

An “initial” consultation document on the Proposal for a Directive of the European Parliament and of the Council on the Safety of Toys

BACKGROUND	<p>On the 25th of January 2008, the European Commission adopted a proposal for a Directive on the Safety of Toys, which will repeal the current Directive 88/378/EEC.</p>
<p>Directive 88/378/EEC, as amended by Directive 93/68/EEC, was transposed into Maltese legislation by Legal Notice 373 of 2002. The revision has a threefold objective: first and foremost there will be new and higher safety requirements to cope with recently identified hazards, secondly it will strengthen manufacturers' and importers' responsibility for the marketing of toys and finally, it will enhance market surveillance obligations of Member States.</p> <p>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 soon be required to draft Malta's position for use during discussions in the European Council. In order to be adopted, this proposal must be discussed and accepted from both the European Parliament and the European Council.</p> <p><u>Suggested Readings:</u></p> <ul style="list-style-type: none"> ▪ The text of the new proposal can be found on: http://ec.europa.eu/enterprise/toys/2008_108_directive.htm 	
KEY POINTS PROPOSED FOR REVISION	<p>The ultimate aim is to improve toys safety in Europe.</p>
<p>The main points of the revision are:</p> <ul style="list-style-type: none"> ▪ Updating and completing the existing provisions to address safety issues that were unknown at the time of the adoption of Directive 88/378/EEC; ▪ Keeping up with technological developments in the toys market, which have given rise to increased consumer concerns; ▪ Improving the implementation and enforcement of the Safety of Toys Directive throughout the European Union; ▪ Clarifying the scope and concepts of the Directive; ▪ Ensuring consistency with the general measures that have been tabled in the general legislative framework for the marketing of goods. This includes alignment of the Directive to the Horizontal Decision in areas such as definitions, general obligations for economic operators, presumption of conformity, formal objection against harmonised standards, rules for the CE-marking, requirements for conformity assessment bodies and the notification procedures. <p>The following issues are prone to have a negative impact on industry costs:</p> <ul style="list-style-type: none"> ▪ New provisions on the chemical requirements – costs related to the REACH regulation; ▪ More stringent requirements on warnings - costs of modifying labelling and packaging; ▪ Changes to the requirements concerning the choking risk; ▪ Clarifying the suffocation risk - increased risk and hazard assessment costs, together with new warnings or 	

labelling;

- Clarifying the general requirement of safety – new conformity assessment procedures to assess safety;
- Changes to the technical file as regards information on chemicals – increased administrative costs;
- Changes to the CE marking and traceability information – costs related to labelling and affixing of CE marking on packaging;
- Costs related to additional testing requirements, e.g. presence of CMR substances and small parts cylinder test for toys in food;

As it could be expected, the incremental costs to SMEs are larger than those of multinationals. But these costs are deemed acceptable as long as they are necessary to attain the objective pursued and remain proportionate to the objective.

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 new revised definition.

DEADLINES

Feed back to arrive at our offices by **20th of March 2007**.

CONTACT DETAILS

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

Regulatory Affairs Directorate,
MALTA STANDARDS AUTHORITY,
Second Floor, Evans Building, Merchants Street,
Valletta, VLT 1179,
Malta

Emails: david.pulis@msa.org.mt;
tristan-charles.camilleri@msa.org.mt;

WE WELCOME AND VALUE YOUR FEEDBACK:

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

BROADENING OF DEFINITION: Do you find any objections in the broadening of the scope in order to include products which may not be exclusively intended for use in play?

Current definition: “A toy shall mean any product or material designed or clearly intended for use in play by children of less than 14yrs of age.”

New definition (Article 1.1): “products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.”

EXCLUSIONS FROM THE SCOPE: The concept of exclusions in Annex I has been maintained but all exclusions have been clarified or expanded and the revised list includes some new exclusions. The revisions affecting exclusions are now in Annex I and in Article 1.2.

Current Definition:	Proposed Modification:
Christmas decorations	Decorative objects for festivities and celebrations
Detailed scale models for adult collectors	Products for adult collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are: detailed and faithful scale models, kits for the assembly of detailed scale models, folk dolls and decorative dolls and other similar articles, historical replicas of toys, reproductions of real fire arms.
Equipment intended to be used collectively in playgrounds	Playground equipment intended for public use.
Sports equipment	Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg
Aquatic equipment intended to be used in deep water	Aquatic equipment intended to be used in deep water and swimming learning devices for children, such as swim seats and swimming aids
Puzzles with more than 500 pieces or without picture, intended for specialists	Puzzles with more than 500 pieces
Air guns and air pistols	Guns and pistols using compressed gas, with the exception of water guns, and bows for archery over 120 cm long
Fireworks, including percussion caps	Fireworks, including percussion caps which are not specifically designed for toys

Slings and catapults	Slings and catapults
“Professional” toys installed in public places (shopping centres, stations, etc)	Automatic playing machines, whether coin operated or not, intended for public use
Sets of darts with metallic points	Products and games using sharp-pointed missiles, such as sets of darts with metallic points
Electric ovens, irons or other functional products operated at a nominal voltage exceeding 24V	Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision; “Functional product” means a product which performs and is used in the same way as a product, appliance or installation intended for use by adults, and may be a scale model of such a product, appliance or installation.
Products containing heating elements intended for use under the supervision of an adult in a teaching context	Products intended for use for educational purposes in schools and in other pedagogical framework under the surveillance of an adult instructor, such as science equipment
Vehicles with combustion engines	Toy vehicles equipped with combustion engines
Toy steam engines	Toy steam engines
Bicycles designed for sport or for travel on the public highway	Bicycles, scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways
Video toys that can be connected to a video screen, operated at a nominal voltage exceeding 24V	Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels
Babies’ dummies	Babies' soothers
Fashion jewellery for children	Deleted
No previous exclusion	Electrical transformers for toys
No previous exclusion	Child-appealing luminaires
No previous exclusion	Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CD
No previous exclusion	Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or on the pavement of these

Do you have any comments on the modified exclusions?

ADDITION OF NEW DEFINITIONS (Article 2) – Certain common principles have been clearly defined. Other definitions have been modified to be in line with the horizontal revision of the New Approach. Should you have any comments please write them beneath the definition being referred to:

- "making available on the market" means any supply of a toy for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

- "placing on the market" means the first making available of a toy on the Community market;

- "manufacturer" means any natural or legal person who designs and manufactures a toy or who has such a toy designed or manufactured, under his name or trademark;

- "distributor" means any natural or legal person in the supply chain, who makes a toy available on the market;

OBLIGATIONS OF MANUFACTURERS (Article 3) – This is a new article introduced to clearly define the obligations of manufacturers. The manufacturers shall:

- Meet the essential requirements set out Article 9 and Annex II.
- Draw up technical documentation according to Article 20.
- Carry out the applicable conformity assessment procedure in accordance with Article 18.
- Draw up the EC Declaration of Conformity referred to in Article 14
- Keep technical documentation and EC Declaration of Conformity for 10yrs after the toy has been placed on the market
- Carry out sample testing of marketed toys and if necessary, keep a register of complaints
- Ensure that toys are adequately labelled with elements allowing their identification (e.g. type, batch, serial or model number).
- Indicate their name and address on the toy or packaging or on a document accompanying the toy

OBLIGATIONS OF AUTHORISED REPRESENTATIVES (Article 4) – This is a new article which defines the obligations of authorised representatives. Authorised Representatives may be appointed by a written mandate and must be established within the European Community. They act on behalf of the manufacturers for specified tasks. The representatives shall at least do the following:

- Keep EC Declaration of Conformity and technical documentation at the disposal of national authorities for 10yrs

- Provide all information necessary to demonstrate the conformity of the toy upon request
- Co-operate with the national authorities in order to avoid risks posed by toys

OBLIGATIONS OF IMPORTERS (Article 5) – This article deals with the responsibilities of importers. The new clarified obligations require that importers:

- Verify that the appropriate conformity assessment procedure has been carried out by the manufacturer, prior to placing the toy on the market. This includes checking that technical documentation exists and all necessary markings are visible.
- Indicate their name and address at which they can be contacted on the toy itself or on the packaging or on a document accompanying the toy.
- Keep a copy of the EC Declaration of Conformity at the disposal of authorities for 10yrs
- Ensure that the technical documentation can be made available upon request from authorities
- (Article 7) An importer who sells a toy under his name or trademark shall be subject to the obligations of the manufacturer.
- (Article 7) An importer who modifies a toy shall be subject to the obligations of the manufacturer.

OBLIGATIONS OF DISTRIBUTORS (Article 6) – It is important to differentiate between a distributor and an importer, as defined in the new Article 2. Under the new Directive, distributors are, in particular, obliged to:

- Verify that the toy bears the required markings and is accompanied by the required documents prior to selling the toy.
- Provide, on request, all the information and documentation necessary to demonstrate the conformity of the toy.
- (Article 7) A distributor who sells a toy under his name or trademark shall be subject to the obligations of the manufacturer.
- (Article 7) A distributor who modifies a toy shall be subject to the obligations of the manufacturer.

TRACEABILITY (Article 8) – All economic operators (manufacturer, representative, importer, distributor) are required to be able to identify the economic operator which has supplied them with the toy and the economic operator to whom they have supplied the toy. This information shall be kept available to the authorities, for each toy, for a period of 10yrs.

ESSENTIAL SAFETY REQUIREMENTS (Article 9 and Annex II) – The definition of toy safety has not changed – “Toys shall not jeopardize the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind behaviour of children.” The concept of foreseeable misuse was, thus, not specifically introduced. However, the following provisions have been introduced:

- Manufacturers must take into account the ability of the users and their supervisors, in particular, in the case of toys intended for children under 36 months of age.
- Toys have to comply with the essential requirements during their foreseeable and normal period of use.

In Annex II, several new elements have been introduced in the essential safety requirements. We suggest that you read the whole text of the proposal to identify all the changes. The main changes include:

- *Asphyxiation risks* – In the current Directive, Annex II, section II, paragraph 1(d) states that toys intended for children under 36 months of age must not present a risk of being swallowed or inhaled. The new text keeps this sentence but adds the concept that no toys shall present a risk of strangulation or suffocation, irrespective of the intended age of users.
- *Toys in food* – toys contained within food or co-mingled with a food must have their own packaging, which must not itself present a risk of suffocation. Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited.
- *Electrically driven ride-on toys* - the maximum design speed of electrically driven ride-on toys shall be limited taking into account the kinetic energy developed by the toy.
- *Sound emissions* - Toys should be so designed and constructed so that the sound from them is not able to impair children’s hearing.
- *Activity toys* - Activity toys shall be constructed so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning as far as possible
- *Chemical Properties* – References to Regulation (EC) 1907/2006 (REACH) have been introduced. A ban on 38 different allergenic fragrances and restrictions on another 26 fragrances has been introduced. There are also new restricted migration limits concerning 19 substances such as Aluminium, Copper, Tin and Zinc.
- *Hygiene Requirements* - Textile toys for children under 36 months shall be washable and shall fulfil the safety requirements also after washing.

WARNINGS (Article 10 and Annex V) – The requirements for warnings have remained as an Annex but have now been complemented by this new article containing the following new provisions:

- Warnings shall be visible, clearly legible and accurate
- Warnings shall be marked on the toy itself, on a label or on the packaging.
- Warnings shall also be written on the instructions for use accompanying the toy, when such instructions are present.
- Warnings specifying the minimum and maximum ages for users shall be visible, legible and conspicuously displayed at the point of sale.

The new Annex V on warnings states that:

- The user limitations for general warnings shall include at least the minimum *or* maximum age of users, and, where appropriate, the ability of the users, the maximum or minimum weight of the users and the need to ensure that the toy is used only under adult supervision.
- Warnings for specific categories of toys have remained unchanged except for new warning requirements for toys in food.

EC DECLARATION OF CONFORMITY (Article 14 and Annex III) – The concept of the Declaration of Conformity has been included in a new article which states that:

- The declaration shall state that the essential safety requirements have been fulfilled and demonstrated.
- The declaration shall have the model structure set out in Annex III.
- By drawing up the declaration, the manufacturer is assuming the responsibility for the compliance of the toy.

The new Annex III states what the Declaration of Conformity should contain, including:

- Name and address of manufacturer or authorised representative.
- Unique toy identification number.
- References to specifications or standards used.
- Signature and designation of responsible person.

CE-MARKING (Articles 15 & 16) – The provisions on CE-marking have been clarified and have been made similar to the provisions in other sectors. New provisions include:

- The CE-marking may only be affixed by the manufacturer or his authorised representative.
- The CE-marking shall be the only marking which attests conformity of the toy with the applicable requirements.
- The visibility and legibility of the CE-marking shall not be hindered by other markings.
- At trade fairs and exhibitions, toys that do not bear a CE-mark and which do not comply with the Directive are allowed as long as they accompanied by a sign which indicates that the toy does not comply with the requirements of the Directive. These toys are not permitted to be sold or distributed free of charge.
- The CE-mark must have a height of at least 5mm.
- For small toys, the CE-marking may be affixed on a label or on an accompanying leaflet.
- If the CE-marking is not visible from outside the packaging, it has to be affixed on the packaging as well.

CONFORMITY ASSESSMENT PROCEDURES (Articles 17, 18 and 19) – In the current Directive, manufacturers could choose between self-verification and third party certification. The new system involves:

- Manufacturer shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present and an assessment of the potential exposure to them.
- If harmonised European standards are used, the manufacturer shall use the procedure of internal production control (Module A – for both design and production).
- If harmonised European standards are not used in full or when third party verification is necessary (due to nature, design and purpose of toy), the manufacturer shall submit the toy for EC type-examination (Module B for design and Module C for production) by a notified body.

TECHNICAL DOCUMENTATION (Article 20 and Annex IV) – According to the new proposal, the technical file referred to in Article 3 shall have the following characteristics:

- Shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the relevant essential requirements.
- Shall contain the documents listed in the new Annex IV.
- Shall be drafted in one of the official languages of the Community. A translation shall be provided by the manufacturer if this is requested by market surveillance authorities, up to a maximum of 30 days following the request for the translation.
- If there are any doubts on the technical documentation, the authorities may ask for further testing from the notified bodies, at the expense of the manufacturer.

The new Annex IV states what the Technical Documentation should contain, including:

- Safety data sheets on chemicals.
- Address of the places of manufacture and storage.
- Colour image of the toy.

NOTIFIED BODIES (Articles 25 and 34) – The requirements for Notified Bodies have been clarified:

- Must be independent from the organisation or product it assesses.
- No personnel responsible for carrying out the conformity assessment tasks shall be involved in the design, production, supply, installation, purchasing or use of the products assessed.
- The activities of the notified body, including its subsidiaries and subcontractors, must be confidential, objective and impartial.
- Must be free from any pressures and inducements that might influence their judgement.
- Personnel shall have appropriate knowledge and understanding of the essential requirements and the requirements for the assessment.
- The remuneration of the conformity assessment body's top level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.
- The conformity assessment body shall take out liability insurance.
- Any changes to the EC type-examination certification must be notified to the notifying authority and other Notified Bodies.

MARKET SURVEILLANCE (Articles 38 and 50) – The clarifications on the powers of market surveillance authorities are:

- The authorities may require from the economic operators and notified bodies any information, including technical documentation and test reports.
- The authorities shall be entitled to enter the premises of the economic operators concerned where it appears necessary for the purposes of carrying out the surveillance of toys.
- The authorities shall introduce a system of penalties which shall be effective, proportionate and dissuasive in nature.

TRANSITIONAL PERIOD (Article 52) – New toys which are manufactured in accordance with Directive 88/378/EEC shall be allowed to be placed on the market for up to 2 years after the new Directive has entered into force.

ANY FURTHER COMMENTS IN GENERAL?

Request a "one-to-one" meeting?

Yes No

Please insert your contact details:

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

Signature: _____

Date _____

Designation: _____