

Revision of the Safety of Toys Regulations



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Introduction to the Toys Sector:

The European toy industry employs over 100,000 people directly and there are over 2000 companies operating in the toy and games sector. Most of them are SMEs. The most important trading partners remain USA (**22% of exports**) and the Far East (**88% of imports**).

Safety is an important issue for toys. The Council directive of 88/378/EEC of 1988 concerning the safety of toys sets a high level of protection for consumers. The directive relies on European standards and also on the Notified Bodies appointed by Member States to undertake conformity assessment.

In Malta, the **Malta Standards Authority** is the Competent Authority for Toys under Directive 88/378/EEC (Legal Notice 373 of 2002).

Basic Principles (1):

The Toys Directive is, and will remain, a “**New Approach Directive**”. The main aim of the New Approach is to remove barriers to free circulation of goods. This approach limits public intervention to what is essential and leaves business and industry the greatest possible choice on how to meet their public obligations.

The **Directives** themselves are compulsory and will be transposed into national law. The Directives only contain the minimum safety criteria to be achieved. These are known as the **Essential Safety Requirements** (ESRs), and arise from certain hazards associated with the product and are mandatory. Products may be placed on the market only if they are in compliance with these requirements.

A **Standard** is technical, non-changing (unless due to technological advances) and voluntary. In practice, a manufacturer will use a standards to fulfil the requirements of the directive. Standards are drafted upon consultation with the industry itself.

Basic Principles (2):

ESRs are a sort of compromise between different national requirements. They define the results to be attained or hazards to be dealt with but do not specify the technical solutions for doing so, as long as the solution is the “*state of the art*”. This flexibility allows manufacturers to choose the way to meet the requirements (e.g. materials, product design, testing).

Preferably, **Harmonized Standards** (EN) are used. Products that comply with such standards only are *presumed to comply* with the corresponding ESRs.

If the manufacturer chooses not to follow EN standards, he has the obligation to prove that his products conform to ESRs by the use of other means of his own choice (e.g. any existing technical specifications).

Member States are, as a general rule, not allowed to maintain or introduce more stringent measures than foreseen in the directive.

Basic Principles (3):

The **CE-marking** is the only marking which symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer. It is a declaration by the person responsible that the product conforms to all applicable Community provisions and that the appropriate conformity assessment procedures have been completed.

Member States must presume that products bearing the CE-marking comply with all the provisions of the applicable directives providing for its affixing. Member States may not prohibit, restrict or impede the placing on the market and putting into service in their territory of products bearing the CE-marking, unless there is suspicion that the provisions relating to CE marking are incorrectly applied.

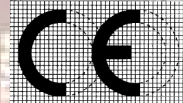
The CE-marking is mandatory when applicable. Where a third party (notified body) is involved in the production control phase according to the applicable directives, its identification number must follow the CE-marking.

It is NOT a quality or safety mark and it is not primarily aimed for consumers.

The Current Toys Regulations:

Toys are defined as "any product or material designed or clearly intended for use in play by children of less than 14 years of age".

The New Approach Concept applied for toys:

- The legislation only lays down essential requirements, leaving the actual technical specifications in harmonised standards.
- The safety criteria cover general risks (protection against health hazards or physical injury) and particular risks (physical and mechanical, flammability, chemical properties, electrical properties, hygiene, radioactivity).
- Manufacturers can choose which conformity assessment route to follow. For toys, the current choice is between self-verification or third-party certification.
- Only toys with this marking enjoy free circulation: 
- Market Surveillance

The Need for a Revision:

A number of deficiencies have been identified over time, which have triggered the need to assess the existing legal framework. A thorough revision of the Directive seems appropriate, with a view to:

- Keeping up with technological developments in the toys market, which have given rise to increased consumer concerns;
- Improving the implementation and enforcement;
- Clarifying scope and concepts;
- Ensuring consistency with revision of the New Approach Principles. This includes alignment 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.

Definition (Article 1):

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: “products designed or intended, **whether or not exclusively**, for use in play by children under 14 years of age.”

Exclusions (Annex I):

The following categories of products are excluded from the new Toys Directive:

- Decorative objects for festivities and celebrations;
- Products for adult collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors ≥ 14 yrs;
- Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass > 20 kg;
- 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;
- Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or on the pavement of these.
- Aquatic equipment intended to be used in deep water and swimming learning devices for children, such as swim seats and swimming aids;
- Puzzles > 500 pieces;

Exclusions (Annex I):

- Guns and pistols using compressed gas, with the exception of water guns, and bows for archery >120cm long;
- Fireworks, including percussion caps which are not specifically designed for toys;
- Products and games using sharp-pointed missiles, such as sets of darts with metallic points;
- Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage >24V 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 intended for use for educational purposes in schools and in other pedagogical framework under the surveillance of an adult instructor, such as science equipment;

Exclusions (Annex I):

- 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;
- Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CD;
- Babies' soothers;
- Child-appealing luminaires;
- Electrical transformers for toys.

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 (NA).

NA definitions: “**making available on the market**”, “**placing on the market**”, “**manufacturer**”, “**distributor**”, “**importer**”, “**economic operators**”.

Risk-related definitions: “**suffocation**”, “**harm**”, “**hazard**”, “**risk**”.

“**Activity Toy**” means a toy which is intended for domestic use and designed to bear the weight of one or more children, excluding ride-on vehicles, and is intended for children to play on or in, such as swings, slides, carousels, climbing frames, trampolines, paddling pools and non aquatic inflatable toys.

Manufacturers (Article 3):

Obligations of Manufacturers – 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.

Authorised Representatives (Article 4):

Obligations of Authorised Representatives – 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

Importers (Article 5):

Obligations of Importers – 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.

Distributors (Article 6):

Obligations of Distributors – 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 Requirements (Article 9):

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.

Essential Requirements (Annex II):

- *Asphyxiation risks* – Toys intended for children under 36 months of age must not, currently, present a risk of being swallowed or inhaled. The new text 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.

Essential Requirements (Annex II):

- *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.
- *Electrical Properties* - Toys shall not be powered by electricity exceeding 24 volts and their accessible parts shall not exceed 24 volts. However, internal voltages may exceed 24V if it is ensured that the voltage and current combination generated does not lead to any risk or harmful electric shock, even when the toy is broken.
- *Hygiene Requirements* - Textile toys for children under 36 months shall be washable and shall fulfil the safety requirements also after washing.

Warnings (Article 10):

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.

Warnings (Annex V):

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.

Magnets in Toys (1):

Several accidents have been reported involving ingestion of magnets resulting in perforation or blockage of the intestines. Most accidents have occurred with children between the ages of 10mts and 8yrs. Medical signs associated with intestinal perforation or blockage can easily be misinterpreted since many children exhibit only flu-like symptoms.

The harmonized European standards in the Toys Sector (EN 71 series) do not currently take into account risks posed by magnets in toys. Therefore, the European Commission introduced the **2008/329/EC Decision**, requiring Member States to ensure that magnetic toys placed or made available on the market display a warning about the health and safety risks they pose.

The Decision will be implemented on **21 July 2008** and remain applicable till **21 April 2009** (until the EN 71 standards are revised).

Magnets in Toys (2):

A 'magnetic toy' means a toy that contains or consists of one or more magnets or one or more magnetic components that are of ingestible shape and size and are accessible to children,

When placed or made available on the Community market, such toys must display the following warning in the official languages of the Member State in which the product is placed or made available on the market:

'Warning! This toy contains magnets or magnetic components. Magnets sticking together or becoming attached to a metallic object inside the human body can cause serious or fatal injury. Seek immediate medical help if magnets are swallowed or inhaled.'

The warning must be clearly visible and legible to the consumer at the point of purchase.

Toys which do not display this warning as of 21 July 2008 will be removed from the market and legal action may be pursued against the responsible economic operators.

Declaration of Conformity (Article 14):

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.

Declaration of Conformity (Annex III):

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):

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.
- 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, 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.

Third Party Verification:

The reasons why third party verification was not imposed on all toys include:

- A number of manufacturers already undertake third party verification.
- Generation of significant costs, especially to SMEs.
- Delays in placing the products on the market.
- Third party verification does not render *per se* all toys put on the market safer. Only the prototype is certified by the third party and thus deficiencies during the production process can not be ruled out and avoided.

Taking into account the expected considerable costs and that mandatory third party verification cannot sufficiently enhance the safety of all individual toys, it was decided that such an option is not proportionate in view to the expected benefits. However, third party verification is mandatory in case harmonised standards covering all the safety aspects for the toy do not exist or are not followed.

Technical Documentation (Article 20):

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.

Technical Documentation (Annex IV):

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.
- Detailed description of the design and manufacture
- Description of the conformity assessment procedure followed;
- Copy of the EC declaration of conformity;
- Test reports and description of the means whereby the manufacturer ensures conformity of production with the harmonised standards
- Copy of the EC type-examination certificate

Market Surveillance (Articles 38, 50):

The main clarifications on the powers of market surveillance authorities are:

- The authorities may request 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.**

Summary:

The proposal will, in particular:

- Prohibit the use of carcinogenic chemical substances;
- Reduce the use of dangerous chemical substances like lead or mercury;
- Prohibit allergenic fragrances;
- Oblige manufacturers to issue appropriate warnings to improve prevention;
- Strengthen the rules that prevent accidents due to small parts in toys;
- Ban products which require food to be consumed before getting access to the toy;
- Require manufacturers to establish comprehensive technical information for all their toys to allow authorities to check the design and manufacture of the toy;
- Reinforce the importer's responsibility for ensuring that toys imported into the EU are safe;
- Enhance the visibility of the CE mark on the toy;
- Strengthen market surveillance activities and border controls.

Useful References:

- European Commission website on <http://ec.europa.eu>
- Guide to the implementation of directives based on the New Approach and the Global Approach (European Commission) on www.newapproach.org
- Commission Proposal COM(2008) 9 - http://ec.europa.eu/enterprise/toys/documents/com_2008_0009_en.pdf
- Directive 88/378/EEC - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31988L0378:EN:HTML>
- Commission Decision 2008/329/EC on Magnetic Toys Warnings - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:114:0090:0093:EN:PDF>

Thank You

For further information, please contact:

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