Revision of Legislation on the Safety of Toys

ANEC-BEUC final contribution - 25 June 2007

In preparation for a revision of Directive 88/378/EEC on the Safety of toys, DG Enterprise and Industry asks all interested parties to contribute to the online consultation on possible modifications to be made to the current Directive on the safety of toys.

Interested parties are invited to submit their comments by 30 June 2007 at the latest.

Please note that the time for an online-session is limited to 90 minutes.

The Commission intends to adopt the proposal of the Commission of a revised Directive 88/378/EEC in the fourth quarter of 2007. The results of this consultation will be used in preparing the proposal. The results will be published in the website of the Toys unit.

Profile of the respondent

You reply… (compulsory)

- On behalf of an organisation, institution or enterprise
- As an individual
- Consumer organisation
- Industry organisation
- Member State
- Standardisation organisation
- Other
- Manufacturing and/or designing toys
- Importing/distributing toys
- Involved in other activities
Contact person name (compulsory)

Country of residence/where your organisation is based (compulsory)

Privacy statement
Contributions to open consultations will be made public including personal data unless you state explicitly that you do not consent to the publication of your personal data. The contact data provided by the stakeholder make it possible to contact the stakeholder to request a clarification if necessary on the information supplied. By responding to this consultation you automatically give permission to the Commission to publish your contribution on the website of the Toys unit. The Commission is committed to user privacy and details on the personal data protection policy can be accessed at: http://europa.eu.int/geninfo/legal_notices_en.htm#personaldata

Do you consent to publication of your reply, personal data included? (compulsory)
- I consent to the publication of this reply, personal data included
- I want this reply to be published anonymously

Do you experience difficulties in classifying products as toys that fall under the toys directive? (compulsory)
- Yes, often
- Yes, sometimes
- Rarely
- No

If yes, for which kind of products have you met difficulties? (optional)
- A Objects which are not exclusive intended for playing but have other purposes as well, such as key rings or objects with decoration purposes
- B Bicycles, scooters,
- C Equipment used for sports, such as roller skates, skateboards,
- D Electrically driven toys/vehicles
- E Aquatic equipment
- F Electronic equipment, peripherals
- G Others, which?
Do you think that clarification of the text of the Directive as regards the above mentioned products would help to solve the problems of classification? (compulsory)

- I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

Do you think that in addition to the possible clarifications to the provisions of the directive, also non binding guidance documents are needed in order to facilitate the classification of products as toys or not (cf. guidance documents published in http://ec.europa.eu/enterprise/toys/eg_guidance.htm)? (compulsory)

- Yes
- No
- I do not know

Definitions (specific to the toys Directive)
The current Toys Directive does not contain any definitions apart from the definition of a “toy” and “placing on the market”. The proposal for a horizontal Decision (http://ec.europa.eu/enterprise/newapproach/review_en.htm) mentioned in the background document contains a number of definitions of horizontal nature which will be taken over to the revised Toys Directive (see Article 6 of the proposal for a horizontal Decision).

Do you think that adopting definitions in the Directive for certain concepts specific to the toys sector, like “functional toys”, “activity toys”, “trampoline”, “design speed”, “risk”, “hasard” would enhance better understanding of its provisions by the enforcement authorities and economic operators and improve the legal certainty? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I don’t know

Essential requirements
I General requirement of safety
The current Directive contains a provision laying down a general requirement of safety that all toys placed on the market in the Community have to fulfill. The general requirement of safety foresees that “users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children”.

Do you think that the safety of toys would be improved if the general safety requirement was modified so as to add an obligation to take into account also the “reasonably foreseeable misuse” of toys by children in addition to “the intended or foreseeable use” of them contained in the present requirement? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

II Particular safety requirements

1. Physical and mechanical properties

a) Suffocation/choking

The present Directive contains the following requirement concerning the choking risk: toys intended for children below the age of 36 months should not present the risk of being swallowed or inhaled. In addition to this, the current Directive requires that (all) toys and their parts and the packaging in which they are contained for sale must not present risk of strangulation or suffocation. The suffocation is generally interpreted to mean the result of airway obstruction external to the mouth and nose, although the current Directive does not contain any definition of “suffocation”.

Do you think that the safety of toys would be improved if provisions of the Directive are modified so as to take into account also the risks of choking presented by toys for children above 36 months when they are intended to be put in the mouth (ie toy instruments)? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
The current directive does not explicitly cover the risks presented by a specific category of toys, that is, by toys which are likely to be put in the mouth also by children more than 36 months, because wetting improves their functioning (i.e., toys with suction cups). These kind of toys present the risk of internal airway obstruction by closing off the flow of air from the mouth and nose when wedged in the mouth or pharynx.

Do you think that this risk should be explicitly covered by the Directive? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

b) Speed limit of electrically driven ride-on toys.

The current Directive does not contain any safety requirements concerning the speed limit of electrically driven ride-on toys. The current standard EN 71:1 sets a limit of 8 km/h for the electrically driven ride-on toys intended for children under 36 months.

Do you think that the Directive should set an essential safety requirement concerning the maximum design speed limit for electrically driven ride-on toys while leaving to the standardisation to set the exact limits (km/h) for different age groups? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

c) Activity toys

The current Directive does not contain any essential safety requirements concerning the risks presented by activity toys (such as swings, slides, trampolines).

Do you think that the Directive should contain an essential safety requirement concerning the risks presented by activity toys (risk of crushing, trapping of body parts or clothing, falls, impacts and drowning)? (compulsory)

- Yes, I agree
- I tend to agree
I tend to disagree
I disagree
I do not know

d) Noise
The current Directive does not contain any essential safety requirements concerning the risks to the hearing presented by the sound coming from toys.

Do you think that the directive should foresee a safety requirement concerning the noise produced by toys while leaving to the standardisation to set the specific limits in decibels? (compulsory)
I agree
I tend to agree
I tend to disagree
I disagree
I do not know

2. Chemical requirements
The current Directive lays down that “toys must be so designed and constructed that, when used as intended or in a foreseeable way, they do not present hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes.”
The Directive also contains a provision requiring that toys must in all cases comply with the relevant Community legislation applying to chemicals. Furthermore, the Directive sets specific bioavailability limits of certain substances in toys (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium).

The Council and the European parliament adopted on the 18th December 2006 Regulation (EC) No 1907/2006 concerning the registration evaluation, authorisation and restriction of chemicals (REACH). The REACH Regulation is also applicable to chemicals used in and to toys placed on the market in the Community. Concerning restrictions on the use of chemicals or authorisations of their use for specific applications, the REACH Regulation is based on the assessment of the risks presented by chemicals (“risk” meaning the combination of hazards presented by chemicals and exposure to them) and not only on their hazardous properties.

Do you think that in addition to the application of the requirements adopted under the REACH-regulation to toys, the toys directive itself should contain specific provisions to restrict/ban the use of certain hazardous substances, such as CMRs, in toys, on the basis of their hazardous properties only, without taking into account whether there is a potential exposure to them? (compulsory)
Yes, I agree
I tend to agree
Do you think that the toys Directive should contain provisions on the presence or use in toys of certain allergenic substances, such as fragrance allergens identified under Directive 76/768/EEC on cosmetic products or substances meeting the criteria for classification as respiratory allergens or skin contact allergens according to Directive 67/548/EEC? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

3. Electrical properties

Current directive lays down that electric toys must not be powered by electricity of a nominal voltage exceeding 24 volts and no part of the toy may exceed 24 volts.

Do you think that the Directive could be modified, without compromising the safety of children, in such way that it would allow internal voltages of toys to exceed the limit of 24 volts in certain cases, that is, when it is ensured that the voltage and the current combination generated do not lead to any risk of harmful electric shock, even when the toy is broken? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

Current Directive does not contain any safety requirement concerning lasers which are nowadays commonly used in toys.

Do you think that the Directive should lay down a safety requirement concerning lasers? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
4. Hygiene

Do you think that in order to ensure a proper hygiene of toys, it should be required that toys for children under 3 years of age are washable and that they shall fulfil the safety requirements also after washing? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I do not know

Warnings

The current Directive lays down that toys must be accompanied by clearly legible warnings in order to reduce inherent risks in their use. The Directive also sets out the warnings and indications to be given for certain categories of toys. This list of specific warning is completed by the standard EN 71.

Do you think that it would be beneficial to the safety of toys if more specific provisions than the ones in the current Directive were laid down on the affixing of warnings? It has in particular been suggested to require that warnings specify, where appropriate for safe use, user limitations, such as minimum and maximum ages or ability of the user of toys or maximum or minimum weight of the users as well as the need to ensure that the toy is used under adult supervision. (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I don’t know

Do you think that the use of toys would be made safer if it was laid down that information required for safe use, in particular, warnings specifying the minimum and maximum ages for users, are visible already at the point of sale? (compulsory)

- Yes, I agree
- I tend to agree
**Affixing of the CE-marking**

Current Directive lays down that the CE-marking shall as a rule be affixed either on the toy or on the packaging. In the case of small toys and toys consisting of small parts the CE-marking may be affixed to the packaging, to a label or to a leaflet.

Do you think that it would significantly facilitate the market surveillance and in this way increase the safety of toys, at least indirectly, if it was required that the CE-marking should, in principle, be affixed on the toy or on the packaging but that if it is not visible from outside the (transparent) packaging, it should be always fixed at least on the packaging? *(compulsory)*

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I don’t know

**Choice of conformity assessment modules**

Under the current Directive manufacturer or his authorised representative established in the community can chose between two modules for conformity assessment:

a) Internal production control where the manufacturer has applied the harmonised standards the reference number of which has been published in the Official Journal of the European Union;

b) Third party verification (EC type examination), if the manufacturer has not applied such harmonised standards covering all the relevant safety requirements or has applied them only in part or if such standards do not exist.

Do you find the present choice of modules for conformity adequate and sufficient for this field? *(compulsory)*

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I don’t know

**Technical documentation required from the manufacturers**
The current Directive requires the manufacturer, his authorised representative in the Community or the person who places the toy on the market to keep the technical file specified in Article 8 available for inspection.

Do you think that it would be reasonable to set a deadline of maximum 30 days for economic operators to respect when the market surveillance authority requests the technical documentation or translation of the relevant parts of it from the relevant economic operators? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I don’t know

Do you think that the technical documentation should contain, in addition to the information contained in the chemical safety data sheets provided by material and chemical suppliers, complementary information about the materials and chemicals present in the toy? (compulsory)

- Yes, I agree
- I tend to agree
- I tend to disagree
- I disagree
- I don’t know

**Enforcement/Specific market surveillance**

The current Directive contains an obligation for the Member States to take the necessary measures to ensure that toys placed on their market are in conformity with the Directive and gives the Member states market surveillance authorities certain powers for that purpose (access on request to the place of manufacture or storage, right to request certain information from the manufacturer, his authorised representative or the importer, right to take samples and carry out testing on them). In addition to these provisions of the Toys Directive, the powers and obligations given to the market surveillance authorities under Directive 2001/95 on the General Product Safety also apply to the market surveillance of toys.

Do you think that the market surveillance in the field of toys is not rigorous enough? (compulsory)

- Yes
- No
- I do not know
Do you think that Member States should invest more in market surveillance of toys? *(compulsory)*

- Yes
- No
- I do not know

Which measures do you think would be effective in reinforcing the present system of market surveillance? *(compulsory)*

- Effective information exchange
- Co-operation between national market surveillance authorities
- Co-operation between national market surveillance authorities and customs authorities
- Reinforced controls at external borders
- Cross border cooperation (market surveillance authorities, customs)
- Preventive measures (measures taken to ensure that non compliant toys are not placed on the market)
- Requests for information from manufacturers and other persons in the distribution chain as well as from Notified bodies
- Other

**Further comments**

Thank you for your participation.

Would you like to make further comments in connection with the issues related to the revision of the Toys Safety Directive that are dealt with by the questions above? *(4000 characters maximum) (optional)*

Many questions are two-fold (eg II.1b/d), which does not allow stakeholders to correctly express their opinion.

The precautionary principle should be introduced in the Directive’s preamble.

We urge for a Comitology Procedure to be implemented to allow flexible adjustments of the Directive by detailing essential requirements (eg chemical limit values), to determine the scope of the Directive and toys for which an EC type approval is needed.

**Definitions**

*Toy*: better definition needed to avoid overlapping (eg toy attached to child care article)  
*Harm*: clearer definition needed making also reference to adverse health effects

**Essential/specific requirements**
What does “normal” behaviour mean? We want this adjective to be deleted. Reasonably foreseeable misuse should always be considered in the general safety requirements but should be extremely well defined to avoid future misinterpretations.

The safety of children with special needs (eg visual impairment) should be taken into account.

The TSD should not imply that 36 months is the only age group for which specific requirements are necessary.

Concerning suffocation/choking, specific requirements should be included for toys in food (eg distinct packaging).

Concerning speed limit of electrically driven ride-on-toys, the maximum design speed should be 6km/h for children under 6 years.

The TSD should set limits related to health and safety issues, including noise. This should not be left to standards bodies.

**Chemicals**

Chemicals of concern are contained in and emitted from toys and may cause skin or respiratory irritations, allergies, but also, even at low doses, long term effects (hormonal disrupting or carcinogenic effects).

Children are exposed to a cocktail of chemicals, from different sources, which may interact with each other. Children, one of the most vulnerable populations, present higher dermal exposure and breathing rate than adults. Only a hazard based precautionary approach can protect them.

CMR substances (categories I-III) should be prohibited in toys as well as fragrances and allergenic substances; endocrine disrupting chemicals (eg phthalates); persistent, bioaccumulative and reprotoxic (PBT) and very persistent very bioaccumulative (vPvB) substances. Heavy metals should be kept at a very minimal concentration or be prohibited.

The ban of these chemicals should be part of the essential safety requirements of toys and no exemptions should be applied. Chemicals in toys should be evaluated (eg fragrances). An approval system is needed. Toys which require dangerous substances for their functioning should be prohibited. As a general rule, the acceptable limit of a chemical in toys should correspond to 10% of the TDI value.

Regarding electrical properties, only class I lasers should be allowed in toys.

For hygienic purposes, toys for children under 36 months must be washable and others should be washable whenever possible.

**Warnings**

Toys should be labelled with warnings on their inherent hazard. Warnings indicating which part may cause harm (eg "small balls") or that the toy contains eg phthalates are not meaningful to consumers. Additional warnings such as "choking hazard" or "chemical hazard" must be included. Safety instructions should be given to reduce the risk during use and foreseeable misuse. An Annex should list warnings and conditions of use.

**CE-marking**

We strongly oppose the CE marking to be addressed to consumers. We want it to be abolished, or at least removed from the toy itself and affixed to the technical documentation.

**Conformity assessment**

EC-type examination should be imposed for toys deserving special attention, not only toys for children under 3 years. A risk assessment is needed to identify them through a comitology procedure and list them in an Annex, eg toys which, in case of failure, lead to severe health effects; toys which caused severe accidents in the past; toys containing dangerous chemicals.

**Technical documentation**
A full chemical content declaration is needed.