

Republika e Kosovës Republika Kosovo - Republic of Kosovo Kuvendi - Skupština - Assembly

Law No. 04/L-039

ON TECHINCAL REQUIREMETNS FOR PRODUCTS AND CONFORMITY ASSESSMENT

Assembly of Republic of Kosovo,

Based on Article 65 (1) of the Constitution of the Republic of Kosovo;

Approves:

LAW ON TECHINCAL REQUIREMETNS FOR PRODUCTS AND CONFORMITY ASSESSMENT

Article 1 Purpose

- 1. This Law regulates the manner of prescribing the technical requirements for products, procedures of conformity assessment with the prescribed requirements and extraction of regulations by the competent Ministries. The provisions of this Law that apply to certain products or product groups regulate at least one of the following elements:
 - 1.1. technical requirements which products that are being placed on the market or in use have to comply with;
 - 1.2. rights and obligations of economic entities that place products on the market or in use;
 - 1.3. conformity assessment procedures;

- 1.4. rights and obligations of bodies conducting procedures of conformity assessment of products with the technical requirements (hereinafter referred to as conformity assessment bodies);
- 1.5. documentation relating to:
 - 1.5.1. conformity: documentation
 - 1.5.2. for the conformity-test;
 - 1.5.3. reports, certificate of conformity or a report-certificate of inspection;
 - 1.5.4. declaration of conformity and required technical documentation to prove the conformity of products that have to be kept available for the competent authorities;
- 1.6. the manner of marking products.

Article 2 Field of implementation

- 1. This law regulates the market surveillance (hereinafter the inspection surveillance) and the validity of conformity documents issued abroad.
- 2. A product placed on the market or in use shall comply with the provisions of regulations in force relating to that product.
- 3. The economic operator that places the products on the market or in use is responsible for their conformity in compliance with Articles 6, 7, 8 and 9 of this Law.
- 4. Economic operators are responsible for the accuracy and completeness of the information relating to their products and shall ensure that the information is in compliance with the prescribe requirements for those products.
- 5. This Law does not apply to prescribing of technical requirements and conformity assessment procedures for products subject to special law

Article 3 **Definitions**

- 1. Terms used in this law shall have the following meaning:
 - 1.1. **Product** materials, semi-products or goods produced through a manufacturing process other than for human food, animal feed, living plants and

animals, products of human origin as well as animal and plants products that are directly related to their reproduction- multiplication in the future;

- 1.2. **Economic operator** the manufacturer, authorized representative, importer and distributor;
- 1.3. **Manufacturer** any natural or legal person that produces the product, or who has shaped or manufactured the product and marketed it under his name or trade mark;
- 1.4. **Authorized Representative** any natural or legal person established in the Republic of Kosovo authorized in writing by the manufacturer for certain tasks, prescribed as an obligation of the manufacturer, which he performs on his behalf;
- 1.5. **Importer** any natural or legal person registered in the Republic of Kosovo, that imports products and places them on the market of Kosovo;
- 1.6. **Distributor** any natural or legal person in the supply chain, other than the manufacturer or importer that makes the product available on the market;
- 1.7. **Placing on the market** the first making available of a product on the market of the Republic of Kosovo;
- 1.8. **Making the products available on the market** any order of a product for distribution, consumption or use on the market of the Republic of Kosovo in the course of a commercial activity, whether in return for payment or free of charge;
- 1.9. **Technical specification** the document that defines the technical requirements that need to met by the product, process or service,
- 1.10. **European standard -** a standard available to the public and adopted by one of the European standardization bodies;
- 1.11. **Harmonized European standard** a European standard which is adopted based on a request of the European Commission and the references of which are published in the Official Journal of the European Union;
- 1.12. **Kosovo standard -** a standard available to the public and adopted by the Kosovo Standardization Agency;
- 1.13. **Accreditation** the procedure for official recognition by an authorized body, of the competence of a conformity assessment body with the standards and technical rules to carry out tasks such as testing, calibration, certification, inspection;
- 1.14. Conformity Assessment the procedure of demonstrating whether

specified requirements related to products, processes, person, system or body have been fulfilled;

- 1.15. **Product conformity marking** the marking used by the manufacturer to indicate that a product is in conformity with all the requirements laid down in the provisions prescribing for its affixing;
- 1.16. **Conformity assessment body** a conformity assessment body that perform conformity assessment activities, including measurements, testing, verifications and controls;
- 1.17. **Designated Conformity assessment body** a conformity assessment body that performs conformity assessment activities based on the decision for authorization which is approved by the competent ministry pursuant to Article 1 paragraph 1 of this Law;
- 1.18. **Notified body** the authorized body for conformity assessment which has been notified by competent ministry to the European Commission and EU member states as an independent third party to carry out conformity assessment for a particular area;
- 1.19. **Recall of a product** any undertaken measure aimed at achieving the return of a dangerous product that has already been made available to the end user;
- 1.20. **Withdrawal of a product** any undertaken measure aimed at withdrawing a product from the market in the entire supply chain;
- 1.21. **Inspection surveillance** the activities carried out and measures taken by the competent ministries to ensure that products placed on the market comply with the requirements set out in the relevant legislation of the Republic of Kosovo;
- 1.22. **Competent inspection body** a competent ministry body of the Republic of Kosovo responsible for carrying out inspection surveillance in the Republic of Kosovo, in compliance with the competences and responsibilities arising from the provisions on the organization and scope of work of the competent ministries and other legislation regulating their competence;
- 1.23. **Inspection surveillance coordination authority** any Community legislation harmonizing conditions for the marketing of products;
- 124. **Release for free circulation -** the process for releasing products for free circulation in accordance with the customs provisions;
- 1.25. **Community harmonization legislation** any Community legislation harmonising conditions for the marketing of products;

- 1.26. **Community** means the European Community;
- 1.27. **RAPEX** system for rapid exchange of information in relation to measures and actions especially for products which present serious danger for consumers' health and safety

Article 4 Prescribing the technical requirements

Pursuant to in Article 1 paragraph 1. of this Law are prescribed technical requirements for products with regard to their safety, protection of life and health of persons and domestic animals and plants, environmental and nature protection as well as other issues relevant for regulating the field related to the provisions.

Article 5 Obligations for issuing sub-legal acts

- 1. Competent ministries in line with their competences and responsibilities form scope of work, issue sub-legal acts in compliance with the European Union harmonized legislation which prescribe technical requirements for products or group of products, and conformity assessment procedures including regular and extraordinary control of products in use when it is prescribed, for the purpose of:
 - 1.1. safety;
 - 1.2. protection of the lives and health of persons, domestic animals and plants;
 - 1.3. environmental and nature protection;
 - 1.4. protection of consumers and other users.
- 2. When adopting the bylaw referred to in paragraph 1. of this Article, international principles and assumed obligations arising from international agreements shall be taken into account with the aim of preventing unnecessary barriers to international trade.
- 3. With the prescriptions from paragraph 1. of this Article, considered that products are in conformity with the essential requirements of applicable provisions if the products comply with the Kosovo standards adopted and harmonised with European standards.
- 4. The register of Kosovo standards from paragraph 3. of this Article is published in the Official Web Site of the ministries which are competent for issuance of provisions under Article 1 paragraph 1. of this Law, in cooperation with the Kosovo Standards Agency.
- 5. In cases when it is considered that the standard of paragraph 3. of this Article or any

part of it does not fully meet the prescribed essential requirements, competent responsible ministries submit to the European Commission the formal elaborated objection for the standard.

- 6. Competent ministries referred to in paragraph 1. of this Article shall promptly inform the public about the activities referred to in paragraph 5. of this Article by publishing on the Official Web Site in accordance with the Law governing the right of access to official documents.
- 7. Competent ministries adopt sub-legal acts under paragraph 1. of this Article in compliance with their competences

Article 6 Obligations of the manufacturer

- 1. When placing a product on the market, a manufacturer is obliged to ensure that his product has been designed and manufactured in accordance with the requirements set out in the provisions related to that product.
- 2. Where the provisions referred to in Article 1 paragraph 1. of this Law require, the manufacturer is obliged to draw up the required technical documentation and carry out or guarantee the application of applicable conformity assessment procedures for products.
- 3. Where compliance of a product with the applicable requirements has been demonstrated by the conformity assessment procedure referred to in paragraph 2. of this Article, manufacturers is obliged to draw up a declaration of conformity in accordance with Article 13 of this Law and affix the conformity marking in accordance with Article 14 of this Law.
- 4. The manufacturer shall keep the technical documentation and the declaration of conformity of the product even after the product has been placed on the market, for a period specified in the provisions referred to in Article 1 paragraph 1. of this Law.
- 5. Manufacturers is obliged ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the applied harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.
- 6. Subject to the risks presented by a product manufacturer is obliged to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints of non-conforming products and product withdrawals and shall keep distributor informed.
- 7. Manufacturers is obliged to guarantee that their products bear a type, batch or serial number or other element allowing their identification. If the size or nature of the product

does not allow it, such information is provided on the packaging or in a document accompanying the product.

- 8. The manufacturer shall indicate his name, registered trade name or registered trade mark and the address at which he can be contacted on the product or, where that is not possible, on its packaging or in the documentation accompanying that product. The address must indicate a single point at which the manufacturer can be contacted.
- 9. Where for certain products, it is required pursuant to provisions referred to in Article 1, paragraph 1 of this Law, the manufacturer shall ensure that the product is accompanied by instructions and safety information in the official languages in Republic of Kosovo.
- 10. Where the manufacturer considers or has reason to believe that a product that is placed on the market is not in conformity with the provisions applicable to the product concerned, he is obliged immediately take the necessary corrective measures to bring that product into conformity with that provision, otherwise withdraws it form the market and prevents its distribution. Where the product presents a risk, manufacturer shall immediately inform the competent inspection surveillance bodies by specifying details, in particular, of the non-conformity of the product and of all corrective measures taken.
- 11. The manufacturer is obliged, further to a reasoned request from a competent inspection bodies, to provide to this body all the information and documentation necessary to demonstrate the conformity of the product, in official language. The manufacturer shall co-operate with the competent inspection bodies, at their request, on any measures taken to eliminate the risks posed by products placed on the market.

Article 7 Authorised representatives

- 1. Manufacturer may, by a written mandate, appoint any natural or legal person established in the Republic of Kosovo as its authorised representative.
- 2. The obligations referred to in Article 6 paragraph 1. of this Law and the drawing up of technical documentation can not be part of the authorised representative's mandate.
- 3. Authorised representative is obliged to perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - 3.1. keep the declaration of conformity and the technical documentation at the disposal of competent inspection bodies for a period that is specified in the applicable provision for that product;

- 3.2. further to a reasoned request from a competent inspection bodies, provide those bodies with all the information and documentation necessary to demonstrate the conformity of a product;
- 3.3. cooperate with the competent inspection bodies, at their request, on any action taken in order to eliminate the risks posed by the product.

Article 8 Obligations of importers

- 1. Importer is obliged to place on the market of the Republic of Kosovo only products that are in compliance with the provisions applicable to such products.
- 2. Before placing a product on the market, the importer shall ensure that the product is accompanied with the complete technical documentation, that the product bears the required conformity marking or other markings. The product also shall be accompanied by the required documents, and that it has met the prescribed criteria set out in Article 6, paragraphs 7. and 8. of this Law.
- 3. Where the importer considers or has reason to believe that a product is not in conformity with the provisions in force, applicable to the product concerned, the importer shall not place the product on the market until it has been brought into conformity with that provision. Where the product presents a risk, the importer is obliged to inform the manufacturer and the competent inspection bodies.
- 4. The importer is obliged to indicate his name, registered trade name or registered trade mark and the address at which he can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying that product.
- 5. Where the provisions referred to in Article 1 paragraph 1. of this Law so require, the importer shall ensure that the product is accompanied by instructions and safety information in the official language.
- 6. The importer is obliged, while a product is under his responsibility, to ensure that storage or transport conditions do not jeopardize its conformity with the prescribed requirements.
- 7. When deemed appropriate subject to the risks presented by a product, the importer is obliged, in order to protect the health and safety of consumers, to carry out testing of samples of marketed products, investigate, and, if necessary, keep a register of complaints of non-conforming products and product withdrawals, and shall keep distributors informed for it.
- 8. Where the importer considers or has reason to believe that a product he has placed on the market is not in conformity with the provisions applicable to the product concerned,

the importer is obliged immediately take the necessary corrective measures to bring that product into conformity with that provision or in the contrary to withdraw it from the market or prevent its distribution. Where the product presents a risk, the importer shall immediately inform the competent inspection bodies, giving details, in particular, of the non-compliance of the product and of all corrective measures taken.

- 9. Where for certain products it is required under the provisions referred to in Article 1, paragraph 1. of this Law, the importer is obliged, for a period specified in the provision applicable to the product concerned, keep a copy of the declaration of conformity at the disposal of the competent market surveillance authorities and make sure that the technical documentation is at the disposal of the competent inspection bodies, upon request.
- 10. The importer is obliged, further to a reasoned request from competent inspection bodies, provide with all the information and documentation necessary to demonstrate the conformity of a product in the official language. The importer is obliged to co-operate with the competent inspection bodies, at their request, on any action taken to eliminate the risks posed by product which he has placed on the market.

Article 9 Obligations of distributors

- 1. When making a product available on the market, a distributor is obliged to act with due care in relation to the applicable requirements.
- 2. Before placing a product on the market, the distributor shall verify that the product bears the required conformity marking or other markings, and that the same is accompanied by the required documents, and by instructions and safety information in the official language. The distributor also verifies whether the manufacturer and the importer have complied with the criteria referred to in Article 6 paragraph 7. and Article 8 paragraph 4. of this Law.
- 3. Where the distributor considers or has reason to believe that a product is not in conformity with the provisions applicable to the product concerned, it is not allowed make the product available on the market until it has been brought into conformity with that provision. Where the product presents a risk, the distributor is obliged to inform the manufacturer and the competent inspection bodies.
- 4. The distributor shall ensure that, while a product is under his responsibility, the storage or transport conditions do not jeopardise its compliance with the prescribed requirements.
- 5. Where the distributor considers or has reason to believe that a product that has been placed on the market is not in conformity with the provisions applicable to the product concerned, the distributor is obliged immediately to undertake corrective measures necessary in order to bring that product into conformity with that provision, or in the contrary to withdraw it or prevent its distribution. Where the product presents a risk, the

distributor shall immediately inform the competent inspection bodies, specifying the details, in particular, of the non-compliance of the product and of all corrective measures taken. If the product was placed on the market of the Member States of the EU, the distributor is obliged also in the same manner to notify the competent inspection bodies of the countries concerned.

6. The distributor is obliged, further to a reasoned request from the competent inspection bodies, to provide to that body all the information and documentation necessary in the official language to demonstrate the conformity of the products. The distributor is obliged to co-operate with the competent inspection bodies, at their request, on any action taken to eliminate the risks posed by products which he has been placed on the market.

Article 10

Cases in which obligations of manufacturers apply to importers and distributors

If the importer or distributor places a product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected, considered to be a manufacturer and shall be subject to the obligations of the manufacturer referred to in Article 6 of this Law.

Article 11 Identification of economic operators

Any economic operators shall, within the period specified in the provisions applicable to the product concerned, on request of the competent inspection body, provide information on the identity of any economic operator who has supplied the product.

Article 12 Conformity assessment

The provisions referred to in Article 1 paragraph 1. of this Law prescribe the conformity assessment procedure for each product or group of products to which the provisions apply.

Article 13 The declaration of conformity

1. The manufacturer shall assume responsibility for the conformity of the product by drawing up a declaration of conformity. The declaration of conformity shall be drawn up in the official language if the product is to be placed on the market of the Republic of Kosovo, respectively translated to the required language or languages of the Member

State of the European Union in which the product is to be placed on the market or made available.

- 2. In the declaration of conformity, it shall be stated that the technical requirements laid down in the provisions applicable to the product concerned are met.
- 3. The declaration of conformity shall contain elements laid down in the provisions referred to in Article 1 paragraph 1. of this Law, applicable to the product concerned.

Article 14 The conformity marking

- 1. Where the provisions referred to in Article 1, paragraph 1. of this Law require the affixing of a conformity marking on the products that comply with all provisions applicable to the products concerned, the prescribed conformity marking shall be affixed before the products are placed on the market. The conformity marking shall be affixed to products for which was prescribed the affixing, and shall not be affixed to any other products. If conformity marking cannot be affixed to the product or its data plate, then the it shall be affixed to the packaging and to the accompanying documents, where such documents are required by the provisions applicable to the product concerned.
- 2. The competent Ministry in charge shall prescribe by sub-legal act the form, the content, the appearance and the manner of use of the conformity marking.
- 3. By affixing the conformity marking when the provisions require so, the manufacturer takes responsibility for the conformity of the product with all the requirements set out in the provisions applicable to the product concerned.
- 4. The affixing of markings, signs or other inscriptions, which are likely to mislead third parties as to the meaning or form of the conformity marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility and legibility of the conformity marking is not thereby impaired.

Article 15 Conformity assessment bodies and the requirements they have to meet

- 1. Pursuant to the provisions of Article 1 paragraph 1. of this Law, the competent Ministry in change sub-legal acts that lay down also specific requirements that must be met by conformity assessment bodies.
- 2. The sub-legal acts issued under paragraph 1. of this Article prescribe the manners of meeting of all specific requirements for bodies that carry out conformity assessment procedures.

3. Based on the provisions referred to in Article 1 paragraph 1 of this Law may be prescribed the procedures for monitoring of conformity assessment bodies and the measures to be taken in case of non-fulfillment of the prescribed requirements referred to in paragraph 1. of this Article and Article 16 of this Law.

Article 16 The minimum requirements

- 1. The minimum requirements that must be met by conformity assessment bodies are the following:
 - 1.1. the professional competence of the staff in the relevant area for which the conformity assessment body is designated;
 - 1.2. the necessary equipment and premises;
 - 1.3. the independence and impartiality in conformity assessment procedures;
 - 1.4. observing professional secrecy;
 - 1.5. liability insurance for the period of designation, unless liability is to be assumed by the state.
- 2. A conformity assessment body shall not be the economic operator for those products that are subject of its assessment, nor shall it be directly involved in the design, manufacture, processing, trade, use or maintenance of those products.

Article 17 The authorization of the assessment bodies

- 1. A conformity assessment body may carry out the conformity assessment activities which are laid down in the provisions referred to in Article 1 paragraph 1 of this Law only pursuant to the decision on designation that is issued by the Ministry of the respective area.
- 2. Where a conformity assessment body demonstrates its conformity with the requirements laid down in the relevant Kosovo standards adopted in compliance with the harmonised European standards, then it shall be presumed to comply with the requirements referred to in Article 15 paragraph 1. and Article 16 of this Law. The accreditation certificate which is awarded by the Kosovo accreditation authority may be regarded as additional proof of compliance of the conformity assessment bodies with the requirements laid down in the Kosovo standards in compliance with the harmonised European standards.

- 3. The decision referred to in paragraph 1 of this Article may be time-limited or valid until a repeal.
- 4. The conformity assessment body shall have to comply with the requirements of the duration of authorization pursuant to the provisions referred to in Article 15 paragraph 1. and Article 16 of this Law.
- 5. If it is established that a conformity assessment body has ceased to comply with the prescribed requirements during the period of its designation, the minister of the Ministry of respective area, which issued the bylaw referred to in Article 1 paragraph 1. of this Law, shall issue a decision whereby the part of designation, in which the body ceased to comply with the requirements, shall be cancelled.
- 6. Against the decisions referred to in paragraphs 1. and 5. of this Article, an administrative dispute may be initiated.
- 7. The Ministry of relevant according to their competences shall notify the European Commission and the Member States of the European Union of the conformity assessment bodies which they have designated and the identification numbers assigned by the European Commission and of any changes in regard to the designations shall notify of the respective ministry.
- 8. The notification procedure referred to in paragraph 7 of this Article as well as the requirements related to the notifying authorities and the requirements related to the notified bodies shall be laid down by the respective ministry.

Article 18 Implementation of duties of conformity assessment procedure

- 1. Conformity assessment body, designated for performing tasks within the meaning of provisions of this Law, shall carry out the conformity assessment procedure based on an application submitted by manufacturers or their authorised representatives and the competent inspection body.
- 2. The conformity assessment body and the applicant shall stipulate mutual rights and obligations concerning the conformity assessment procedures to be carried out in a written contract.

Article 19 Validity of document of conformity issued abroad

1. Documents of conformity issued abroad shall be valid in the Republic of Kosovo if they are issued in accordance with the international agreements concluded by the Republic of Kosovo.

- 2. The competent ministries in compliance with this law shall recognise documents of conformity test report, certificate of conformity and the report or examination certificate, issued abroad, provided that the following preconditions are met cumulatively:
 - 2.1. that it is prescribed that the conformity assessment procedure for the product concerned are carried out by the designated conformity assessment body;
 - 2.2. that in the Republic of Kosovo there is no designated conformity assessment body;
 - 2.3. that the conformity assessment has been carried out by conformity assessment bodies that have been notified by the Member States of the European Union to the European Commission and the list of which has been published in the Official Journal of the European Union.
- 3. Identification of recognized documents issued abroad and registered bodies of conformity assessment, whose documents are recognisable, are governed by the respective Ministry which are competent for issuing regulations under Article 1, paragraph 1 of this Law. The register of notified bodies for conformity assessment, the documents of which are recognised shall be a public book that is kept, updated and published on the official sites of the competent ministry.

Article 20 The exchange of information with other countries

The manner and procedures for the exchange of information with other countries and international organisations in the field of standards, technical regulations and regulations on information society services shall be prescribed by the Government of the Republic of Kosovo.

Article 21 Inspection surveillance

- 1. Inspection surveillance shall ensure that products placed on the market or made available satisfy the requirements which provide for a high level of protection of public interests, such as: health and safety in general, health and safety at the workplace, the protection of consumers, and protection of the environment and security.
- 2. The inspection surveillance shall ensure to prevent or prohibit the distribution or to prohibit or restrict the placing on the market of products that are regulated by legislation in force, which is in compliance with EU laws even when products are used in compliance with the intended purpose or in conditions which can be prescribed, and when they are installed and maintained as required, but which can be reasonably foreseen

that could endanger the health of users or otherwise are not in conformity with the requirements prescribed by the legislation in force.

- 3. The inspection surveillance in co-ordination with the competent authorities shall notify, the European Commission and the Members States of the measures taken in accordance with paragraph 2. of this Article.
- 4. The provisions on inspection surveillance shall also apply to products assembled or manufactured for the manufacturer's own use where provided so in a special law or other acts.
- 5. The provisions on inspection surveillance shall apply in so far as there are no specific provisions with the same objective in other legislation that is in compliance with the European Union legislation.

Article 22 Impartiality of the Inspector

- 1. Inspection surveillance over the implementation of this Law and sub-legal acts adopted pursuant to this Law, shall be carried out by competent inspectors, in accordance with their responsibilities and competences deriving form the sub-legal acts regulating the organisation and scope of work of competent ministries and other sub-legal acts determining their competences.
- 2. Inspectors are obliged to carry out their duties independently, fairly, impartially and without bias, and shall observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to the legislation of the Republic of Kosovo.

Article 23 Notification on taken measures

- 1. Any measure taken in the course of inspection surveillance in accordance with the applicable law, which is in line with the European Union legislation, by which it is prohibited or restricted the placement of products on the market, it is prevented the distribution of the product or the product is withdrawn from the market, shall be proportionate and shall state the exact grounds on which it is based.
- 2. The economic operator shall be notified in writing of all measures taken and of the legal remedies at his disposal and of the time limits to which such remedies are subject.
- 3. Before the taking of any measurer, the economic operator shall be given the opportunity to declare within an appropriate time period of not less than ten (10) days, unless it is not possible because of the urgency of the measures to be taken to protect

health or safety relating to the public interests prescribed by the relevant legislation in force.

- 4. If action has been taken and the economic operator was not provided in advance with an opportunity to declared, he shall be provided with an opportunity to declare as soon as possible.
- 5. All measures referred to in paragraph 1 of this Article shall be promptly withdrawn or amended after the economic operator has carried out his obligations.

Article 24 The competencies of the inspection body

- 1. The inspection body within its area of competence:
 - 1.1. establishes, periodically updates and implements sector specific inspection surveillance programmes covering the sectors for which it is responsible to conduct inspection surveillance;
 - 1.2. follows up complaints or reports on issues relating to risks arising in connection with products;
 - 1.3. monitors information on accidents and harm to health suspected to have been caused by products;
 - 1.4. verifies that corrective action has been taken by the economic operators concerned:
 - 1.5. follows up scientific and technical knowledge concerning safety issues;
 - 1.6. checks and evaluates the functioning of the inspection surveillance system and its efficiency on a regular basis and, upon request, reviews and when necessary revises the existing inspection surveillance approaches and organizations;
 - 1.7. notifies the European Commission and the Member States of the European Union of all data which the economic operator must provide in accordance with Article 23, paragraph 3 of this Law. All subsequent data must be clearly set out in relation to the data previously submitted.

Article 25 Notification and information

- 1. Competent ministries shall keep the public informed on their respective websites about the inspection surveillance bodies within their competences and responsibilities in accordance with the Law which regulates the right of access to information.
- 2. The body for the coordination of inspection surveillance shall:
 - 2.1. inform the European Commission of surveillance bodies and their areas of scope and competence;
 - 2.2. inform the European Commission and the Member States of the EU of the programmes referred to in Article 24 of this Law, and make them available to the public, by way of electronic communication and, where appropriate, by other means;
 - 2.3. inform the European Commission of the results of checks and verifications of the functioning of the inspection surveillance system and its efficiency at least once in four (4) years. The results shall be made available to the public, by way of electronic communication and, where appropriate, by other means.
- 3. The competent inspection surveillance bodies of the Republic of Kosovo shall cooperate and exchange information with the competent market surveillance authorities of the Member States of the EU and the European Commission regarding their market surveillance programmes and all issues relating to products presenting risks.
- 4. The competent inspection surveillance bodies of the Republic of Kosovo shall give the market surveillance authorities of other Member States of the European Union assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure and by participating in investigations initiated in other Member States.

Article 26 The system for the rapid exchange

1. The procedure of notifying the European Commission concerning non-consumer semiproducts covered by the Community harmonisation legislation which present a serious risk requiring a rapid intervention, including a serious risk the consequences of which are not immediate, is carried out through the system for the rapid exchange of information concerning measures and actions, in particular to products which present a serious risk to the health and safety of consumers- in hereinafter the RAPEX.

- 2. The headquarter of the trade Inspectorate is the place for contact with the European Commission for all official notifications available which are sent and received through the RAPEX.
- 3. The contact point referred to in paragraph 2. of this Article shall provide the European Commission with information at its disposal on products presenting a risk regarding, in particular, identification of products, the origin and the product supply chain, identification of risks, results of testing carried out, nature and duration of measures taken, voluntary measures taken, contacts with the economic operators concerned and justification for action or inaction, and concerning any alterations or withdrawal of measures taken
- 4. Contact points are the network of state bodies which send official notifications to the contact point referred to in paragraph 2. of this Article and which receive official notifications from the contact point referred to in paragraph 2. of this Article.

Article 27 The data confidentiality

- 1. The competent inspection body shall provide the public with information at its disposal concerning dangers regarding a product with a view to reducing the risk of injury or other damages.
- 2. Inspection bodies shall keep data confidential whenever necessary to protect a commercial secret or keep personal data secret in accordance with the valid provisions, in relation to the requirement that the data concerned must be made public to the greatest possible extent with a view to protecting the interests of users in the Republic of Kosovo.
- 3. The competent inspection body and the economic operators shall co-operate to prevent or reduce the risks arising from products placed on the market or made available by those economic operators.
- 4. Whenever the competent inspection body decides to withdraw a product, it shall inform the economic operator concerned at the address indicated on the product, its packaging or the document accompanying that product.

Article 28 Inspectors' authorisations

1. During the inspection surveillance, inspectors are authorized to require economic operators to make available the required documents and information, and enter the premises of economic operators, where that is necessary and reasonable, and take the necessary product samples.

- 2. In the course of inspection surveillance, the inspector shall perform appropriate checks on the characteristics of products on an adequate scale, by means of conformity prescribed documentary checks through visual checks and, where appropriate, physical and laboratory checks on the basis of adequate samples, taking into account the established principles of risk assessment, objections and other information.
- 3. Where an economic operators present test reports or certificates of conformity, issued by an accredited conformity assessment body, the competent inspection body shall take such reports or certificates into consideration.
- 4. Where it is reasonably suspected in the course of inspection surveillance that a product does not comply with the prescribed technical requirements in spite of the relevant conformity assessment procedures having been carried out, the inspector shall take adequate samples of the product to have them tested by conformity assessment bodies which was not involved in the testing and conformity assessment of the same product before it was placed on the market or in use.
- 5. Where an inspector during inspection surveillance of the characteristics of a product verifies and has reason to believe that a product might pose a risk to the life and health of human beings, consumers and other users, or with a view to protecting other public interests referred to in Article 21, paragraph 1. of this Law, shall issue a decision temporarily prohibiting, for the period as foreseen by sub-legal act for the performance of various examinations, checks and assessments of safety, the delivery, the offer of delivery, advertising or exhibiting of the product.
- 6. Inspector it is determined, after a visual and physical check of a product or after the testing has been completed, if that a product does not comply with the prescribed technical requirements or that a product which is compliant with technical requirements, and which is used in accordance with its intended purpose or under conditions which can be reasonably foreseen and when properly installed or maintained, presents a serious risk, is liable to compromise the health or safety of users, the inspector shall, by a decision; prohibit or restrict its placing on the market, prohibit distribution or use, order the withdrawal or recall of the product from the market and/or use stating the reasons for the measures taken. If established that the product presents a risk to the life and health of human beings, consumers and other users, or with a view to protecting other public interests referred to in Article 21, paragraph 1. of this Law, the inspector shall order the products to be destroyed under appropriate conditions or to be rendered otherwise inoperable and for that the inspector shall notify the public.
- 7. Pursuant to paragraph 6 of this Article, the inspector shall provide to the competent bodies the proves for non-conformity which may be the following:
 - 7.1. failure to meet the essential requirements referred to in Article 2 of this Law;
 - 7.2. non-conformity with the applicable standards foreseen for the type of product concerned;

- 7.3. incorrect implementation of standards foreseen for the type of product concerned;
- 7.4. deficiencies in the prescribed standards in a way that it that it was appraised that it does not satisfy fully the essential requirements for the type of product concerned. The competent ministry shall notify the European Commission of the measures taken in accordance with subparagraph 1. of this paragraph without delay, while stating the reasons for adopting those measures.
- 8. The decision as to whether the product poses a serious risk shall be based on adequate risk assessment which shall taken into account the degree of danger and the probability of its emergence, further to the prescribed requirements in the relevant applicable legislation of the Republic of Kosovo, or in the relevant Community harmonisation legislation. The possibility of reaching a high level of safety or the existence of other products posing a lesser risk shall not constitute grounds for prejudice that a product presents a serious risk.
- 9. The inspector shall order an economic operator to remove irregularities and shall set a reasonable period within which the irregularities must be remedied if he establishes that a product the economic operator placed or made available on the market- a product with a formal deficiency:
 - 9.1. does not have prescribed markings or is incorrectly marked;
 - 9.2. does not have the prescribed documents of conformity, test report, certificate of conformity, or a report or examination certificate and the declaration of conformity or the declaration of conformity is incomplete;
 - 9.3. does not have or has incomplete prescribed technical documentation, or the technical documentation is unavailable:
 - 9.4. does not have the prescribed instructions and information on the safety of the product or if the prescribed instructions and information on safety do not accompany the product;
 - 9.5. does not include information on the product in the official language.
- 10. If the economic operator does not remove the deficiencies within the set period referred to in paragraph 9. of this Article, the inspector shall issue a decision in which he shall prohibit the placement on the market, distribution or use of the products with formal deficiencies.
- 11. The competent inspector shall order by a decision the removal of the irregularities or deficiencies determined in the course of inspection and he shall determine an appropriate period during which the irregularities, deficiencies have to be removed.

- 12. Where the inspector takes the measures referred to in this Article, the inspector shall act in a way that ensures that the measures are implemented proportionately to the seriousness of the risk while taking into account the principle of precaution, that is, that the measure taken is appropriate in view of the nature of the impending danger or risk.
- 13. An appeal against the decision issued by the inspector referred to in paragraphs 5., 6., 10. and 11. of this Article shall not postpone its enforcement.

Article 29 The costs of supervision surveillance

The costs of testing, product conformity assessment shall be borne by the economic operator who placed or made a product available on the market that is not compliant with technical requirements.

Article 30 International cooperation

Inspection bodies may co-operate with competent bodies of third countries with the view to exchanging information, technical support, promotion and facilitation of access to the European systems, and in the support of the activities related to conformity assessment, market surveillance and accreditation.

Article 31 Verification of products before the import aiming the placement on the market

- 1. Before the approval of products for free circulation, the customs authorities or the competent customs office is authorized to carry out appropriate checks on the characteristics of products which entered the customs territory of the Republic of Kosovo, in accordance with the Article 28 paragraphs 1., 2. and 3. of this Law.
- 2. The customs shall prohibit temporarily further implementation of the required customs procedure for the release of a product for free circulation when in the course of the verification referred to in paragraph 1. of this Article it is verified that:
 - 2.1. the product displays characteristics which give cause to believe that the product, when properly installed, maintained and used, presents a serious risk to health, safety, the environment and nature or any other public interest referred to in Article 21 paragraph 1. of this Law;
 - 2.2. the product is not accompanied by the written or electronic documentation required by the applicable regulations;

- 2.3. the product is not marked in accordance with the applicable provisions;
- 2.4. the conformity marking has been affixed to the product in a false or misleading manner.
- 3. The customs is obliged to immediately notify in writing the competent inspection body of any such temporarily suspension-prohibition,
- 4. In the case of temporary prohibition of the implementation of custom procedures related to perishable products, then the customs shall, as far as possible, allows the storage of products or for the vehicles used for transport shall be made the accommodation-placement in conformity with the necessary requirements to keep those products safe.
- 5. Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, the customs authorities shall take due account of such reports or certificates.
- 6. The provisions of Articles 25 paragraphs 3. and 4., Articles 31, 32 and 33 of this Law shall apply in respect of the customs authorities without prejudice to the application of regulations providing for more specific systems of co-operation between the customs authorities.

Article 32 The release for free circulation of products

- 1. Products the release of which has been suspended by the customs authorities pursuant to Article 31 of this Law shall be released for free circulation if, within three (3) working days of the suspension of the release those authorities have not been notified of any action taken by the competent inspection body, and provided that all the other requirements pertaining to the placement of products concerned in regard to the required customs procedures have been fulfilled.
- 2. Where the competent inspection body finds that the product referred to in Article 31, paragraphs 2. and 3. of this Law does not present a serious risk to health and safety or that it is not contrary to the provisions of valid regulations applicable to the product concerned, it shall be released for free circulation by the customs authorities, provided that all the other requirements prescribed for the release of the goods concerned into the required customs procedure have been fulfilled.

Article 33 Placing the Endorsement

- 1. Where the competent inspection body finds that a product presents a serious risk, it shall take measures to prohibit that product from being placed on the market and shall require the competent customs to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself: "Dangerous product-release for free circulation not authorised-Law on Technical Requirements for Products and Conformity Assessment".
- 2. Where the competent inspection body finds that a product does not comply with prescribed technical requirements it shall take appropriate action, which may, if necessary, include prohibiting the product's being placed on the market. The competent inspection body which prohibits the product to be placed on the market, shall require the competent customs office not to approve the release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself: "Dangerous product-release for free circulation not authorized-Law on Technical Requirements for Products and Conformity Assessment".
- 3. Where the product referred to in paragraphs 1. or 2. of this Article is subsequently declared for a customs procedure other than release for free circulation and provided that the competent inspection body does not object, the endorsements set out in paragraphs 1. and 2. of this Article shall be transferred, under the same conditions, on the documents used in connection with that procedure.
- 4. Where the competent inspection body deems it necessary and proportionate, it may order the products that present a serious risk to be destroyed or otherwise rendered inoperable.
- 5. Where within the set time period the importer fails to comply with in paragraph 4. of this Article, the competent inspection body may take all measures necessary, including the issuing of a decision on the seizure of the product for destruction, which is organised and carried out by the competent inspection body at the cost of the importer, which shall settle the cost of destruction within (8) days of the date of submission of a notification stating that the product was destruction, and to the contrary the costs shall be collected by involuntary settlement. Enforcement shall be carried out by the competent tax administration having territorial competence or based on the address of the importer, in accordance with the regulations governing involuntary collection of tax debt.
- 6. The competent inspection bodies shall provide customs authorities with information on product types in which a serious risk of non-conformity within the meaning of paragraphs 1. and 2. of this Article has been identified and of actions taken and decisions issues within the meaning of the provisions of this Article.

Article 34 Punitive provisions

- 1. Legal persons shall be fined in an amount from one thousand fifteen $(1,500.00) \in \text{to}$ twenty thousand $(20,000.00) \in \text{if they}$:
 - 1.1. do not implement the provisions referred to in Article 5, paragraph 1. of this Law;
 - 1.2. do not implement the provisions referred to in Article 36 paragraphs 2. and 3. of this Law;
 - 1.3. place a product on the market or make it available on the market contrary to Article 2 of this Law;
 - 1.4. place a product on the market contrary to Article 6 and 8 of this Law;
 - 1.5. fail to comply with Article 7 paragraph 3. of this Law;
 - 1.6. make the product available contrary to Article 9 of this Law;
 - 1.7. contrary to Article 14, paragraph 1. of this Law, do not affix the prescribed conformity marking;
 - 1.8. contrary to Article 14 paragraph 4. of this Law, affix to products markings which are similar to conformity markings to such a degree that they could cause misunderstanding on the market or mislead consumers;
 - 1.9. contrary to Article 15 of this Law conduct activities of the conformity assessment bodies in the conformity assessment procedures;
 - 1.10. contrary to Article 6 paragraph 11., Article 8 paragraph 10. Article 9 paragraph 6. of this Law, fail to provide the competent inspection bodies with all necessary information and documents necessary to prove conformity of the product in the official language, or fail to co-operate with the competent inspection bodies to remedy or avoid risks presented by the product which they placed on the market or made available on the market,
 - 1.11. contrary to Article 11 of this Law, fail to submit to the conformity assessment bodies information on the identification of economic operators;
 - 1.12. contrary to Article 28 paragraph 1. of this Law, deny the taking of samples of the product by the competent inspector necessary for a laboratory check;

- 1.13. contrary to Article 28 paragraphs 5., 6., 8., 9. and 10. of this Law, do not act in accordance with the enforcement measures of competent market surveillance authorities;
- 1.14. fail to act in accordance with Article 33 paragraph 4. of this Law.
- 2. The responsible person in the legal person shall also be fined for the misdemeanours referred to in paragraph 1. of this Article in an amount from one hundred $(100.00) \in \text{to}$ three thousand $(3,000.00) \in$
- 3. Natural persons who are traders/craftsmen and persons engaged in other independent activities shall also be fined for the misdemeanours, referred to in paragraph 1. of this Article, committed in relation to the performance of their trade/craft or independent activity in an amount from two hundred (200.00) €to fifteen thousand (15,000.00) €

Article 35 The formal deficiency

- 1. The competent inspector shall not file an indictment or issue a misdemeanour order for the Article 34 paragraph 1. of this Law in relation to a product with a formal deficiency which:
 - 1.1. does not have prescribed markings or is incorrectly marked;
 - 1.2. does not have documents of conformity- test report, certificate of conformity, reports or examination certificate and declaration of conformity or the declaration of conformity is incomplete;
 - 1.3. does not have technical documentation, it is incomplete or technical documentation is unavailable;
 - 1.4. does not have the prescribed instructions and information on the safety of the product or if the prescribed instructions and information on safety do not accompany the product;
 - 1.5. does not include information on the product in the official language, if during inspection surveillance or at the latest within ten (10) days of the date of the inspection surveillance the economic operator remedies the irregularities established during inspection surveillance with respect to which the inspector established that the economic operator committed them for the first time.

Article 36 The issuance of sub-legal acts

Based on the provisions of Article 17 paragraph 8. of this Law, relevant ministries are obliged to issue sub-legal acts within twelve (12) months from the date of entry into force of this Law.

Article 37 Transitional provisions

- 1. The provisions of Article 5 paragraph 5. and 6., Article 17 paragraph 7., Article 25 paragraphs 2., 3. and 4., Article 26 and Article 31 paragraphs 5. and 6. of this Law shall enter into force upon accession of the Republic of Kosovo in the European Union or upon the entry into force of Agreement of Conformity Assessment and Acceptance of industrial products (ACAA) for products covered by this agreement.
- 2. At the date of accession of the Republic of Kosovo in the European Union cease to apply the provisions of the Article 19 paragraph 2. and 3.

Article 38 Repealing provisions

With the entry into force of this Law, the Law No.02/L-20 On Technical Requirements for Products and Conformity Assessment and the Law No.03/L-092 Amending and Supplementing the Law Nr.02/L-20 On Technical Requirements for Products and Conformity Assessment are repealed.

Article 39 Entry into force

This law shall enter into force fifteen (15) days after its publication in the Official Gazette of the Republic of Kosovo.

Law No. 04/L-039 29 August 2011

President of the Assembly of the Republic of Kosovo

Jakup KRASNIQI