

Pursuant to Article 95, item 3 of the Constitution of Montenegro, I hereby pass the

**ENACTMENT PROMULGATING THE LAW ON GENERAL PRODUCT SAFETY**

I hereby promulgate the Law on General Product Safety adopted by the Parliament of Montenegro at its seventh meeting of the first regular session in 2008, on 29 July 2008.

No: 01-1550/2

Podgorica, 4 August 2008

President of Montenegro

**Filip Vujanović, m.p.**

**LAW ON GENERAL PRODUCT SAFETY**  
**(Official Gazette of Montenegro, No. 48/08 from 11 August 2008)**

**I General Provisions**

**Subject of the Law**

**Article 1**

This Law shall regulate the requirements that must be met by the products placed on the market, obligations of producers and distributors, manner of providing information and exchange of information about product risks.

**Application of the Law**

**Article 2**

- (1) This Law shall apply to the products whose safety is not regulated by separate regulations.
- (2) If safety of products is regulated by the regulations referred to in paragraph 1 of this Article, this Law shall apply to the risks and categories of risks not regulated by these regulations.
- (3) This Law shall not apply to used products delivered as antiques, and to the products that must be repaired or reconditioned prior to their use, provided that the deliverer informs thereof the person to whom the product is delivered in writing.
- (4) Harmonisation with the requirements prescribed by this Law shall not exclude the liability of the producer for damage incurred by a product with a defect, in accordance with the regulations that such liability is determined by.

## **Definitions**

### **Article 3**

For the purpose of this Law, the following terms shall have the following meaning:

- 1) **product** shall mean any product that is, in the course of a commercial activity, made available to consumers and other users, including also the product, in the context of providing a service, whether for consideration or not, and whether new, used or reconditioned;
- 2) **safe product** shall mean any product that, under foreseen or foreseeable conditions of use, including duration, putting into service, installation and maintenance requirements, where applicable, does not present any risk or only the minimum risk compatible with the product's use, considered to be acceptable in accordance with a high level of protection for the safety and health of persons;
- 3) **dangerous product** shall mean any product that is not a safe product;
- 4) **misleading product** shall mean any non-food product that by its form, colour, smell, appearance, packaging, label or size reminds of a food product, so that there is a probability that consumers, in particular children, will not differ it from food products, and it can therefore be used in a manner that can represent a risk for their health and life;
- 5) **producer** shall mean:
  - business organization, entrepreneur or physical person that makes or reconditions the product, as well as any other person presenting himself as a person who makes or reconditions the product affixing to the product his name, trade mark or other distinctive mark;
  - producer's representative with the registered office in Montenegro, if the producer's registered office is not in Montenegro, or the importer if the registered office of the producer's representative is not in Montenegro;
  - another business organization, entrepreneur or physical person that in the course of its commercial activity is included in the supply chain, insofar as their activities may affect the safety of a product;
- 6) **distributor** shall mean any business organization, entrepreneur or physical person that is in the course of its commercial activity included in the supply chain, if its activity does not affect the safety of a product;
- 7) **party concerned** shall mean a consumer, user and any other person that is associated to the use of a product, as well as participants in the supply chain, and competent bodies;
- 8) **serious risk** shall mean any risk for safety and health of consumers and other users, including those the effects of which are not immediate, requiring rapid intervention by producers, distributors and competent bodies;
- 9) **preventing distribution and sale** shall mean any measure aimed at preventing the distribution, display, or offer and sale of a dangerous product;
- 10) **recall** or **withdrawal** shall mean any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers and other users by the producer or distributor;
- 11) **RAPEX** (Community Rapid Information System) shall mean the system for rapid exchange of information in the European Communities about the products representing a serious risk.

## **II SAFETY REQUIREMENTS AND CRITERIA**

### **Safety Requirements**

#### **Article 4**

- (1) Producer shall be obliged to place only safe products on the market.
- (2) When assessing the safety of a product, the following in particular shall be taken into account:
  - the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
  - the effect on other products, where it is foreseeable that it will be used with other products;
  - labelling of the product, any warnings and instructions for its use and any other data regarding the product;
  - the categories of consumers most at risk when using the product, in particular children and the elderly.
- (3) The possibility of obtaining higher levels of safety or availability of other products presenting a lesser degree of risk shall not constitute a ground for considering a product to be unsafe product.
- (4) It shall be prohibited to produce, import, export or place on the market misleading products.

### **Standard Conformity Criterion**

#### **Article 5**

- (1) A product shall be presumed safe as far as the risks or risk categories are concerned, if it conforms to the applicable standards in Montenegro (hereinafter referred to as: Montenegrin standards), adopted on the basis of the European standards, the references of which have been published in the Official Gazette of Montenegro.
- (2) The Ministry competent for standardization activities (hereinafter referred to as: the Ministry) shall be publish the references of the standards referred to in paragraph 1 of this Article.

### **Safety Assessment Criteria**

#### **Article 6**

- (1) In case of absence of the standards referred to in Article 5 of this Law, safety of products shall be assessed on the basis of the following:
  - Montenegrin standards adopted on the basis of the relevant European standards that are not published in the manner determined by Article 5 of this Law;
  - other Montenegrin standards;
  - EC Commission recommendations setting guidelines on product safety assessment;
  - product safety codes of good practice in the area concerned;
  - the state of the art and technology;
  - reasonable consumer expectations concerning product safety.

- (2) Producers, distributors and competent bodies shall assess safety of products referred to in paragraph 1 of this Article.

**Protective Clause**  
**Article 7**

Competent inspection body may take appropriate measures prescribed by this Law, if, on the basis of obtained evidence, it establishes that a product is not safe, although the product is in conformity with the safety requirements or criteria referred to in Articles 2, 4, 5, and 6 of this Law.

### **III OBLIGATIONS OF PRODUCERS AND DISTRIBUTORS**

**Obligations of Producers**  
**Article 8**

- (1) Producer shall be obliged to provide consumers and other users, in writing, with the relevant information and instructions necessary for risk assessment when using products throughout the entire foreseen or usual duration, if such risks are not obvious without an adequate warning.
- (2) A written instruction or warning referred to in paragraph 1 of this Article shall not exempt a producer from the obligation to place safe products on the market.
- (3) Producer shall be obliged to assess risks and take adequate measures commensurate with the characteristics of the product in order to prevent risks.
- (4) The measures referred to in paragraph 3 of this Article shall be:
- warning the consumers and other users about risks which the products might pose;
  - additional indication of data about the producer and data about the product (serial number or lot of products);
  - sample testing of marketed products, records and analysis of complaints and keeping distributors informed of such activities;
  - preventing distribution and sale;
  - recall or withdrawal of product, when other measures do not suffice to prevent the risks involved, in accordance with a precautionary principle.
- (5) The measures referred to in paragraphs 3 and 4 of this Article shall be taken by a producer, at its discretion, or at the request of competent inspection body.

**Obligations of Distributors**  
**Article 9**

- (1) Distributor shall be obliged, in the course of its commercial activity, to act with due care to ensure the supply of safe products.

- (2) Distributor must not supply products which it knows or should have known, on the basis of available information or its professional knowledge and experience, do not comply with the safety requirements.
- (3) Distributor shall be obliged, in the course of its commercial activity, to participate in monitoring the safety of products placed on the market, in particular by:
  - passing on information on product risks to the participants in the supply chain, consumers and competent state bodies;
  - keeping, providing and submitting the documentation necessary for tracing the origin of products and identity of producer, at the request of the parties concerned;
  - cooperation in implementation of the measures taken by producers and competent state bodies to prevent the risks.

### **Joint Obligations of Producers and Distributors**

#### **Article 10**

- (1) Producers and distributors shall be obliged to inform a competent inspection body with no delay and in writing, if:
  - they know or should have known based on available information and professional knowledge and experience that a certain product placed on the market is dangerous, or
  - they assess that a certain product placed on the market poses a serious risk.
- (2) The notification referred to in paragraph 1 of this Article shall contain in particular:
  - available information and data enabling the identification of the product and its origin (producer, name of the product, lot/batch of products, and similar);
  - detailed description of the risk associated with the product;
  - description of measures taken to prevent the risks.
- (3) Producers and distributors shall be obliged, at the request of a competent inspection body, to cooperate in implementing the measures aimed at preventing the risks associated with the products that they deliver or have delivered.
- (4) The Ministry shall prescribe more detailed contents of the notification referred to in paragraphs 1 and 2 of this Article.

## **IV PROVISION AND EXCHANGE OF INFORMATION**

### **Transparency of Information**

#### **Article 11**

- (1) Information available to the competent bodies relating to risks to consumers and other users' health and safety that may be posed by products shall be the information of public interest.
- (2) The competent bodies shall be obliged to submit the information about the risks referred to in paragraph 1 of this Article at the request of the parties concerned. The information about the risks shall contain in particular the data on: product identification (producer,

product name, lot/batch of products, and similar), the nature of the risks associated with the use of the product, and the measures taken for the purpose of preventing the risks.

- (3) The information about the risks referred to in paragraphs 1 and 2 of this Article shall be available to the public, even if they are determined as business secret by another law.

### **Exchange of Information Article 12**

- (1) Exchange of information about the risks shall be done among the competent bodies of Montenegro, as well as between the bodies of Montenegro and the European Communities. The exchange of information with the European Communities shall be done through the RAPEX system.
- (2) The information referred to in paragraph 1 of this Article shall represent the notification about:
- application of the protective clause referred to in Article 7 of this Law;
  - measures taken by the competent bodies and activities implemented by producers and distributors regarding the products that represent a serious risk.
- (3) The Government of Montenegro shall determine the bodies competent for the exchange of information and more detailed procedure regarding the exchange and contents of information referred to in paragraphs 1 and 2 of this Article.

## **V SUPERVISION**

### **Competencies of Inspection Bodies Article 13**

- (1) Inspection supervision of implementation of this Law shall be performed by Ministries and other state administration bodies competent for: trade affairs, energy affairs, construction affairs, mining affairs, agricultural affairs, health affairs, protection at work affairs, transportation affairs; telecommunication affairs, tourism affairs, environmental protection affairs, educational affairs; internal affairs, and the affairs in the area of sports; through the inspectors competent for a relevant area, or authorized persons, in accordance with law.
- (2) Inspection supervision of implementation of provisions of this Law relating to misleading products shall be done by an inspector of the body competent for health affairs, regardless of the type of product in question.

### **Measures taken by Inspection Bodies Article 14**

- (1) In addition to the authorizations determined by the regulations referred to in Article 13 of this Law, the competent inspection bodies shall have the authorizations to take the following measures for every product:

- to perform and organize checks on the product safety properties, on an adequate scale, up to the final stage of use;
  - to require all necessary information from producers or distributors;
  - to take samples of products for the purpose of checks.
- (2) In addition to the authorizations referred to in paragraph 1 of this Article, the competent inspection bodies shall have the obligation to take the following measures:
- 1) for any product associated with risks in certain conditions:
    - to order that such a product is marked with easily comprehensible warnings of the risks it may present in the official languages of Montenegro;
    - to make its placement on the market subject to prior safety requirements are met;
  - 2) for any product associated with risks for certain persons, to order that they be given warning of the risks in good time and in an appropriate form, including also the publication of special warnings through the mass media;
  - 3) for any product that could be dangerous, to temporarily ban its offer, display, supply and putting into service, until the safety assessment procedure is terminated;
  - 4) for any dangerous product, to ban its placement on the market and impose the accompanying measures necessary for enforcement of the ban measure;
  - 5) for any dangerous product already on the market:
    - to order or organize immediate prevention of distribution and sale of the product and alert consumers and other users to the risks such product presents;
    - to order or organize together with producers and distributors recall of such product;
    - to order, for a product determined in a final procedure as dangerous, its destruction in suitable conditions;
- (3) Competent inspection bodies may take the measures, in accordance with this Law, not only against producers and distributors, but also against traders and other persons, when necessary to do so in the course of supervision.
- (4) Appeal against the decision on measures referred to in this Article shall be submitted within eight days from the day of decision submission. The appeal shall not postpone the enforcement of the decision.

### **Obligations of a Customs Authority**

#### **Article 15**

- (1) A customs authority shall, in a customs procedure, postpone for three days the release of the product or the lot/batch of products, and immediately inform thereof a competent inspection body, if it establishes that:
- specific products or the lot/batch of products show certain characteristics that cause a reasonable doubt that they could pose a serious risk for health and safety of consumers;
  - specific products or the lot/ batch of products are not accompanied with the prescribed documents or that they are not marked in a prescribed manner.

- (2) If a competent inspection body does not take the prescribed measures within three business days, or does not inform a customs authority about taking the measures within that deadline, a customs authority shall release the product or the lot/batch of products whose release has been delayed, provided that other prescribed requirements are met.

### **Precautionary Principle**

#### **Article 16**

Due to possible direct or indirect risks for health and safety of consumers and other users, competent inspection bodies shall be obliged to act in a manner proportional to the seriousness of the risks and with due care when taking the prescribed measures, and in particular the measures referred to in Article 14, paragraph 2 of this Law.

## **VI PUNITIVE PROVISIONS**

### **Offences**

#### **Article 17**

- (1) A pecuniary fine in the amount from 30 fold to 300 fold of the minimum cost of labour in Montenegro shall be imposed on a business organization or entrepreneur, if they:
- 1) place on the market a product that is not safe (Article 4, paragraph 1);
  - 2) produce, import, export or place on the market misleading products (Article 4, paragraph 4);
  - 3) fail to provide consumers and other users with relevant information and instruction for risk assessment (Article 8, paragraph 1);
  - 4) fail to assess the risk commensurate with the characteristics of the product and fail to take measures in accordance with Article 8, paragraphs 4 and 5 of this Law;
  - 5) fail to pass on the information about the risks involved with the product, fail to keep, provide and submit the documentation necessary for tracing the origin of product and identity of producer, or fail to cooperate in implementation of measures that producers and competent state bodies take for the purpose of preventing the risks (Article 9, paragraph 3);
  - 6) fail to inform a competent inspection body that the product they have placed on the market is dangerous, or it represents a serious risk (Article 10, paragraphs 1 and 2);
- (2) A pecuniary fine in the amount from 2 fold to 20 fold of the minimum cost of labour in Montenegro shall be imposed for the offence referred to in paragraph 1 of this Article on a responsible person of the legal entity or physical person.



## **VII TRANSITIONAL AND FINAL PROVISION**

### **Deadline for Adoption of Regulations Article 18**

Enabling regulations for implementation of this Law shall be adopted within 6 months from the effective day of this Law.

### **Coming into Effect Article 19**

This Law shall come into effect on the eighth day upon the day of its publication in the Official Gazette of Montenegro.

SU-SK No: 01-333/10  
Podgorica, 29 July 2008

**Parliament of Montenegro**  
Speaker of the Parliament  
**Ranko Krivokapić, m.p.**