consumers' health is considered to be particularly at risk. We therefore believe that lower concentration limits for CMR in toys than those required in the proposal are justified and should be established in the Directive in order to protect our most vulnerable citizens.

3.2 Allergenic and sensitising substances

We support the call from the European Parliament for a **ban on all fragrances (not only the allergenic ones) and sensitisers** in its September Resolution on toy safety.

Unfortunately, the Commission proposal only foresees a ban of 38 allergenic substances and the obligatory labelling of 26 other allergenic fragrances. Similar requirements already exist in the existing Cosmetics Directive (i.e. 35 are banned and 26 require labelling).

In our view, these requirements are not sufficient. Fragrances are recognised as the leading cause of allergies (e.g. in cosmetic products). A 2002 study[13] was already highlighting that allergy centres worldwide (including Denmark, Singapore, Slovenia and the USA, with the exception of the UK) reported an increase in fragrance allergy in the previous decade. This could be explained by the increasing number of fragranced products (e.g. cosmetics, household products, air fresheners, toys).

---

[10] CMR Category 1: substances carcinogenic to man; CMR Category 2: substances regarded as carcinogenic to man due a strong presumption; CMR Category 3: substances 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.

[11] Directive 76/768/EEC

[12] Directive 1999/45/EC

[13] Prevalence of Fragrance Allergy. Pamela L. Scheinman, New England Medical Center, Boston, Mass., USA. Dermatology 2002;205:98-102.

It is commonly recognised that allergies, including asthma, can start at any age but studies show that the majority of people develop the first symptoms before the age of ten. We therefore believe that the use of fragrances, in particular those classified as allergenic, should be prohibited in toys.

Further, the Commission proposal does not foresee any requirements for the use of sensitizers other than allergenic fragrances. We call for all substances classified as sensitizers (by inhalation, by contact with skin etc.) to be prohibited in toys. This is even more justified for toys which can be placed in the mouth, as well as cosmetic toys and toys which can be considered as preparations (e.g. paints, finger paints).

3.3 Migration limits

The Commission proposal establishes migration limits for elements (some of which are classified as CMR such as lead, cadmium, chromium (VI) and nickel) that are not to be exceeded in accessible parts of toys.

In this context, in line with our demand for a ban of CMR substances in all parts of toys, we ask for these **limit values to also apply to non-accessible parts of toys**. However, we believe these **limit values should be based on the content** of elements in the toys rather than on the element's migration potential (particularly as no harmonised test method for an element's migration exists).

Finally, the Commission proposal contains migration levels for only "dry, brittle, powder-like or pliable" and "liquid or sticky" toy materials. This means that for all other toy materials (such as solid paper, plastics, glass, ceramics and metal materials including their coatings) – indeed the vast majority of toys - no limits are foreseen. This is a serious omission.

3.4 Substances of very high concern (SVHC) other than CMR

3.4.1. Endocrine disrupting chemicals

Endocrine disrupters are substances similar to hormones, in particular thyroid and sexual hormones (such as phthalates which have already been partially banned). They can bind to hormone receptors and interfere with hormonal systems causing unwanted effects. Both animals and human beings can be affected.

In the context of the implementation of the EU Community Strategy for Endocrine Disrupters[14], the Commission has established a candidate list of endocrine disrupting compounds. In 2004[15], this list contained 553 substances of which 66 were identified as priority substances with evidence of endocrine disruption (Category 1). A recent DHI study commissioned by DG Environment[16] expands the EU priority list from 66 chemicals to 194.

Furthermore, there is a known potential problem with the release of endocrine disrupters from materials in contact with drinking water and bottled water. Endocrine disrupters are also specifically addressed in the EU Water Policy Framework. Under the new EU Chemicals Policy (REACH), these substances are covered by the authorisation procedure as "substances of equivalent concern", which will be identified on a case by case basis. Even though a revision to ensure that endocrine

[14] COM (1999)706
[15] SEC(2004) 1372.
[16] Study on enhancing the Endocrine Disrupter priority list with a focus on low production volume chemicals, DHI, May 2007.http://ec.europa.eu/environment/endocrine/documents/final_report_2007.pdf

disrupters will have to follow the substitution route is foreseen under REACH, it is not expected before 2013.

Finally, children, as with every other population group, are exposed daily to combinations of several chemical substances. These chemicals interact with each other leading to synergistic or accumulative effects on health and the environment. Recent studies[17] have shown that endocrine disrupters which have only small effects on an individual basis may induce important additive effects when combined with other similar chemicals.

In conclusion, we consider that a precautionary approach should be applied without delay regarding endocrine disrupters in toys in order to protect children. We therefore ask for **all endocrine disrupting chemicals listed in the EU priority list to be prohibited in toys**.

3.4.2. PBT and vPvB

Persistent, bio-accumulative and toxic chemicals (PBT) as well as very toxic and very bio-accumulative (vPvB) chemicals are considered as substances of very high concern.

The use phase and related exposure of children to chemicals contained in toys should be addressed and risk reduction measures are urgently needed. The disposal of toys may also have great environmental impacts. We therefore also need to reduce impact of chemicals contained in toys which are released into the environment. The possible impacts include direct toxic effect, eutrophication, oxygen depletion, loss of species and endocrine disruption. To this aim, a **prohibition of the use of PBT and vPvB chemicals should be introduced** in the Directive.

3.5 Other dangerous substances

Chemicals falling in other classes of dangerous substances such as “very toxic”, “toxic”, “harmful”, “corrosive”, “irritant” or non-classified (or not yet classified) substances which pose health hazards are not covered at all by the Commission proposal which is a serious omission. Furthermore, no systematic procedure is foreseen to identify such substances e.g. based on reports by national enforcement agencies and to establish substance exclusions or limits whenever a problem is identified. One could envisage a reporting obligation for national authorities and market surveillance bodies. Restrictions of use and limits for these chemicals should be established and approved by making use of the comitology procedure.

3.6 Materials used in toys for children under 3 years

We ask for legislators to **allow in toys for children younger than three years only those chemicals already allowed in food contact materials** in the EU[18]. According to the EU legislation, food contact materials should not transfer their components into the foodstuff in unacceptable quantities (so-called migration of components). For instance, the legislation establishes specific restrictive measures e.g. migration limits for plastics and rubbers.

We appreciate the EU legislation related to food contact materials cannot directly be used for toys due to differences in migration conditions. However, we consider it

[17] Christiansen, S. et al., 2008 and Mertzdorff, S. B. et al., 2007, respectively available at http://toxsci.oxfordjournals.org/cgi/content/abstract/98/1/87 and http://www.blackwell-synergy.com/doi/abs/10.1111/j.1365-2605.2007.00866.x

[18] Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food.

necessary to make use of this legislation in the toy directive as far as the safety of children under three years is concerned. Again, one could stipulate the principle in the toy directive and leave it to the comitology procedure to establish details (test conditions, simulants, limits, etc.).

3.7 Compositional and labelling requirements

The Commission's proposal foresees labelling requirements on dangerous chemical content only for cosmetic toys. We ask for these **labelling requirements to be applied for cosmetic toys as well as toys which can be considered as preparations** (e.g. chemical sets for children, finger paints, plasticine etc).

4. EC-type examination should be obligatory for certain types of toys

4.1. CE Marking

The existing Directive has shown the Supplier's Declaration of Conformity to be insufficient in ensuring the protection of children. If a toy is claimed to be manufactured to the harmonised standards supporting the Directive, no further assessment is needed before the toy is placed on the European market. This possibility remains unchanged in the proposed revision of the Directive. The Mattel case showed that 22 million toys could be placed on the global market; all of which carried CE Marking and yet were not in conformity the European toy legislation.

The Mattel recalls have clearly demonstrated that CE Marking is no guarantee of safety or consumer confidence and that it gives no added value to consumers. Unsafe CE Marked products are continuing to be found on the EU market.

As a consequence of this, ANEC and BEUC want to see **CE Marking relegated to the technical file** of a product which the European legislation also requires. It should not continue to be a visible product marking able to confuse and mislead consumers.

4.2. EC-type examination

At present, EC-type approval is required only when the manufacturer does not follow a standard or when no standard exists for a certain risk. However, as shown by the Mattel recalls from 2006 and 2007, we believe that **EC-type examination should be made obligatory for certain categories of toys** (e.g. magnetic toys).

Legislation in the US is moving in this direction. Independent third-party examination may soon become obligatory for all toys for children under six years of age in the US as established in the Consumer Product Safety Reform Act passed by the Congress and Senate. The two bills are now undergoing a reconciliation process to become law.

In our view, the following types of toys should undergo an obligatory EC-type examination:

- toys intended for children under three years (e.g. rattles);
- toys which, for functional reasons, cannot be designed to eliminate all risks (e.g. toys with high accessible surface temperature, magnetic toys);
- toys which, in case of a failure, can lead to severe health impacts of a child (e.g. a toy containing a laser);
- toys which have caused severe accidents in the past (c.f. Rapex notifications);
- toys which have raised considerable concern in enforcement activities.

The comitology procedure, described earlier, could help to identify and select these categories. Once identified, the categories could be listed in annex to the directive.

Finally, we appreciate that EC-type examination performed only on prototypes does not guarantee safety. We therefore strongly support the recommendation of the EP study on toy safety and liability issues to have regular audits of manufacturer production systems to complement EC-type examination. Moreover, we consider the recent requirement of the US Senate for a public database of complaints to be established is sound and should be implemented in the EU.

5. Warnings

In general, consumer organisations are concerned about the increasing use of warnings and labels. These should not preclude the manufacturer from an obligation to ensure that the toy does not present an avoidable risk or hazard to the user or third parties.

The **most relevant warning labels,** i.e. those which are necessary for the safe use of a toy, **must always be indelibly and conspicuously labelled** on the toy itself or/and on the packaging in such a way that the consumer can read the information before purchase. This includes warnings specifying that:

- the toy is not suitable for children under three years,
- the toy should not be used in traffic,
- the toy should not be used in deep water,
- the toy should not be used by children with a weight of more than 20kg,
- a toy imitation helmet has no protective function.

In particular, warnings that should be remembered every time the toy is used, or a long time after the toy is purchased, should be permanently marked on both the toy and the packaging.

All warnings consisting of phrases ought to be preceded by the word "Warning" in order to make it clear to consumers that the information relates to safety.

The European Standards Organisations[19] recommend a minimum size of 20 mm for product information relevant to consumers on larger surfaces. However, only a minimum size of 10 mm for this warning is foreseen in the European Standard EN 71-6. This is too small to attract the attention of parents before purchase, particularly as other information unrelated to safety is displayed on the packaging.

[19] CEN/CENELEC Guide 11 on 'Product information relevant to consumers - Guidelines for standard developers'.

We therefore ask for a minimum diameter for the pictogram for toys not intended for children under 36 months to be set up in the legislation.

In the preparatory memorandum of the Commission's proposal, it is foreseen that the Commission will prepare **guidelines on the presentation of warnings** together with stakeholders. We welcome this proposal but regret it is not clearly mentioned in the legal text.

It should require that warnings indicate the **inherent harm / hazard** (e.g. part of the toy which can cause harm; the chemical composition of the toy) as well as **the related risks** of hazards involved in using the toy (e.g. suffocation risk; chemical contamination) and to the ways of avoiding them.

6. Requirements for toys in food

Toys embedded in food are prohibited in many countries including the United States, and this should also be the case in the EU. Despite fatal and near fatal accidents, food containing toys continues to be sold in the EU.

In this context, we support as a step in the right direction the prohibition of toys attached to the food product in such a way that the food needs to be eaten in order to reach the toy. However, for toys in food that will still be sold on the European market, we believe the requirements should be strengthened as follows:

- such products should bear specific warnings indicating that the product contains a toy, irrespective of the age of the child;
- the warning label should not be distorted (e.g. folded or crumpled) or able to be easily distorted, as this could impair the legibility of the warning;
- toys in food should distinguish themselves clearly by colour, consistency and size from the food;
- the size of the toy should not present any choking hazard and should not fit into the 'small parts test cylinder';
- although it is important to require through legislation that toys in food must have their own packaging, it is crucial this packaging itself does not present any risk of asphyxiation, strangulation, suffocation or choking

The current proposal states only that the packaging must not present risk of strangulation or asphyxiation caused by external airway obstruction. We strongly recommend adding that the risk of strangulation and asphyxiation should not be caused by internal airway obstruction.

END