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In accordance with article 20 paragraph 4 from the Law on product safety (Official Gazette of the Republic of Macedonia, number 33/2006 and 63/2007), the Minister of Economy with the consent of the Minister of health adopted

RULEBOOK FOR TOY SAFETY

I. GENERAL PROVISIONS

Subject - matter

Article 1

This Rulebook regulates the essential requirements to be fulfilled by the toys for children (hereinafter: toys); procedure, manner and conditions for conformity assessment of toys; conditions to be met by the bodies that take part in the conformity assessment procedure; type of documents accompanying the toy when placed on the market; obligations and manner of labeling the toys; instruction for the application of standards and other technical specifications; form and content of the technical documentation, as well as the manner and the duration of its safekeeping and the protective clause and notification procedure.

Objective

Article 2

The objective of this Rulebook is to ensure that all economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that under normal and reasonably foreseeable conditions of use, the toys they place on market do not jeopardise the safety and health of children and that they make available on the market only toys which comply with the essential requirements set by this Rulebook.

Article 3

Scope

This Rulebook shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.

The products listed in Annex I which is part of this rulebook, shall not be considered as toys within the meaning of this Rulebook.

Exception

Article 4

This Rulebook shall not apply to the following toys:

- (a) playground equipment intended for public use;
- (b) automatic playing machines, whether coin operated or not, intended for public use;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines; and
- (e) slings and catapults.

Definitions

Article 5

For the purposes of this Rulebook the following definitions shall apply:

1. 'making available on the market' means any supply of a toy for distribution, consumption or use on the market in the Republic of Macedonia in the course of a commercial activity, whether in return for payment or free of charge;
2. 'placing on the market' means the first making available of a toy on the market of the Republic of Macedonia;
3. 'manufacturer' means:
 - any physical or legal entity that manufactures a toy or orders the design or the manufacture of the toy, when its principal place of business is in the Republic of Macedonia and when it puts its name, trademark or other specific mark, or an entity that repairs the toy;
 - the representative of the manufacturer in case the manufacturer does not have a place of business in the Republic of Macedonia, or in case the manufacturer has not registered a representative office in the Republic of Macedonia, the importer of the toy and
 - any other legal or physical entity that professionally participates in the supply chain, up to the point where his activity influences the safety of the toy.
4. 'authorised representative' means any natural or legal person established within the Republic of Macedonia who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks deriving from the representation liabilities determined with the authorisation pursuant to law;
5. 'importer' means any natural or legal person established within the Republic of Macedonia who places a toy from another country on the market of the Republic of Macedonia;
6. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a toy available on the market;
7. 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor
8. 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in the corresponding European rulebooks based on a request made from the European Commission;
9. 'national standard' means a standard adopted by the Standards Institute of the Republic of Macedonia in a regular standardization procedure, being a transposition of a European harmonized standard.
10. 'harmonisation legislation' means any Community legislation harmonising the conditions for the marketing of products;
11. 'accreditation' shall have the meaning assigned to it by the Law on accreditation of the Republic of Macedonia
12. 'conformity assessment' means the process demonstrating whether specified requirements relating to a toy have been fulfilled;
13. 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;
14. 'recall' means any measure aimed at achieving the return of a toy that has already been made available to the end user;
15. 'withdrawal' means any measure aimed at preventing a toy in the supply chain from being made available on the market;
16. 'market surveillance' means the activities and measures undertaken in coordination with the authorities in charge of market surveillance in order to ensure that the products fit with the requirements adopted based on those laws, that do not jeopardize the health, safety or other aspects of protection of public interest;
17. 'CE marking' means a marking by which the manufacturer indicates that the toy is in conformity with the applicable requirements set out in this Rulebook;

18. '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 which may be a scale model of such product, appliance or installation;
19. 'functional toy' means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and which may be a scale model of such product, appliance or installation;
20. 'aquatic toy' means a toy intended for use in shallow water which is capable of carrying or supporting a child on the water;
21. 'design speed' means representative potential operating speed that is determined by the design of the toy;
22. 'activity toy' means a toy for domestic use in which the support structure remains stationary while the activity is taking place and which is intended for the performance by a child of any of the following activities: climbing, jumping, swinging, sliding, rocking, spinning, crawling and creeping, or any combination thereof;
23. 'chemical toy' means a toy intended for the direct handling of chemical substances and mixtures and which is used in a manner appropriate to a given age-group and under the supervision of an adult;
24. 'olfactory board game' means a toy the purpose of which is to assist a child to learn to recognise different odours or flavours;
25. 'cosmetic kit' means a toy the purpose of which is to assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, tooth-paste and conditioners;
26. 'gustative game' means a toy the purpose of which is to allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas;
27. 'harm' means physical injury or any other damage to health, including long-term health effects;
28. 'hazard' means a potential source of harm;
29. 'risk' means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm;
30. 'intended for use by' means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group.

II. ESSENTIAL REQUIREMENTS TO BE FULFILLED BY TOYS

Essential safety requirements

Article 6

1. Toys may not be placed on the market unless they comply with the essential safety requirements:

- - regarding general safety requirement is concerned, in Article 7 of this Rulebook, and,
- - regarding the particular safety requirements are concerned, in Annex II, which is of this Rulebook

2. Toys placed on the market shall comply with the essential safety requirements during their foreseeable and normal period of use.

General safety requirements

Article 7

1. Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

2. The ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.

3. Labels affixed in accordance with Article 30 paragraph 4 of this Rulebook and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

Data (information)

Article 8

1. The safety of toys should be determined by reference to the intended use, while taking into account the foreseeable use, and bearing in mind the behaviour of children, who do not generally show the same degree of care as the average adult user.

2. Where a hazard cannot be sufficiently minimised by design or safeguards, the residual risk could be addressed by product-related information directed at the supervisors, taking into account their capacity to cope with the residual risk.

3. According to acknowledged methods of risk assessment, it is not appropriate for information to supervisors or a lack of history of accidents to be used as a substitute for design improvements.

Free movement

Article 9

Access making available of the toys on the market, in accordance with this Rulebook is free.

III. PROCEDURE, MANNER AND CONDITIONS UNDER WHICH THE CONFORMITY ASSESSMENT OF TOYS IS PERFORMED

Safety assessments

Article 10

Manufacturers 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, as well as an assessment of the potential exposure to such hazards.

Applicable conformity assessment procedures

Article 11

Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in Articles 12 and 14 of this Rulebook to demonstrate that the toy complies with the requirements set out in Article 7 and Annex II of this Rulebook.

Internal production control

Article 12

If during the course of manufacture, the manufacturer had applied national standards or harmonized standards encompassing the appropriate requirements for the safety of the toy, he shall apply module A, i.e. internal production control over the manufacture described in Annex VI of this Rulebook.

EC-type examination

Article 13

1. In the following cases, the toy shall be submitted to EC-type examination, as referred to in Article 14 of this Rulebook, together with the conformity to type procedure set out in Module C of Annex VIII to this Rulebook:

(a) where national standards or harmonized standards covering all relevant safety requirements for the toy, do not exist;

- (b) where the national standards or harmonized standards referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;
- (c) where one or more of the national standards or harmonized standards referred to in point (a) has been published with a restriction;
- (d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

Type examination

Article 14

1. An application for EC-type examination, performance of that examination and issue of the EC-type examination certificate shall be carried out in accordance with the procedures set out in Module B of Annex VII to this Rulebook.
2. EC-type examination shall be carried out in the manner specified in the second indent of point 2 of that Module B of Annex VII.
3. The application for an EC-type examination shall include a description of the toy and an indication of the place of manufacture, including the address.
4. When a conformity assessment body carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, the analysis of the hazards that the toy may present carried out by the manufacturer in accordance with Article 10 of this Rulebook.
5. The EC-type examination certificate shall include a reference to this Directive, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference to the relevant test report.
6. The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.
7. The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in Article 7 and Annex II of this Rulebook.
8. The technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in the Macedonian language.

Technical documentation

Article 15

1. The technical documentation referred to in Article 24, paragraphs 2 and 3 of this Rulebook shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in Article 7 and Annex II. It shall, in particular, contain the documents listed in Annex IV.
2. The technical documentation shall be drawn up in the Macedonian language.
3. Following a reasoned request from the market surveillance authority, the manufacturer shall provide a translation of the relevant parts of the technical documentation, and the market surveillance authority may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.
4. If the manufacturer does not comply with the requirements of paragraphs 1 and 2 of this Article, the market surveillance authority may require it to have a test performed by a conformity assessment body at its own expense within a specified period in order to verify compliance with the national standards and essential safety requirements set forth with this Rulebook.

IV. CONDITIONS TO BE MET BY THE BODIES THAT TAKE PART IN CONFORMITY ASSESSMENT

Requirements relating to notified bodies

Article 16

1. A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses.
2. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.
3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed toys that are necessary for the operations of the conformity assessment body or the use of such toys for personal purposes.
4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of those toys, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.
5. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.
6. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
7. Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of Article 14, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.
8. At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:
 - (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks, i.e. at least one specialist in sanitary chemistry and at least one engineer in pharmacy, chemistry and technology;
 - (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
 - (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.
9. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
10. The personnel responsible for carrying out the conformity assessment activities shall have:
 - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential requirements, of the applicable national and harmonised standards and of the relevant national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

11. The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured.

12. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

13. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with its national law, or the Member State itself is directly responsible for the conformity assessment.

14. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 14 of this Rulebook.

Presumption of conformity

Article 17

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant national standards or parts thereof, it shall be presumed to comply with the requirements set out in Article 16 of this Rulebook, insofar as the applicable national standards cover those requirements.

Formal objection to a harmonised standard

Article 18

Where the Republic of Macedonia has a formal objection to the harmonised standards, Article 33 of this Rulebook shall apply.

Subsidiaries of and subcontracting by conformity assessment bodies

Article 19

1. Where a conformity assessment body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 16 of this Rulebook.

2. Conformity assessment bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Conformity assessment bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 14 of this Rulebook.

Operational obligations of conformity assessment bodies

Article 20

1. Conformity assessment bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 14 of this Rulebook.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

3. Where a conformity assessment body finds that the requirements set out in Article 7 and Annex II or in corresponding national standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue the EC-type examination certificate as referred to in Article 14, paragraphs 6, 7 and 8 of this Rulebook.

4. Where, in the course of the monitoring of conformity following the issue of a EC-type examination certificate, a conformity assessment body finds that a toy is no longer in compliance, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EC-type examination certificate if necessary.

5. The corrective measures referred to in paragraph 4 of this Article mainly include a request to the manufacturer to withdraw all non-conformed products from the market, and, if possible with regard to the product concerned, remove the cause of non-conformity. If it is impossible to remove the cause of non-conformity, the manufacturer shall retain all non-conformed products.

6. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EC-type examination certificates, as appropriate.

Content of information

Article 21

1. Conformity assessment bodies shall inform the Ministry of economy and Ministry of health of the Republic of Macedonia of the following:

(a) any refusal, restriction, suspension or withdrawal of an EC-type examination certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification, and any other activity performed, including cross-border activities and subcontracting.

2. Conformity assessment bodies shall provide the other bodies which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

V. TYPE OF DOCUMENTS ACCOMPANYING THE TOY WHEN PLACED ON THE MARKET OR PUT INTO USE, FOR AND CONTENT OF THE TECHNICAL DOCUMENTS, AS WELL AS THE MANNER AND DURATION OF THEIR SAFEKEEPING

Obligations of manufacturers

Article 22

1. When placing their toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 7 and Annex II.

2. Manufacturers shall draw up the required technical documentation in accordance with Article 15 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 11 of this Rulebook.

3. Where compliance of a toy with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in Article 29, and affix the CE marking, as set out in Articles 30 and 31.

4. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.

5. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in toy design or characteristics and changes in the national standards by reference to which conformity of a toy is declared shall be adequately taken into account.

6. When deemed appropriate with regard to the risks presented by a toy, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any such monitoring.

7. Manufacturers shall ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.

8. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

9. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in the Macedonian language.

10. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the requirements set forth in this Rulebook shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, manufacturers shall immediately inform the market surveillance authorities, giving details, in particular, of the non-compliance and of any corrective measures taken.

11. Manufacturers shall, further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy, in a language easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

Authorised representatives

Article 23

1. The obligations laid down in Article 22, paragraph 1 and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EC declaration of conformity and the technical documentation at the disposal of market surveillance authorities for a period of 10 years after the toy has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.

Obligations of importers

Article 24

1. Importers shall place only compliant toys on the market of the Republic of Macedonia.

2. They shall ensure that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 22, paragraphs 7 and 8 of this Rulebook.

3. Where an importer considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 6 and Annex II, it shall not place the toy on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

4. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

5. Importers shall ensure that the toy is accompanied by instructions and safety information in the Macedonian language.

6. Importers shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 7 and Annex II.

7. When deemed appropriate with regard to the risks presented by a toy, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.

8. Importers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the requirements set forth in this Rulebook shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Importers shall, for a period of 10 years after the toy has been placed on the market, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

10. Importers shall, further to a reasoned request from the market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy in a language easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by toys which they have placed on the market.

Obligations of distributors

Article 25

1. When making a toy available on the market, distributors shall act with due care in relation to the applicable requirements.

2. Before making a toy available on the market, distributors shall verify that the toy bears the required conformity marking, that it is accompanied by the required documents and by instructions and safety information in Macedonian language, and that the manufacturer and the importer have complied with the requirements set out in Article 22, paragraphs 7 and 8 and Article 24, paragraph 4 of this Rulebook.

3. Where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 6 and Annex II, it shall not make the toy available on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the distributor shall inform the manufacturer or the importer, as well as the market surveillance authorities, to that effect.

4. Distributors shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 6 and Annex II.

5. Distributors who consider or have reason to believe that a toy which they have made available on the market is not in conformity with the relevant with this rulebook shall make sure that the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the toy presents a risk, distributors shall immediately inform the market surveillance authorities in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

6. Distributors shall, further to a reasoned request from a market surveillance authorities, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have made available on the market.

Cases in which obligations of manufacturers apply to importers and distributors

Article 26

An importer or distributor shall be considered a manufacturer for the purposes of this rulebook and be subject to the obligations of the manufacturer under Article 22 where it places a toy on the market under its name or trademark or modifies a toy already placed on the market in such a way that compliance with the applicable requirements appointed with this Rulebook, may be affected.

Identification of economic operators

Article 27

1. Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a toy;
 - (b) any economic operator to whom they have supplied a toy.
2. Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and for a period of 10 years after they have been supplied with the toy, in the case of other economic operators.

VI. LIABILITY TO LABEL TOYS

Warnings

Article 28

1. Where appropriate for safe use, warnings made for the purposes of Article 7 paragraph 1 shall specify appropriate user limitations in accordance with Part A of Annex V, which is part of this Rulebook.
2. The warnings for the categories of toys intended for children under 36 months of age, are listed in part B of Annex V. As regards the categories of toy listed in Part B of Annex V, the warnings set out therein shall be used. The warnings set out in points 2 to 10 of Part B of Annex V shall be used as worded therein.
3. Toys shall not bear one or more of the specific warnings set out in Part B of Annex V where that warning conflicts with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.
4. The manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them.
5. The warnings shall be preceded by the words 'Warning' or 'Warnings', as the case may be.
6. Warnings which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, shall appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including in cases where the purchase is made on-line.

Declaration of conformity

Article 29

1. The declaration of conformity shall state that the fulfilment of the requirements set out in Article 6 and Annex II has been demonstrated.
2. The declaration of conformity shall as a minimum contain the elements specified in Annex III to this rulebook, as well as the results of the applied conformity assessment procedure, and shall be continuously updated.

General principles of the CE marking

Article 30

1. Toys made available on the market shall bear the CE marking.
2. The CE marking shall be subject to the general principles set out in Article 31 of this rulebook.
3. It shall be presumed that toys bearing the CE marking comply with the requirements set out in this rulebook.
4. Toys not bearing a CE marking or which do not otherwise comply with the requirements set out in this rulebook may be shown and used at trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that they do not comply with this rulebook and that they will not be made available in the Republic of Macedonia and EU before being brought into conformity.

Rules and rulebooks regarding the application of the CE marking

Article 31

1. The CE marking shall be affixed only by the manufacturer or his authorised representative.
2. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set forth in this rulebook and the relevant national standards.
3. The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited.
4. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.
5. The CE marking shall be affixed visibly, legibly and indelibly to the toy, to an affixed label or to the packaging.
6. In the case of small toys and toys consisting of small parts, the CE marking may alternatively be affixed to a label or an accompanying leaflet.
7. Where, in the case of toys sold in counter displays, that is not technically possible as prescribed in paragraphs 5 and 6, and on condition that the counter display was originally used as packaging for the toy, the CE marking may be affixed to the counter display.
8. Where the CE marking is not visible from outside the packaging, if any, it shall as a minimum be affixed to the packaging.
9. The CE marking shall be affixed before the toy is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

VII. USE OF STANDARDS AND OTHER TECHNICAL SPECIFICATIONS

Presumption of conformity

Article 32

Toys which are in conformity with national standards or parts thereof, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 6 and Annex II.

Formal objection to a harmonised standard

Article 33

1. When the Republic of Macedonia considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 7 and Annex II, the Republic of Macedonia shall bring the matter before the Committee set up by EU rulebooks, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.
2. In the light of the Committee's opinion, the EU Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned.
3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

VIII. PROTECTION CLAUSE

Precautionary principle

Article 34

When competent market surveillance authorities take measures as provided for in this rulebook, they shall take due account of the precautionary principle.

Instructions to the notified body

Article 35

1. Market surveillance authorities may request a conformity assessment body to provide information relating to any EC-type examination certificate which that body has issued or withdrawn, or which relates to any refusal to issue such a certificate, including the test reports and technical documentation.
2. If a market surveillance authority finds that a toy is not in conformity with the requirements set out in Article 6 and Annex II, it shall, where appropriate, instruct the conformity assessment body to withdraw the EC-type examination certificate in respect of that toy.
3. Where necessary, and in particular in the cases specified in the second subparagraph of Article 14, paragraph 5, the market surveillance authority shall instruct the conformity assessment body to review the EC-type examination certificate.

Procedure for dealing with toys presenting a risk

Article 36

1. Where the market surveillance authorities have taken action pursuant to the respective provisions of the market surveillance rulebooks, or where they have sufficient reason to believe that a toy covered by this rulebook presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the toy concerned covering all the requirements laid down in this rulebook.
2. With regard to paragraph 1, the relevant economic operators shall cooperate as necessary with the market surveillance authorities.
3. The relevant economic operator shall ensure that appropriate corrective action is taken in respect of toys which that operator has made available on the market of the Republic of Macedonia.
4. The market surveillance authorities inform the relevant conformity assessment body thereof.
5. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the relevant economic operator to take.
6. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 2, the market surveillance authorities shall take appropriate provisional measures to prohibit or restrict the toy being made available on the market of the Republic of Macedonia, to withdraw the toy from that market or to recall it.
7. The market surveillance authorities for the measurement of paragraph 6 of this article shall inform the Commission and the other Member States
8. The information referred to in paragraph 6 shall include all available details, in particular the data necessary for the identification of the non-compliant toy, the origin of the toy, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.
9. The market surveillance authorities shall indicate whether the non-compliance is due to either:
 - (a) failure of the toy to meet requirements relating to the health or safety of persons; or
 - (b) shortcomings in the harmonised standards referred to in Article 19 conferring a presumption of conformity.
10. Where, within three months of receipt of the information referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by the Republic of Macedonia, that measure shall be deemed to be justified.

Exchange of information — Rapid Information Exchange System

Article 37

1. If a measure referred to in Article 36 paragraph 6 is a type of measure which is required under Article 18 of Law on product safety to be notified through the Community Rapid Information

Exchange System, it shall not be necessary to make a separate notification under Article 36 paragraph 6 of this Rulebook, provided that the following conditions are met:

- (a) the Rapid Information Exchange notification indicates that the notification of the measure is also required by this rulebook; and
- (b) the supporting evidence referred to in Article 36 paragraph 7 is enclosed with the Rapid Information Exchange notification.

Formal non-compliance

Article 38

Without prejudice to Article 36 of this Rulebook, where the market surveillance authorities makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) that the CE marking has been affixed in violation of Article 30 or 31;
- (b) that the CE marking has not been affixed;
- (c) that the EC declaration of conformity has not been drawn up;
- (d) that the EC declaration of conformity has not been drawn up correctly;
- (e) that technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, Market surveillance authorities concerned shall take appropriate measures to restrict or prohibit the toy being made available on the market, or shall ensure that it is recalled or withdrawn from the market.

IX. TRANSITIONAL AND FINAL PROVISIONS

Article 39

The provisions of Article 35 and 36 paragraphs 5, 7 and 10 of this rulebook shall apply after the accession of the Republic of Macedonia to the European Union

Article 40

With the entrance into force of this rulebook, the following shall cease to apply Rulebook for attribute of toys which are place on the market (Official Gazette of the Republic of Macedonia number 90/04).

Article 41

This rulebook shall enter into force eight days after its publishing in the Official Gazette of the Republic of Macedonia.

ANNEX I

List of products that, in particular, are not considered as toys within the meaning of this Rulebook

(as referred to in Article 2)

1. Decorative objects for festivities and celebrations
2. Products for 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:
 - (a) detailed and faithful scale models;
 - (b) kits for the assembly of detailed scale models;
 - (c) folk dolls and decorative dolls and other similar articles;
 - (d) historical replicas of toys; and
 - (e) reproductions of real fire arms.
3. Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg
4. Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark
5. Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways
6. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof
7. Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids
8. Puzzles with more than 500 pieces
9. Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long
10. Fireworks, including percussion caps which are not specifically designed for toys
11. Products and games using sharp-pointed missiles, such as sets of darts with metallic points
12. 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
13. Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment
14. 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
15. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs
16. Babies' soothers
17. Child-appealing luminaires
18. Electrical transformers for toys
19. Fashion accessories for children which are not for use in play

ANNEX II

PARTICULAR SAFETY REQUIREMENTS

I. Physical and Mechanical Properties

1. 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.

2. Accessible edges, protrusions, cords, cables and fastenings on toys must be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as far as possible.

3. Toys must be designed and manufactured in such a way as not to present any risk or only the minimum risk inherent to their use which could be caused by the movement of their parts.

4. (a) Toys and their parts must not present a risk of strangulation.

(b) Toys and their parts must not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.

(c) Toys and their parts must be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

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

(e) The packaging in which toys are contained for retail sale must not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.

(f) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent its being swallowed and/or inhaled.

(g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(h) 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. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in points (c) and (d).

5. Aquatic toys must be designed and manufactured 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.

6. 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 intended user can open easily from the inside.

7. 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 generated 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.

The maximum design speed of electrically driven ride-on toys must be limited so as to minimise the risk of injury.

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

9. Toys must be manufactured so as to ensure that:

(a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched; and

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

10. Toys which are designed to emit a sound shall be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing.

11. Activity toys shall be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and of falls, impacts and drowning as far as possible. In particular, any surface of such a toy accessible for one or more children to play on shall be designed to bear their load.

II. Flammability

1. Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:

(a) they do not burn if directly exposed to a flame or spark or other potential source of fire;

(b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);

(c) if they do ignite, they burn slowly and present a low rate of spread of the flame;

(d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

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

2. Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in Section 1 of Appendix B, 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 mixtures which may become flammable due to the loss of non-flammable volatile components.

3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in the first subparagraph of Article 8, paragraph 1.

4. Toys and, in particular, chemical games and toys, must not contain as such substances or mixtures:

(a) which, when mixed together, may explode through chemical reaction or through heating;

(b) which may explode when mixed with oxidizing substances; or

(c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

III. Chemical Properties

Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in Article 8 paragraph 1 of this Rulebook.

Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

Toys that are themselves substances or mixtures must comply also with the legislation in the field of classification, packaging and labeling of dangerous substances, legislation regarding the classification, packaging and labeling of dangerous preparations and legislation regarding the classification, packaging and labeling of dangerous substances and mixtures.

Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) in legislation regarding substances, shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in rulebooks referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in Article 8 paragraph 1;

That decision may be taken if the following conditions are met:

(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee of the EU and found to be safe, in particular in view of exposure;

(ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and

(iii) the substance or mixture is not prohibited for use in consumer articles under this or other rulebook.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in Article 8 paragraph 1); or

That decision may be taken if the following conditions are met:

(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee of the EU and found to be safe, in particular in view of exposure; and

(ii) the substance or mixture is not prohibited for use in consumer articles under this or other rulebook.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.

7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in legislation in the field of materials coming in contact with food and the related specific measures for particular materials.

8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.

9. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.

10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in respective legislation relating to cosmetic products (1).

11. Toys shall not contain the following allergenic fragrances:

No	Name of the allergenic fragrance	CAS number
1.	Alanroot oil (Inula helenium)	97676-35-2
2.	Allylisoithiocyanate	57-06-7
3.	Benzyl cyanide	140-29-4
4.	4 tert - Butylphenol	98-54-4
5.	Chenopodium oil	8006-99-3

6.	Cyclamen alcohol	4756-19-8
7.	Diethyl maleate	141-05-9
8.	Dihydrocoumarin	119-84-6
9.	2.4-Dihidroxy-3-methylbenzaldehyde	624-20-0
10.	3.7-Dimethyl-2-octen-1ol (6.7-Dihydrogeraniol)	40607-48-5
11.	4.6-Dimethyl-8-tert-butylcoumarin	17874-34-9
12.	Dimethyl citraconate	617-54-9
13.	7.11-Dimethyl-4.6.10-dodecatrien-30one	26651-96-7
14.	6.10-Dimethyl-3.5.9-undekatrien-2-one	141-10-6
15.	Diphenylamine	122-39-4
16.	Etyl acrylate	140-88-5
17.	Fig leaf.fresh and preparations	68916-52-9
18.	trans-2-Heptanal	18829-55-5
19.	trans-2-Heptanal diethyl acetal	67746-30-9
20.	trans-2-Heptanal dimethyl acetal	18318-83-7
21.	Hidroabietyl alcohol	13393-93-6
22.	4-Ethoxy-phenol	622-62-8
23.	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
24.	7-Methoxycoumarin	531-59-9
25.	4-Methoxyphenol	150-76-5
26.	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
27.	1-(p-Methoxyphenyl)-3-penten-3-one	104-27-8
28.	Methyl trans-2-butenoate	623-43-8
29.	6-Methylcoumarin	92-48-8
30.	7-Methylcoumarin	2445-83-2
31.	5-Methyl-2.3-hexanedione	13706-86-0
32.	Costus root oil (Saussurea lappa larke)	8023-88-9
33.	7-Ethoxy-4-methylcoumarin	87-05-8
34.	Hexahydrocoumarin	700-82-3
35.	Peru balsam crude	8007-00-9
36.	2-Pentylidene-cyclohexanone	25677-40-1
37.	3.6.10-Trimetyl-3.5.9-undekatrien-2-one	1117-41-5
38.	Verbana iol (Lippia citriodora Kunth)	8024-12-2
39.	Musk ambrete	83-66-9
40.	4-Phenyl-3-buten-2-one	122-57-6
41.	Amyl cinnamal	122-40-7
42.	Amylcinnamyl alcohol	101-85-9
43.	Benzyl alcohol	100-51-6
44.	Benzyl salicylate	118-58-1
45.	Cinnamyl alcohol	104-54-1
46.	Cinnamal	104-55-2
47.	Citral	5392-40-5
48.	Coumarin	91-64-5
49.	Eugenol	97-53-0

50.	Geraniol	106-24-1
51.	Hidroxy-citronellal	107-75-5
52.	Hidroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
53.	Isoeugenol	97-54-1
54.	Oakmoss extracts	90028-68-5
55.	Treemoss extracts	90028-67-4

However, the presence of traces of these fragrances shall be allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

No	Name of the allergenic fragrance	CAS number
1.	Anyzil alcohol	105-13-5
2.	Benzyl benzoate	120-51-4
3.	Benzyl cinnamate	103-41-3
4.	Citronellol	106-22-9
5.	Farnesol	4602-84-0
6.	Hexyl cinnamaldehyde	101-86-0
7.	Lilial	80-54-6
8.	d-Limonene	5989-27-5
9.	Methyl heptine carbonate	111-12-6
10.	3-methyl-4-3-buten-2-one	127-51-5

12. The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- (i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- (ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of respective legislation
- (iii) if applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V.

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle powder-like or pliable material	mg/kg in liquid or sticky material	mg/kg in scraped-off toy material
Aluminium	5625	1406	70000
Antimony	45	11.3	560
Arsenik	3.8	0.9	47

Barium	4500	1125	56000
Boron	1200	300	15000
Cadmium	1.9	0.5	23
Chromium (III)	37.5	9.4	460
Chromium (VI)	0.02	0.005	0.2
Cobalt	10.5	2.6	130
Copper	622.5	156	7700
Lead	13.5	3.4	160
Manganese	1200	300	15000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4500	1125	56000
Tin	15000	3750	180000
Organic tin	0.9	0.2	12
Zinc	3750	938	46000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in Article 8, paragraph 1.

IV. Electrical Properties

1. Toys shall not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts shall not exceed 24 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken.

2. 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 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.

3. Electric toys must be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

4. Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source.

5. Electric toys must provide adequate protection against fire hazards.

6. Electric toys must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for the operation of the toy, and must operate at a safe level in compliance with the generally acknowledged state of the art.

7. Toys which have an electronic control system must be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor.

8. Toys must be designed and manufactured in such a way that they do not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation.

9. The electrical transformer of a toy shall not be an integral part of the toy.

V. Hygiene

1. Toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.
2. A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy shall, to this end, be washable, except if it contains a mechanism that may be damaged if soaked. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

VI. Radioactivity

Toys shall comply with all relevant measures adopted under Chapter III of the Treaty establishing the European Atomic Community.

Appendix A

List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III

<i>Substance</i>	<i>Classification</i>	<i>Permitted use</i>
<i>Nickel</i>	<i>CMR 2</i>	<i>in stainless steel</i>

Appendix B

CLASSIFICATION OF SUBSTANCES AND MIXTURES

1. Criteria for classifying substances and mixtures for the purposes of point 2 of Part II

Substances

The substance fulfils the criteria for any of the following hazard classes or categories set out in legislation regarding classification, packaging and labeling of dangerous preparations:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

Mixtures

The mixture is dangerous within the meaning of legislation regulating the field of chemicals.

2. Legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part III

From 20 July 2011 until 31 May 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with legislation regulating the field of chemicals.

From 1 June 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in legislation regarding classification, packaging and labeling of dangerous preparations.

3. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part III

Substances

Point 4 of Part III concerns substances classified as CMR category 1A and 1B established in legislation regarding classification, packaging and labeling of dangerous preparations

Mixtures

From 20 July 2011 until 31 May 2015, point 4 of Part III concerns mixtures classified as CMR category 1 and 2 under legislation regulating the field of chemicals.

From 1 June 2015, point 4 of Part III concerns mixtures classified as CMR category 1A and 1B established in legislation regarding classification, packaging and labeling of dangerous preparations.

4. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III

Substances

Point 5 of Part III concerns substances classified as CMR category 2 established in legislation regarding classification, packaging and labeling of dangerous preparations.

Mixtures

From 20 July 2011 until 31 May 2015, point 5 of Part III concerns mixtures classified as CMR category 3 under legislation regulating the field of chemicals.

From 1 June 2015, point 5 of Part III concerns mixtures classified as CMR category 2 established in legislation regarding classification, packaging and labeling of dangerous preparations.

5. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR)

The EU Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction in the categories listed below and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly.

Substances

Article 46(3) concerns substances classified as CMR category 1A, 1B and 2 established in legislation regarding classification, packaging and labeling of dangerous preparations.

Mixtures

From 20 July 2011 until 31 May 2015, paragraph 1 of this Point 5 concerns mixtures classified as CMR category 1, 2, 1999 and 3 under legislation regulating the field of chemicals.

From 1 June 2015, paragraph 1 of this Point 5 concerns mixtures classified as CMR category 1A, 1B and 2 established in legislation regarding classification, packaging and labeling of dangerous preparations.

Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with legislation regarding classification, packaging and labeling of dangerous preparations

ANNEX III

DECLARATION OF CONFORMITY

1. No ... (unique identification of the toy(s))
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy.
5. The object of the declaration described in point 4 is in conformity with the relevant Community harmonisation legislation:
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
7. Where applicable: the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:

8. Additional information:
Signed for and on behalf of:
(place and date of issue)
(name, function)(signature)

ANNEX IV

TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 15 shall contain:

- (a) a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
- (b) the safety assessment(s) carried out in accordance with Article 10;
- (c) a description of the conformity assessment procedure followed;
- (d) a copy of the declaration of conformity;
- (e) the addresses of the places of manufacture and storage;
- (f) copies of documents that the manufacturer has submitted to a notified body, if involved;
- (g) test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 12; and
- (h) a copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 13.

ANNEX V

WARNINGS

(as referred to in Article 30)

PART A

GENERAL WARNINGS

The user limitations referred to in Article 30, paragraphs 1, 2 and 3 shall include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

PART B

SPECIFIC WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS

1. Toys not intended for use by children under 36 months

Toys which might be dangerous for children under 36 months of age shall bear a warning such as 'Not suitable for children under 36 months' or 'Not suitable for children under three years' or a warning in the form of the following graphic:



These warnings shall be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

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

2. Activity toys

Activity toys shall bear the following warning:

'Only for domestic use'.

Activity toys attached to a crossbeam as well as other activity toys, where appropriate, 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 the correct assembly of the toy, indicating those parts which can present a danger if incorrectly assembled. Specific information regarding a suitable surface on which to place the toy shall be given.

3. Functional toys

Functional toys shall bear the following 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 will 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 imitation. It shall also be indicated that the toy must be kept out of the reach of children under a certain age, which shall be specified by the manufacturer.

4. Chemical toys

Without prejudice to the application of the provisions laid down in applicable Community legislation on the classification, packaging and labelling of certain substances or mixtures, the instructions for use of toys containing inherently dangerous substances or mixtures shall bear a warning of the dangerous nature of these substances or mixtures 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 toy must be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

In addition to the instructions provided for in the first subparagraph, chemical toys shall bear the following warning on their packaging:

'Not suitable for children under (*) years. 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 which lead to a chemical reaction or similar substance alteration during use.

5. Skates, roller skates, online skates, skateboards, scooters and toy bicycles for children

Where these toys are offered for sale as toys, they shall bear the following warning:

'Protective equipment should be worn. Not to be used in traffic'.

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 or third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

6. Aquatic toys

Aquatic toys shall bear the following warning:

‘Only to be used in water in which the child is within its depth and under adult supervision’.

7. Toys in food

Toys contained in food or co-mingled with food shall bear the following warning:

‘Toy inside. Adult supervision recommended’.

8. Imitations of protective masks and helmets

Imitations of protective masks and helmets shall bear the following warning:

‘This toy does not provide protection’.

9. Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps

Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps shall carry the following warning on the packaging, which shall also be permanently marked on the toy:

‘To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees in a crawling position’.

10. Packaging for fragrances in olfactory board games, cosmetic kits and gustative games

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part III of Annex II and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point shall contain the following warning:

‘Contains fragrances that may cause allergies’.

(*) Age to be specified by the manufacturer.

Annex VI

Module A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the toys satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the conformity of the toy to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the toy,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the national standards and/or other relevant technical specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those national standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and

— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured toys with the technical documentation referred to in point 2 and with the requirements of this rulebook.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual toy that satisfies the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a toy model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Annex VII

Module B

EC-type examination

1. EC-type examination is the part of a conformity assessment procedure in which a conformity assessment body examines the technical design of a product and verifies and attests that the technical design of the toy meets the requirements of the legislative instrument that apply to it.

2. EC-type examination may be carried out in either of the following manners:

— examination of a specimen, representative of the toy envisaged, of the complete product (production type),

— assessment of the adequacy of the technical design of the toy through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the toy (combination of production type and design type),

— assessment of the adequacy of the technical design of the toy through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EC-type examination with a single conformity assessment body of his choice.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other body,

— the technical documentation. The technical documentation shall make it possible to assess the toy's conformity with the applicable requirements of this rulebook and shall include an adequate analysis

and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the toy. The technical documentation shall contain, wherever applicable, at least the following elements:

— a general description of the toy,

- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the national standards and/or other relevant technical specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this rulebook where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports,
- the specimens representative of the production envisaged. The body may request further specimens if needed for carrying out the test programme,
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant national standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The conformity assessment body shall:

For the toy:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the toy;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant national standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The conformity assessment body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the authorities, the conformity assessment body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the body shall inform the manufacturer accordingly.

The manufacturer shall inform the body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.

8. Each conformity assessment body shall inform the Ministry of economy of the Republic of Macedonia concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each conformity assessment body shall inform the other conformity assessment bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other conformity assessment bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the conformity assessment body. The conformity assessment body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Annex VIII

Module C

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Conformity marking and declaration of conformity

3.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

3.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on

the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.