



## An “initial” consultation document in preparation of the upcoming European Commission’s proposal to amend the Safety of Toys Directive 88/378/EEC

<b>KEY POINTS PROPOSED FOR REVISION</b>	<p>The European Commission intends to adopt a proposal for a revised Directive on the Safety of Toys in late 2007. The purpose of this consultation exercise is to keep you informed on the latest developments regarding the Safety of Toys Directive and to collect your feedback, which will then be used to start drafting Malta’s position in preparation to the upcoming Commission proposal.</p>
<p>The technological developments in the toys market have raised new issues with respect to the safety of toys, and made consumers express increased preoccupations in this regard. The European Commission intends to adopt a proposal for a revised Directive on the Safety of Toys in late 2007.</p> <p>The revision will mainly focus on:</p> <ul style="list-style-type: none"> <li>▪ Updating and modernising the safety requirements – in particular in areas such as <b>noise emission</b> and <b>chemicals</b>.</li> <li>▪ Clarifying the scope and concepts of the Directive.</li> <li>▪ Ensuring a coherent implementation and enforcement of the legislation.</li> <li>▪ Simplifying the current legislative framework.</li> </ul> <p>Other areas that will probably be tackled in the revision include:</p> <ul style="list-style-type: none"> <li>▪ Improving safety requirements for electrical properties, speed limits, suffocation and choking hazards, lasers, activity toys</li> <li>▪ Introducing the concept of foreseeable <i>misuse</i>, together with foreseeable use of toys.</li> <li>▪ Clarification of the scope with regard to certain new products such as videogames and electrically driven vehicles.</li> <li>▪ Clarification of rules on CE-marking (rules on its affixing, special rules for toys at fairs).</li> </ul> <p><u>Suggested Readings:</u></p> <ul style="list-style-type: none"> <li>▪ Commission Web page on Toys at <a href="http://ec.europa.eu/enterprise/toys/index_en.htm">http://ec.europa.eu/enterprise/toys/index_en.htm</a> which includes links to guidance documents (such as for Phthalates in toys), results of impact assessment studies and effects of the new chemicals legislation REACH.</li> <li>▪ An online consultation is currently being organized by the European Commission Directorate General for Enterprise and Industry. It is aimed at all interested parties and the outcome of this consultation will be used in the drafting of the revision proposal. This online consultation closes on the 30<sup>th</sup> of June 2007 and can be found on <a href="http://ec.europa.eu/enterprise/toys/public_consultation.htm">http://ec.europa.eu/enterprise/toys/public_consultation.htm</a>.</li> </ul>	
<b>BACKGROUND</b>	<p>Directive 88/378/EEC as amended by Directive 93/68/EEC and transposed into Maltese legislation by Legal Notice 373 of 2002.</p>
<p>Council directive 88/378/EEC of 3<sup>rd</sup> May 1988 on the safety of toys sets a high level of protection for consumers.</p> <p>The Directive applies to toys, defined as "<i>any product or material designed or clearly intended for use in play by children of less than 14 years of age</i>", with some exceptions.</p> <p>The Directive lays down the safety criteria or "<b>essential safety requirements</b>" which toys must meet during manufacture and before being placed on the market. The safety criteria cover risks such as physical and mechanical, flammability, chemical</p>	

properties, electrical properties, hygiene and radioactivity.

Manufacturers, or their authorised representatives established in the community, can choose between **self-verification** (through internal production control) or **third party verification** or **certification**.

**WHO WILL BE AFFECTED?**

Competent Authorities, Manufacturers, Notified Bodies, Importers, Distributors and Consumers of Toys.

**WHAT PRODUCTS WILL BE AFFECTED?**

- Products considered as toys under the current Directive.
- Borderline products that may fall under or out of the Toys Directive if the definition is changed.

**DEADLINES**

Feed back to arrive at our offices by **13<sup>th</sup> of July 2007**.

**CONTACT DETAILS**

Replies / feedback is to be sent by post or email to the addresses below:

Consumer and Industrial Goods Directorate,  
MALTA STANDARDS AUTHORITY,  
Second Floor, Evans Building, Merchants Street,  
Valletta, VLT 1179,  
Malta

Emails: [anthony.camilleri@msa.org.mt](mailto:anthony.camilleri@msa.org.mt);  
[david.pulis@msa.org.mt](mailto:david.pulis@msa.org.mt);  
[joseph.micallef@msa.org.mt](mailto:joseph.micallef@msa.org.mt).

**WE WELCOME AND VALUE YOUR FEEDBACK:**

a) Are you a manufacturer, importer, distributor or consumer of toys? Please identify yourself.

b) **DEFINITION AND SCOPE** - Do you have any suggestions to improve the definition of a toy or clarify the scope of the Toys Directive? Do you believe there is any legal uncertainty in the scope and definition of a toy, especially with respect to new products?

c) **GENERAL SAFETY REQUIREMENTS** - Would you object the introduction of an obligation to take into account the “*reasonably foreseeable misuse*” together with the “intended foreseeable use”?

d) **CHOKING / SUFFOCATION RISKS** – Do you think that there are any risks related to choking and suffocation that are not tackled in the current version of the Directive? The present Directive contains a requirement stating that toys intended for children below 36 months of age should not present the risk of being swallowed or inhaled. Do you have any comments on this threshold of 36mts of age?

e) **SPEED LIMITS** - What is your opinion on the maximum design speed limit for electrically driven ride-on toys? Would you agree with the introduction of an essential safety requirement in the Directive concerning this speed limit while leaving it to standards to set the exact limits (km/h) for different age groups?

f) **ACTIVITY TOYS** – Would you agree with the introduction of an essential safety requirement dealing with the risks present by activity toys (e.g. risk of crushing, trapping of body parts or clothing, falls, impacts and drowning)?

g) **NOISE EMISSIONS** - What, in your opinion, is the best approach to regulate noise emissions by toys? Would you agree with the introduction of a safety requirement concerning noise emissions whilst leaving it to standards to set the specific limits in decibels?

h) **VOLTAGE REQUIREMENTS** – The 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 have any suggestion on how the Directive could be modified in order to allow internal voltages of toys to exceed 24 volts in cases when it is ensured that the voltage and current combination generated do not lead to any risk of harmful electric shock, even when the toy is broken?

i) **LASERS** – Lasers are not mentioned in the current safety requirements. Do you have any comments on the introduction of a safety requirement concerning lasers?

j) **WASHING OF TOYS** - Would you have any objections to the introduction of a requirement stating that toys for children under 3yrs of age should be washable and that they shall fulfill the safety requirements also after washing?

k) **WARNING LABELS** - What is your opinion on the introduction of more specific provisions regarding warning labels? Would you agree with the addition of warnings specifying both minimum and maximum ages, ability of user, and maximum and minimum weight of users?

l) **AGE LABELLING** - What would your opinion be if it is requested that warnings specifying the minimum and maximum ages for users are made already visible at the point of sale?

m) **CE-MARKING** - In order to facilitate market surveillance activities, it may be required that the CE-marking would always be affixed on the outer packaging in cases where the markings on the toy itself are not visible. What is your opinion on such requirement if it is introduced?

n) **CONFORMITY ASSESSMENT PROCEDURES** - Do you find the present choice of conformity assessment modules adequate and sufficient for your field? If not, why? What improvements would you suggest?

- o) **TECHNICAL DOCUMENTATION** - Do you think that the technical documentation (specified in Article 8) should, in addition to the information contained in the chemical safety data sheets provided by material and chemical suppliers, contain complementary information about the materials and chemicals present in the toy?

p) **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.

1. In addition to the application of the requirements adopted under the REACH regulation, do you think that the toys directive itself should contain specific provisions to restrict/ban the use of certain hazardous substances, such as Phthalates and other carcinogenic substances, in toys, on the basis of their hazardous properties only, without taking into account whether there is a potential exposure to them?
2. Do you agree 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?

Should you be interested in attending, The Malta Standards Authority is organising the 2<sup>nd</sup> Information Seminar on REACH (Registration, Evaluation, Authorisation & Restriction of Chemicals). The seminar is going to be held at the **Malta Enterprise**, Industrial Estate San Gwann on **Wednesday 13<sup>th</sup> June 2007**. Registration is from 13.30, with the seminar starting at 14.00 sharp. The agenda will be sent out in the near future.

**Kindly confirm your attendance by completing and returning the Registration Form attached at the end of this document at your earliest convenience.**

- q) **GENERAL CONSEQUENCES** - What, if any, in your opinion would be the negative or positive consequences of the proposed amendments? Please explain.

- r) **OTHER REMARKS** - In general, do you foresee any possible room for simplification and clarification in the requirements? Are there any current unclear or conflicting requirements at the moment? Please provide any further comments below.

s) Request a “one-to-one” meeting?

Yes       No

t) Please insert your contact details:

Full name and Surname:	
Company:	
Telephone no.:	Fax no.:
e-mail:	

u) Signature: \_\_\_\_\_

Date \_\_\_\_\_

Designation: \_\_\_\_\_



**MALTA STANDARDS AUTHORITY**  
**Second Floor, Evans Building**  
**Merchants Street,**  
**Valletta VLT 1179,**  
**Malta**

**Phone No. (+356) 21242420**  
**Fax No: (+356) 21242406**  
**Vat No: 1515-0502**

## 2<sup>nd</sup> Information Seminar on REACH

13<sup>th</sup> June 2007  
 MSA

To register for the captioned seminar please fill in this form and return the information using one of the methods provided below.

By e-mail (preferred):    [audreyanne.anastasi@msa.org.mt](mailto:audreyanne.anastasi@msa.org.mt)

By fax:                      Audrey Anne Anastasi – (+356) 21242406

<i>Name of Organization</i>					
<i>Address</i>					
<i>Name of Applicant</i>					
<i>Designation</i>					
<i>Tel No:</i>		<i>Fax No:</i>		<i>Mobile No:</i>	
<i>E-Mail:</i>					

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*The information supplied to MSA on this form shall be treated in strictest confidence in terms of the Data Protection Act 2002 and subsequent amendments.*