L.N. 16 of 1996

QUALITY CONTROL (EXPORTS, IMPORTS AND LOCAL GOODS) ACT (CAP. 225)

Safety of Toys Order 1996 (Order No. M32 of 1996)

IN exercise of the powers conferred by section 3 of the Quality Control (Exports, Imports and Local Goods) Act, and in accordance with that section, the Malta Board of Standards has made the following order:—

Citation and commencement.

1.1 This order may be cited as the Safety of Toys Order 1996, and may be referred to as Order No. M32 of 1996.

1.2 This order shall become operative on the 1st July, 1996.

1.2.1 The requirement of paragraph 8 of this order and the CE marking shall not be obligatory prior to the 1st January, 1997.

Scope.

2.1 This order shall apply to toys as defined in paragraph 3.1.1 of this order.

Definitions.

3.1 In this order

3.1.1 "toy" shall mean any product or material designed or clearly intended for use in play by children of less than 14 years of age but excluding those products which are listed in Schedule 1 of this order;

3.1.2 "the Community" means the European Community;

3.1.3 "the Directive" means Council Directive 88/378/EEC[1] as amended by Council Directive 93/68/EEC[2] on the approximation of the laws of the Member States concerning the safety of toys;

3.1.4 "CEN" means the European Committee for Standardisation;

3.1.5 "EN" means European Standard issued by CEN;

3.1.6 "OJ" means Official Journal of the European Communities;

3.1.7 "harmonised standard" means a technical specification adopted by the European Committee for Standardisation or the European

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[1] OJ No. L187, 16.07.1988, p.1
[2] OJ No. L220, 30.08.1993, p.1

Committee for Electrotechnical Standardisation or both, upon a remit from the European Commission in accordance with Council Directive 83/189/EEC[3] laying down a procedure for the provision of information in the field of technical standards and regulations;

3.1.8 "essential safety requirements" means the requirements set out in Schedule 2 of this order;

3.1.9 "approved body" means a body approved to carry out EC type examination as laid down in the Directive. The names of such approved bodies are published in the Official Journal of the European Communities.

Applicability.

4.1 The provisions of this order are applicable to imported toys and toys manufactured for the local market.

Placing on the market.

5.1 Toys may be placed on the market only if they do not jeopardise the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.

5.2 In the condition in which it is placed on the market, taking account of the period of foreseeable and normal use, a toy must meet the safety and health conditions laid down in this order.

5.3 For the purpose of this order, the expression "placed on the market" shall cover both sale and distribution free of charge.

Conformity.

6.1 Toys cannot be placed on the market unless they meet the essential safety requirements when tested in accordance with the methods laid down in harmonised standards, where applicable.

6.2 It shall be presumed that toys bearing the CE marking laid down in paragraph 9.2 of this order comply with all the provisions of this order including the conformity assessment procedures laid down in the Directive. Conformity of toys with the standards applicable in the Member States of the European Union which transpose the harmonised standards, the reference numbers of which have been published in the Official Journal of the European Communities, shall result in a presumption of conformity with the essential safety requirements.

6.3 It shall be presumed that toys in respect of which the manufacturer has not applied the standards referred to in paragraph 6.2 of this order or has applied them only in part, or for which no such standards exist, satisfy the essential requirements where, after receipt

[3]OJ No. L109, 26.4.1983, p.8

of an EEC type-examination certificate, their conformity with the approved model has been certified by the affixation of the CE marking.

Withdrawal or restriction from market.

7.1 Where it is ascertained that toys bearing the CE marking which are used as intended or in accordance with paragraph 5 of this order are likely to jeopardise the safety and/or health of consumers and/or third parties, all appropriate measures shall be taken to withdraw the products from the market, or to prohibit or restrict their placing on the market.

CE marking and certificates of conformity.

8.1 Before being placed on the market, toys manufactured in accordance with the harmonised standards referred to in paragraph 6.2 of this order must have affixed to them the CE marking by which the manufacturer or his authorised representative established in Malta confirms that the toys comply with those standards.

8.1.1 The manufacturer established in Malta shall keep the following information available for inspection:

8.1.1.1 – a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity of production with the standards referred to in paragraph 6.2 of this order and, as appropriate: an EC type-certificate drawn up by an approved body; copies of the documents the manufacturer has submitted to the approved body; a description of the means whereby the manufacturer ensures conformity with the approved model,

8.1.1.2 – the addresses of the places of the manufacture and storage,

8.1.1.3 – detailed information concerning the design and manufacture.

8.1.2 Where the manufacturer is not established in Malta, his representative established in Malta or the person who places the toy on the local market shall be responsible for the provision of the information referred to in paragraph 8.1.1 of this order on demand by the competent authorities within a period of three months from the date of being so requested.

8.2 Toys which do not conform in whole or in part to the standards referred to in paragraph 6.2 of this order must have affixed to them, before being placed on the market, the CE marking by which the manufacturer established in Malta confirms that the toy concerned conforms to the model examined in accordance with the procedures laid down in the Directive which an approved body has stated complies with the essential requirements.

8.2.1 The manufacturer established in Malta shall keep the following information available for inspection:

8.2.1.1 – a detailed description of manufacture,

8.2.1.2 – a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity with the approved model,

8.2.1.3 – the addresses of the places of manufacture and storage,

8.2.1.4 – copies of the documents the manufacturer has submitted to an approved body in accordance with the Directive,

8.2.1.5 – the test certificate for the sample or a certified copy thereof.

8.2.2 Where the manufacturer is not established in Malta, his representative established in Malta or the person who places the toy on the local market shall be responsible for the provision of the information referred to in paragraph 8.2.1 of this order on demand by the competent authorities within a period of three months from the date of being so requested.

Labelling.

9.1 The CE marking referred to in paragraphs 6, 7 and 8 of this order and the name and/or trade name and/or mark and address of the manufacturer or his authorised representative or the importer into Malta shall as a rule be affixed either to the toy or on the packaging in a visible, easily legible and indelible form. In the case of small toys and toys consisting of small parts these particulars may be affixed in the same way to the packaging, to a label or to a leaflet. Where the said particulars are not affixed to the toy, the consumer's attention must be drawn to the advisability of keeping them.

9.2 The CE conformity marking shall consist of the initials "CE" taking the form of the specimen given in Schedule 4 of this order.

9.3 The affixing of markings on the toys which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the toys, their packaging or a label provided that the visibility and legibility of the CE marking is not thereby reduced.

9.4 The particulars referred to in paragraph 9.1 of this order may be abbreviated provided that the abbreviation enables the manufacturer, his authorised representative or the importer into Malta to be identified.

9.5 The labelling shall include the warnings and indications of precautions to be taken during use that have been given for certain toys as set out in Schedule 3 of this order.

9.6 The requirements of paragraphs 9.4 and 9.5 of this order shall appear in Maltese and/or English not excluding the addition of any other language.

SCHEDULE 1

ANNEX I OF THE DIRECTIVE

PRODUCTS NOT REGARDED AS TOYS
FOR THE PURPOSE OF THIS ORDER

1. Christmas decorations
2. Detailed scale models for adult collectors
3. Equipment intended to be used collectively in playgrounds
4. Sports equipment
5. Aquatic equipment intended to be used in deep water
6. Folk dolls and decorative dolls and other similar articles for adult collectors
7. "Professional" toys installed in public places (shopping centres, stations, etc.)
8. Puzzles with more than 500 pieces or without picture, intended for specialists
9. Air guns and air pistols
10. Fireworks, including percussion caps[4]
11. Slings and catapults
12. Sets of darts with metallic points
13. Electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts
14. Products containing heating elements intended for use under the supervision of an adult in a teaching context
15. Vehicles with combustion engines
16. Toy steam engines
17. Bicycles designed for sport or for travel on the public highway

[4]With the exception of percussion caps specifically designed for use in toys without prejudice to more stringent provisions already existing.

18. Video toys that can be connected to a video screen, operated at a nominal voltage exceeding 24 volts

19. Babies' dummies

20. Faithful reproductions of real fire arms

21. Fashion jewellery for children.

SCHEDULE 2

ANNEX II OF THE DIRECTIVE

ESSENTIAL SAFETY REQUIREMENTS FOR TOYS

I. General Principles

1. In compliance with the requirements of Article 2 of the Directive, the 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 nominal behaviour of children. Such risks are those:

(a) which are connected with the design, construction or composition of the toy;

(b) which are inherent in the use of the toy and cannot be completely eliminated by modifying the toy's construction and composition without altering its function or depriving it of its essential properties.

2. (a) The degree of risk present in the use of a toy must be commensurate with the ability of the users, and where appropriate their supervisors, to cope with it. This applies in particular to toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

(b) To observe this principle, a minimum age for users of toys and/or the need to ensure that they are used only under adult supervision must be specified where appropriate.

3. Labels on toys and/or their packaging and the instructions for use which accompany them must draw the attention of users or their supervisors fully and effectively to the risks involved in using them and to the ways of avoiding such risks.

II. Particular Risks

1. Physical and mechanical properties

(a) Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.

(b) Accessible edges, protrusions, cords, cables and fastenings on toys must be so designed and constructed that the risks of physical injury from contact with them are reduced as far as possible.

(c) Toys must be so designed and constructed as to minimise the risk of physical injury which could be caused by the movement of their parts.

(d) Toys, and their component parts, and any detachable parts of toys which are clearly intended for use of toys which are clearly intended for use by children under 36 months must be of such dimensions as to prevent their being swallowed and/or inhaled.

(e) Toys, and their parts and the packaging in which they are contained for retail sale must not present risk of strangulation or suffocation.

(f) Toys intended for use in shallow water which are capable of carrying or supporting a child on the water must be designed and constructed so as to reduce as far as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.

(g) Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the latter can open easily from the inside.

(h) Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy developed by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

(i) The form and composition of projectiles and the kinetic energy they may develop when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no unreasonable risk of physical injury to the user or to third parties.

(j) Toys containing heating elements must be so constructed as to ensure that:

– the maximum temperature of any accessible surfaces does not cause burns when touched,

– liquids and gases contained within toys do not reach temperatures or pressures which are such that their escape from a toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physiçal injury.

2. Flammability

(a) Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which:

1. do not burn if directly exposed to a flame or spark or other potential seat of fire; or

2. are not readily flammable (the flame goes out as soon as the fire cause disappears); or

3. if they do ignite, burn slowly and present a low rate of spread of the flame; or

4. irrespective of the toy's chemical composition, are treated so as to delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

(b) Toys which, for reasons essential to their functioning, contain dangerous substances or preparations as defined in Council Directive 67/548/EEC[5], in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or preparations which may become flammable due to the loss of non-flammable volatile components.

(c) Toys must not be explosive or contain elements or substances likely to explode when used as specified in Article 2(1) of the Directive. This provision does not apply to toy percussion caps, for which reference should be made to point 10 of Schedule 1 and the related footnote.

(d) Toys and, in particular, chemical games and toys, must not contain as such substances or preparations:

– which, when mixed, may explode:

– through chemical reaction, or through heating,

– when mixed with oxidising substances,

– which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

3. Chemical properties

1. Toys must be so designed and constructed that, when used as specified in Article 2(1) of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes.

[5]OJ No. 196, 16.8.1967, p.1/67

They must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations.

2. In particular, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day:

0,2 µg for antimony,
0,1 µg for arsenic,
25,0 µg for barium,
0,6 µg for cadmium
0,3 µg for chromium,
0,7 µg for lead,
0,5 µg for mercury,
5,0 µg for selenium,

or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence.

The bioavailability of these substances means the soluble extract having toxicological significance.

3. Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC[6] in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used.

However, where a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardisation (CEN) according to the procedure of the committee set up by Directive 83/189/EEC, provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Schedule 3.

4. Electrical properties

(a) 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.

(b) Parts of toys which are connected to, or liable to come into contact with a source of electricity capable of causing electric shock, together with the

[6] OJ No. L187, 16.7.1988, p.14

cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.

(c) Electric toys must be so designed and constructed as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

5. Hygiene

Toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness in order to avoid any risk of infection, sickness and contamination.

6. Radioactivity

Toys must not contain radioactive elements or substances in forms or proportions likely to be detrimental to a child's health. Council Directive 80/836/Euratom shall apply[7].

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[7]OJ No. L246, 17.9.1980, p. 1

SCHEDULE 3

ANNEX IV OF THE DIRECTIVE

WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING TOYS

Toys must be accompanied by appropriate clearly legible warnings in order to reduce inherent risks in their use as described in the essential requirements, and specifically:

1. Toys not intended for children under 36 months

Toys which might be dangerous for children under 36 months of age shall bear a warning, for example: 'Not suitable for children under 36 months' or 'Not suitable for children under three years' together with a brief indication, which may also appear in the instructions for use, of the specific risks calling for this restriction.

This provision does not apply to toys which, on account of their function, dimensions, characteristics, properties or other cogent grounds, are manifestly unsuitable for children under 36 months.

2. Slides, suspended swings and rings, trapezes, ropes and similar toys attached to a crossbeam

Such toys shall be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at intervals, and pointing out that, if these checks are not carried out, the toy may cause a fall or overturn.

Instructions must also be given as to correct assembly of the toy, indicating those parts which can present dangers if it is incorrectly assembled.

3. Functional toys

Functional toys or their packaging shall bear the marking "Warning: to be used under the direct supervision of an adult".

In addition, these toys shall be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions would expose the user to the hazards – to be specified – normally associated with the appliance or product of which the toy is a scale model or an imitation. It will also be indicated that the toy must be kept out of the reach of very young children.

'Functional toys' means toys which are used in the same way as, and are often scale models of, appliances or installations intended for adults.

4. Toys containing inherently dangerous substances or preparations. Chemical toys

(a) Without prejudice to the application of the provisions laid down in Community directives on the classification , packaging and labelling of dangerous substances or preparations, the instructions for use of toys containing inherently dangerous substances or preparations shall bear a warning of the dangerous nature of these substances or preparations and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toys must be kept out of reach of very young children.

(b) In addition to the instructions provided for in (a), chemical toys shall bear the following marking on their packaging:

"Warning: for children over[8] years of age only. For use under adult supervision".

In particular, the following are regarded as chemical toys: chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys.

5. Skates and skateboards for children

If these products are offered for sale as toys they shall bear the marking:

"Warning: protective equipment should be worn"

Moreover, the instructions for use shall contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user and third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

6. Toys intended for use in water

The toys intended for use in water defined in section II.1.(f) of Schedule 2 shall contain the warning in accordance with CEN's brief to adapt standard EN/71, parts 1 and 2:

"Warning! Only to be used in water in which the child is within its depth and under supervision".

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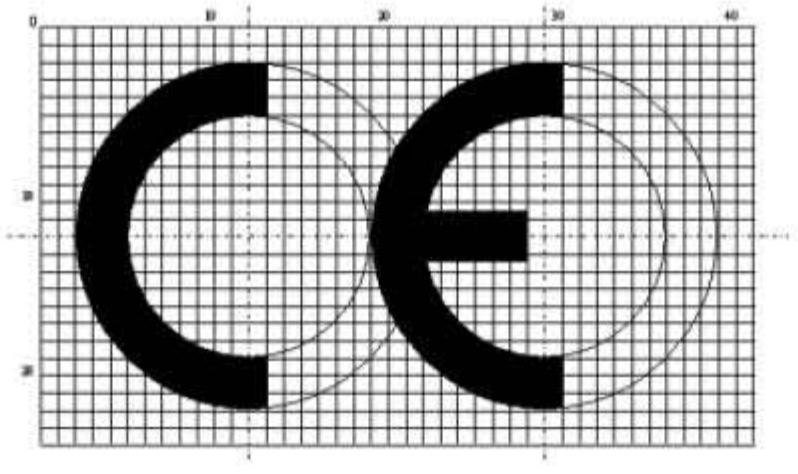
[8]Age to be decided by the manufacturer.

SCHEDULE 4

ANNEX V OF THE DIRECTIVE

CE CONFORMITY MARKING

The CE conformity marking shall consist of the initials "CE" taking the following form:



If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

Ipubblikat mid-Dipartiment ta' l-Informazzjoni – 3, Pjazza Kastilja – Published by the Department of Information - *3, Castille Place*
Mitbugħ fl-Istamperija tal-Gvern – *Printed at the Government Printing Press*

Prezz 16c – *Price 16c*