

Based on Article IV.4.a) of the Constitution of Bosnia and Herzegovina, the Parliamentary Assembly of Bosnia and Herzegovina, at the session of the House of Representatives on 27th July 2004 and the session of the House of Peoples on 9th September 2004, has adopted the

LAW ON MARKET SURVEILLANCE IN BOSNIA AND HERZEGOVINA

I. GENERAL PROVISIONS

Objectives and Scope

Article 1

1. This Law shall regulate the surveillance of products placed on the market of Bosnia and Herzegovina (hereinafter: market surveillance), determine the general principles and establish a market surveillance system, its organization and functioning, as well as the duties and responsibilities of producers and distributors within the market surveillance system.
2. Market surveillance shall be conducted by the competent authorities by monitoring the conformity of products placed on the market or put into service with the prescribed product safety requirements, and undertaking, when necessary, appropriate measures so that products are brought in line with those requirements, in order to ensure a high level of protection to the health and safety of humans, animals, plants, property, and the environment.
3. This Law shall apply to all products defined in Article 2 of this Law for which the safety requirements will be given in the Law on General Product Safety or by specific technical requirements.

Definitions

Article 2

Terms used in this Law shall have the following meaning:

- a) **Product** means any product intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, which is supplied or made available, whether for consideration or not, in the course of commercial activity including products supplied or made available as part of providing a service, whether new, used or reconditioned.

This definition of product shall not apply to second-hand products supplied as antiques or to products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.

This definition of product shall apply to equipment, apparatus, instruments and other products whose safety is regulated by specific technical regulations.

- b) **Safe product** means any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only minimum risks compatible with the product's use, considered to be acceptable and consistent with high level of protection for the safety and health of humans, taking into account the following points in particular:
 - the characteristics of the product, particularly its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance,
 - the effect of a product on other products, where it is reasonably foreseeable that it will be used with other products,
 - the presentation of the product, labelling, warnings and instructions for its use and disposal and any other indication or information regarding the product,
 - the categories of consumers at risk when using the product, in particular children and the elderly.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not in itself constitute grounds for considering a product to be dangerous.

- c) **Dangerous product** means any product which does not meet the definition referred to in Paragraph (b) of Item 1 of this Article.
- d) **Serious risk** means any risk, requiring rapid intervention by competent authorities including a risk where the effects are not immediate.
- e) **Producer** means any natural or legal person established in Bosnia and Herzegovina responsible for the conformity of a product with general or specific safety requirements according to the provisions of the Law on General Product Safety and/or specific technical regulations with a view to either placing it on the market under his own name and/or putting it into service for his own purposes.
- f) **Distributor** means any person in the supply chain, whose activity does not affect the safety properties of a product,
- g) **Recall of a product** means any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor,
- h) **Withdrawal** means any measure aimed at preventing the distribution, display and offer of a product to the consumer.
- i) **Placing a product on the market** is the initial action of making a product available, either for payment or free of charge, for the first time on the market of Bosnia and Herzegovina, with the aim of distribution or use in the market in Bosnia and Herzegovina.
- j) **Putting a product into service** is the moment of first use of a product within Bosnia and Herzegovina by the end user.
- k) **Technical regulation** is a regulation that provides technical requirements, either directly or by referring to a standard, technical specification, instruction for use or code of practice, or incorporating the content of these documents.
- l) **Market surveillance** comprises the whole system of measures, procedures and activities of competent authorities which are being carried out in order to ensure that products placed on the market comply with applicable safety requirements, and includes surveillance and taking corrective measures for the purpose of bringing them in line with the prescribed requirements.

II. GENERAL PRINCIPLES OF MARKET SURVEILLANCE

Article 3

Market surveillance shall be carried out by the competent authorities through the following activities:

- a) Monitoring whether, in terms of safety requirements, products placed on the market or put into service comply with the provisions of the regulations in Item 3 Article 1 of this Law;
- b) Undertaking measures to ensure compliance of the product safety requirements with the said regulations.

Precaution and Proportionality

Article 4

In undertaking measures to ensure compliance of the product safety requirements with the regulations in Item 3 of Article 1 of this Law, and particularly when deciding on measures directed at withdrawal and recall of products, the competent authorities shall act in a manner proportional to the seriousness of the risk, and taking due account of the precautionary principle.

Cooperation

Article 5

With the view of ensuring efficient market surveillance, which includes uniform and effective application of this Law as well as of the regulations in Item 3 of Article 1 of this Law, avoidance of different practices of market surveillance and overlapping of competencies in conducting market surveillance, all competent authorities taking part in the market surveillance system shall cooperate with each other, developing mutual trust and transparency, enabling and promoting cooperation with other states and international organizations.

Transparency

Article 6

1. Information available to the bodies in the market surveillance system which pertain to safety and health risks for humans and animals or environmental protection, as well as the information on measures undertaken is available to the public.
2. Information available to the public from Item 1 of this Article does not include product data considered a professional secret, except in instances when safety risks are of such proportion that circumstances surrounding a particular case require that they be publicly announced in order to prevent such risks.
3. All bodies of the market surveillance system are responsible to ensure effective compliance with the protection of professional secrets by its officials, servants or employees.

III. ORGANISATION AND FUNCTIONING OF THE MARKET SURVEILLANCE SYSTEM

Market Surveillance System

Article 7

The market surveillance system shall monitor the compliance of products placed on the market with the product safety requirements set forth in the Law on General Product Safety and specific technical regulations, fulfilling the obligations of producers and distributors arising from these regulations and implementation of measures on the part of competent authorities in order to harmonize product safety requirements with these regulations.

Organization and Functioning of the Market Surveillance System

Article 8

The market surveillance system in Bosnia and Herzegovina is comprised of:

- a) The Market Surveillance Agency of Bosnia and Herzegovina (hereinafter: the Agency),
- b) Inspection and other administrative bodies of the Federation of Bosnia and Herzegovina, the Republika Srpska, and District Brcko of Bosnia and Herzegovina authorized to carry out inspections and other activities related to product control on the market of Bosnia and Herzegovina (hereinafter: competent authorities)

Powers and Responsibilities of the Competent Authorities

Article 9

1. With the view to implementing this Law, and in particular of attaining the objectives of market surveillance as set in Article 7 of this Law, the competent authorities shall be authorized, where appropriate, to take, inter alia, the following measures:
 - a) For any product:

- to organize, even after it has been placed on the market as being safe, appropriate check on its safety properties, on an adequate scale, up to the final stage of use or consumption;
 - to take samples of products and subject them to safety checks;
 - to require all necessary information from the parties concerned;
- b) For any product that could pose risks under certain conditions:
- to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of Bosnia and Herzegovina, on the risks it may present;
 - to make its marketing subject to prior conditions so as to make it safe;
- c) For any product that could pose a risk for certain persons:
- to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;
- d) For any product that could be dangerous:
- for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;
- e) For any dangerous product:
- to ban its placing on the market and introduce the accompanying measures;
- f) For any dangerous product already on the market:
- to order or organize its actual and immediate withdrawal, and alert consumers to the risks it presents;
 - to order or coordinate or, if appropriate, to organize together with producers and distributors its recall from consumers and its destruction in suitable conditions.
2. When taking measures in the context of surveillance of products for which safety requirements have been determined in the regulations from Item 3 of Article 1 of this Law, the competent authorities shall promote and encourage voluntary action by producers and distributors, in accordance with the obligations incumbent on them in these regulations, including where applicable the development of codes of good practice.
3. If necessary, the competent authorities shall organize or order the measures provided for in paragraph (f) of this Article if the action undertaken by the producers and distributors in fulfilment of their obligations is unsatisfactory or insufficient.
- Recall shall take place as a last resort.
4. The competent authorities shall have the power to take the necessary action to apply the appropriate measures such as those provided for in paragraph (b) to (f) of this Article, in the case of products posing a serious risk. These circumstances shall be determined by assessing each individual case on its merits.
5. The decision to withdraw or recall a product shall be substantiated; it shall contain instructions on legal redress; and shall be presented to the stakeholder without undue delay. An appeal and a request for judicial review of a decision to withdraw and recall a product shall be ensured according with the procedure set forth in the relevant law on administrative procedure and the law on administrative dispute.

Subjects concerned by measures taken by the Competent Authorities

Article 10

The measures in Article 9 of this Law to be taken by the competent authorities shall address, when appropriate:

- a) the producer as defined in Article 2 of this Law;

- b) distributors, within the limits of their respective activities, and in particular the party responsible for the first stage of distribution on the market of Bosnia and Herzegovina;
- c) any other person, when necessary, with a view to cooperation in action taken to avoid risks arising from a product.

Establishment of the Market Surveillance Agency of Bosnia and Herzegovina

Article 11

1. In order to ensure a functional and efficient market surveillance system, performance of technical, coordinating and other tasks from this Law and from international conventions and international treaties binding Bosnia and Herzegovina, the Market Surveillance Agency of Bosnia and Herzegovina is established by this Law.
2. The Agency shall be an independent administrative unit, shall be considered a legal entity and shall have all the rights and obligations set forth in this Law.
3. The Agency shall be financed out of the budget of the institutions of Bosnia and Herzegovina.

Functioning, management and responsibility of the Agency

Article 12

1. Agency shall be managed by the Director in cooperation with the Deputy Director and Assistant Directors in accordance with the Law, the internal Rulebook of the Agency and other legal acts.
2. The Director and the Deputy Director shall be appointed by the Council of Ministries for the period of four years with possible extension of their mandate for another four years. Assistant Directors shall be selected in accordance with the Law on civil service of BiH. (Official Gazette BiH, No. 19/02, 35/03, 4/04 and 17/04).
3. Director, Deputy Director and Assistant Directors shall not be from the same constituent nationality of Bosnia and Herzegovina.
4. Director and Deputy Director are responsible to the Council of Ministers of Bosnia and Herzegovina.

Mission of the Agency

Article 13

The Agency's mission shall consist of the following:

1. Ensuring a systematic, harmonized and efficient market surveillance system in Bosnia and Herzegovina.
2. Developing international cooperation in the area of market surveillance, including integration of Bosnia and Herzegovina into institutional and administrative structures of international cooperation.
3. Promoting and developing scientific and professional knowledge, insights and methodology and their application in formulating and implementing market surveillance policies.
4. Promoting and developing professional capacities in all market surveillance structures.
5. Affirming the principles of independence, impartiality and non-discrimination in market surveillance.
6. Raising the level of safety of humans and animals and the protection of the environment from dangerous products.

Responsibilities of the Agency

Article 14

With a view to implementing this Law, the Agency shall be responsible, inter alia:

- a) to coordinate and harmonize the activities of the Market Surveillance System in Bosnia and Herzegovina;
- b) to ensure uniform enforcement of the product safety legislation on the territory of Bosnia and Herzegovina including interpreting the regulations on product safety and issuing the guidelines for their implementation;
- c) to participate in the preparation and drafting of all regulations on product safety whether adopted on the entity or state level, ensuring the application of the current scientific and professional knowledge and good practices, particularly contemporary experiences and legal practices of the EU Member States;
- d) to participate, encourage, and aid the development of professional capacities in all market surveillance structures;
- e) to provide scientific and technical support to all competent bodies in the areas within its mission regarding issues related to market surveillance.
- f) to promote capacity building in the area of certification and testing and demonstration of competence through accreditation;
- g) to ensure uniform procedures for acting on consumer complaints regarding product safety or performance of the competent bodies, their centralized record keeping, following the decision and informing the public of the availability of such a mechanism, in order to offer equal protection to all citizens throughout the market of Bosnia and Herzegovina;
- h) to establish efficient formal and/or informal mechanisms for mutual cooperation of all actors in the market surveillance system.
- i) to continuously inform the public and all interested parties of the activities in the market surveillance;
- j) to carry out international cooperation in the field of market surveillance, especially the cooperation with the European Union and Member States authorities as well as the World Trade Organization, to follow and implement the responsibilities of Bosnia and Herzegovina arising from that cooperation and to initiate legislative, administrative and institutional measures necessary for the cooperation;
- k) to periodically inform the authorities of Bosnia and Herzegovina and its Entities on the situation in the area of market surveillance.

Cooperation within the Market Surveillance System

Article 15

1. In order to ensure effective market surveillance, aimed at guaranteeing a high level of protection of health and safety of humans, animals, plants, property, and the environment, all bodies within the market surveillance system shall work together, developing mutual trust and transparency, ensuring the application of appropriate means and procedures, and in particular:
 - a) the establishment, periodic update and implementation of sectoral surveillance programs according to categories of products or risks and monitoring surveillance activities, findings and results;
 - b) follow-up and updating the scientific and technical knowledge concerning the safety of products;
 - c) periodic review and assessment of the functioning of control activities and their effectiveness and, if necessary, revision of the surveillance approach and current organization.

IV. DUTIES AND RESPONSIBILITIES OF PRODUCERS AND TRADE WITHIN THE MARKET SURVEILLANCE SYSTEM

Duties and responsibilities of producers and trade

Article 16

1. Producers and distributors shall understand and ensure application of the laws and technical regulations on product safety applicable to products within their respective activities.
2. Producers shall apply applicable codes, such as the Code of Good Manufacturing Practices (GMP), the Code of Good Laboratory Practices (GLP), and establish and operate applicable control systems like Hazard Analysis and Critical Control Points (HACCP).

V. SPECIAL REQUIREMENTS AND RESPONSIBILITIES OF THE MARKET SURVEILLANCE AGENCY OF BOSNIA AND HERZEGOVINA

Communication on Risks and Dangerous Products

Article 17

1. The Agency shall in a timely fashion communicate risks and information on dangerous products to the public and all interested parties in Bosnia and Herzegovina and abroad.
2. The Agency shall act, within the scope of its authority, in cooperation with the bodies from other European states competent for product safety, in particular in the form of administrative cooperation to ensure:
 - a) the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;
 - b) the establishment and execution of joint surveillance and testing projects;
 - c) the exchange of expertise and best practices and cooperation in training activities;
 - d) improved cooperation with the European Community with regard to the tracing, withdrawal and recall of dangerous products.

VI. TRANSITIONAL PROVISIONS

Article 18

This Law shall enter into force on the eighth day following that of its publication in the Official Gazette of Bosnia and Herzegovina and it will also be published in the Official Gazettes of the Entities and Brcko District of Bosnia and Herzegovina.

Number 102/04

9. September, 2004

Sarajevo

Speaker of the
House of Representatives
of the Parliamentary Assembly BiH
Martin Raguz

Speaker of the
House of Peoples
of the Parliamentary Assembly BiH
Goran Milojevic