GENERAL PRODUCT SAFETY ACT

I. INTRODUCTORY PROVISIONS

Subject of the Act

Article 1

This Act shall lay down general safety of products that are placed on the market, criteria for the assessment of product conformity with the general safety requirement, the obligations of producers and distributors, the content and the methods of informing and exchanging the information relating to risks to consumer and other user health and safety posed by products, and the surveillance of product safety.

Application

Article 2

This Act shall apply to all products defined as products by this Act, except to the products that are covered by other specific safety regulations.

Where the specific safety regulations referred to in paragraph 1 of this Article do not cover the matters related to the obligations of producers and distributors, information and surveillance, this Act shall apply.

Where the specific regulations referred to in paragraphs 1 and 2 of this Article do not apply to all aspects of risks or categories of risks that may be caused by the product, this Act shall apply only to those risks or categories of risks.

Liability for damage

Article 3

Fulfillment of the requirements set forth in this Act shall not affect the responsibility of the producers with regard to the damage caused by products, and/or defective products pursuant to the regulations relating to their liability for the products.

Definitions

Article 4

For the purposes of this Act:

1) ***product*** shall mean any final product, including products in the context of providing a service – which is supplied or made available to the consumer or other user whether for consideration or not in the course of a commercial activity, and whether new, used or reconditioned. This definition shall not apply to second-hand products, supplied as antiques or as 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;

2) ***antique*** shall mean any object of cultural, historical, artistic, scientific or any other similar value, that is at least 100 years old, as well as any object less than 100 years old that is considered rare due to the fact that it is not produced or manufactured any more;

3) ***safe product*** shall mean 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 the minimum risks, and which is - under the normal conditions of use - considered to be acceptable and consistent with a high level of protection for the safety and health of consumers and other users, taking into account in particular:

(1) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(2) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(3) the presentation of the product, the labeling, any warnings and instructions for its use and disposal, storage or destruction after use, and any other indication or information regarding the product;

(4) the categories of consumers at risk when using the product, in particular children and the elderly.

4) ***dangerous product*** shall mean any product which does not meet the definition of "safe product" in this Act. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be dangerous;
5) ***fraudulent products / appearing to be other than they are*** shall mean a dangerous product which possess a form, odor, color, appearance, packaging, labeling, volume or size resembles and is not foodstuffs, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence use it, which might be dangerous to their health and life;
6) ***serious risk*** shall mean any serious risk requiring rapid intervention by the competent authorities, irrespective of the fact whether the risk has an immediate effect or not, but it may pose a serious risk to consumer and other user health and safety;
7) ***producer*** shall mean:

(1) the manufacturer of the product and any legal person, entrepreneur or natural person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product, under the condition that they are registered with the competent authority in the Republic of Serbia or have the residence in its territory.

(2) manufacturer's representative, when the manufacturer is not registered with the competent authority in the Republic of Serbia, or does not have residence in its territory.

(3) importer, when the manufacturer or manufacturer's representative is not registered with the competent authority in the Republic of Serbia, or does not have residence in its territory.

(4) any other legal person, entrepreneur or natural person, professionally included in the supply chain, insofar as their activities may affect the safety properties of a product;

8) ***distributor*** shall mean any legal person, entrepreneur or natural person, professionally included in the supply chain whose activity does not affect the safety properties of a product;
9) ***consumer*** shall mean any natural person to whom the product is supplied or available and who uses the product for personal or household-related needs;

10) ***other user*** shall mean any natural person to whom the product is supplied or made available and who uses the product for personal or business related needs;
11) ***recall*** shall mean any action or measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers or other users by the producer or distributor;
12) ***withdrawal*** shall mean any action or measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer;
13) ***rapid information exchange system*** shall mean a rapid information and alert system used by competent and other institutions and organizations in Serbia, designed to facilitate actions and measures taken pertaining to risks a dangerous product can pose to consumers and other users' health and safety.
14) ***RAPEX*** shall mean the system for the rapid exchange of information among the countries of European Union and the European Community Commission (hereinafter: Commission) of measures and actions taken to prevent serious risk posed by dangerous product to the health and safety of consumers;
15) ***Harmonized European Standard*** shall mean a standard adopted by European standardization organizations, as ordered by the Commission, and published in the Official Journal of the European Community.

II. CRITERIA FOR THE ASSESSMENT OF PRODUCT CONFORMITY WITH GENERAL REQUIREMENT FOR PRODUCT SAFETY

General Requirement for Product Safety

Article 5

Producers shall be obliged to place only safe products on the market.

Requirement for Fraudulent Products / Products Appearing to be Other Than They Are

Article 6

The manufacture, import, export or placing on the market of the products appearing to be other than they are, shall be prohibited.

List of Standards

Article 7

In the absence of specific regulations referred to in Article 2 of this Act, a product shall be presumed safe in compliance with the relevant Serbian national standards drawn up on the basis of European standards, the List of Standards which has been published in the Official Gazette of the Republic of Serbia, when it meets the requirements of those standards.

List of Standards from the paragraph 1 of this Article shall be defined by the Minister in charge of standardization.

Other Criteria for the Assessment of Product Conformity

Article 8

In the absence of specific regulations referred to in Article 2 of this Act, and/or, standards referred to in Article 7 of this Act, the conformity of a product to the general safety requirement shall be assesses by taking into account the following elements:

1) Serbian national standards drawn up on the basis of relevant European standards other than those stated in the list referred to in Article 7 of this Act;
2) other Serbian national standards;
3) recommendations of the Commission, setting guidelines on product safety assessment;
4) product safety codes of good practice in force in the sector concerned;
5) the state of the art and technology;
6) reasonable consumer expectations concerning safety.

Protective Clause

Article 9

The competent authority shall take appropriate measures according to the competencies given by this Act and other laws (hereinafter: competent authority) where there is evidence that the product is dangerous despite its conformity with the safety requirements set forth in specific regulations referred to in Article 2 of this Act, and/or the criteria for the assessment of product conformity set forth in Articles 7 and 8 of this Act**.**

III. OBLIGATIONS ON PRODUCERS AND DISTRIBUTORS

Obligations on Producers

Article 10

Within the limits of their respective activities producers shall provide consumers and other users the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.

The presence of warnings referred to in previous paragraph does not exempt the producer from compliance with the other requirements laid down in this Act and other regulations.

Within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

1) analyze and assess the risks which these products might pose in a timely manner;
2) warn the consumers and other users about the risks that have been assessed and/or identified;
3) withdraw the product from the market or recall it from consumers in order to prevent or reduce the risk to the level considered to be acceptable in compliance with item 3) of Article 4 of this Act.

The actions and measures referred to in paragraph 3 of this Article must include in particular:

1) an indication (on the product or its packing) of the identity and details of the producer and the product reference or the batch of products (series of products, batch charge, etc.);
2) in all cases where necessary, carrying out of sample testing of marketed products, investigating and keeping a register of complaints and keeping distributors informed of such actions.

Action such as that referred to in paragraph 3, items 2) and 3) and paragraph 4 of this Article shall be undertaken by the producers at their discretion or at the request of the competent authority.

Recall shall take place by the producer at his discretion when the producer finds other measures not sufficient to prevent or minimize the risks involved. Recall may be carried out within the framework of codes of good practice on the matter concerned, where such codes exist in the Republic of Serbia.

Obligations on Distributors

Article 11

Distributors shall be required - within the limits of their respective activities - to act with due professional care to help to ensure compliance with the applicable safety requirements by:

1) supplying or making available only the products which they know or should have persumed – on the basis of information in their possession and of their professional activity – are safe;
2) tracking and passing on the information on product risks;
3) keeping and providing the documentation necessary for tracing the producer’s identity and the origin of products;
4) cooperating in the action taken by producers and the competent authorities to prevent, avoid and minimize the risk to the level considered to be acceptable in compliance with item 3) of Article 4 of this Act.

Mutual Obligations on Producers and Distributors

Article 12

Where producers and distributors as professionals know, on the basis of the information in their possession, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately notify the competent inspection authority to that effect.

The notification referred to in the paragraph 1 shall be submitted in writing and shall contain, in particular:

1) the details, enabling exact identification of the product or the batch it belongs to (series of products, batch charge, etc.);
2) complete details of risks posed by the product concerned;
3) all information available, necessary for tracing the product;
4) all the details of action taken to prevent risk to the consumer.

At the request of the competent authority the producers and distributors shall be obliged to cooperate in implementation of the actions and measures - necessary to avoid the risks posed by products which they supply or have supplied.

If the producers or the distributors fail to submit the notification referred to in paragraph 1 of this Article, or if they do not act in accordance with the request referred to in paragraph 3 of this Article, the competent authority shall take the required action according to the competencies set forth by this Act or other regulations.

The Minister in charge of trade (hereinafter: the Minister) shall prescribe the content of the request referred to in paragraph 3 of this Article.

IV. INFORMATION PROCEDURE AND THE EXCHANGE OF INFORMATION

Public Disclosure of Information

Article 13

Information obtained by the competent authority relating to the risk to consumers and other users health and safety posed by products, shall be disclosed to the public, regardless of being deemed professional secrecy by regulation or other act.

The competent authority is obliged to disclose to the applicant the information of public interest referred to in paragraph 1 of this Article, at his request; it shall contain in particular the details of product identification, the nature of the risks related to its use and the measures and actions taken by the competent authority, producer, or distributor, aimed at prevention or minimization of risk to the level considered to be acceptable.

The information about the measures and actions taken by the producer and/or distributor referred to in paragraph 2 of this Article, shall not be disclosed to the general public if the information refers to scientific or technological solution deemed professional secrecy.

Unless otherwise determined by this Act, the law on citizens' free access to public information shall apply to exercising the right referred to in paragraphs 1 and 2 of this Article.

Exchange of Information

Article 14

With respect to the products presenting serious and other risks to the health and safety of consumers and other users, the competent authority shall use the system of the rapid exchange of information, in particular when it:

1) orders withdrawal or recall of the product presenting a serious risk;

2) takes and recommends, or coordinates taking the appropriate risk-related actions and measures by the producer or distributor;

3) is aware that the producer and distributor intend to implement appropriate action in order to remove or minimize the risk posed by the product that has been placed on the market.

The Government shall, at the proposal of the ministry in charge of trade, specify the establishment and operation of the system for the rapid exchange of information and appoint the competent authority in charge of collection and dissemination of the information referred to in paragraph 1 of this Article.

Article 15

The competent authority for collection and dissemination of the information referred to in paragraph 2 of Article 14 of this Act shall notify the Commission through RAPEX of the serious risk posed by a dangerous product and of the measures that have been taken insofar. It shall also specify the reasons for adoption, modifications or withdrawal of such measures.

If the competent authority referred to in paragraph 1 of this Article considers that the effects of the risk do not or cannot go beyond the territory of the Republic of Serbia, it shall notify the Commission of the measures taken insofar as they are likely to be of interest to other states and in particular if they have been adopted in response to the prevention, removal and control of a new risk which has not yet been reported to the Commission in other notifications.

The Government shall prescribe the form and content for the notification of the Commission referred to in paragraphs 1 and 2 of this Article, at the proposal of the Minister in charge of trade.

Implementation of a Commission Decision

Article 16

When for the implementation of a Commission Decision imposing prohibition or restriction of placing on the market and export of a certain product or of a group of products posing serious risk to the health and safety of consumers, a special regulation must be adopted, the Government shall, within 20 days from official publication of the Decision, at the latest, adopt a decree specifying the rules of conduct for producers and distributors with respect to the implementation of a Commission Decision.

V. SURVEILLANCE

Inspection and Customs Surveillance

Article 17

Compliance with the provisions of this Act and regulations passed for its implementation shall be controlled by the ministries within the respective scope of their authority, based on the rules relating to the organization of national administration and the rules defining the respective responsibilities and obligations on the ministries.

The inspection surveillance shall be performed by the ministries referred to in paragraph 1 of this Article through their inspecting officers, based on the rules relating to the organization of national administration and the rules defining the inspection surveillance.

The inspection surveillance of the implementation of the provisions of this Act applicable to the products of fraudulent appearance shall be performed by the Ministry of Health through its inspecting officers.

The competent customs authorities shall suspend release/import of the products and/or the batches/series of products which are not accompanied with the legally required documents or are not adequately marked to ensure compliance with the applicable safety requirements.

If the competent customs authority finds that in spite of the existence of documents and markings referred to in paragraph 4 of this Article, individual product shows certain characteristics causing reasonable doubt that they may pose serious risk to consumer's and other user's health and safety, it shall immediately notify the competent inspection authority.

The notification referred to in paragraph 5 of this article shall contain in particular the information enabling exact identification of the product or the batch it belongs to (series of products, batch charge, etc.), producer, importer, end user of imported product, detailed description of any risks inherent in the product and information important for tracking the product.

In clearing the goods, the competent customs authority shall temporarily suspend the clearing procedure if it finds that there is a reasonable doubt of clearing a product of fraudulent appearance, and immediately notify the competent inspecting officer who shall within 24 hours upon being notified, carry out the inspection surveillance and find out whether the product is of fraudulent appearance.

The competent customs authority shall not allow export or import of the product, referred to in Article 6 of this Act, if the competent inspecting officer found it is the product of fraudulent appearance and banned on its import or export.

If, within the timeframe specified in paragraph 7 of this Article, the competent inspecting officer fails to find that the product is of fraudulent appearance, the competent customs authority shall continue with clearing procedure and release the product.

Measures Taken by the Inspection Authorities

Article 18

In addition to the powers to take appropriate measures based on other rules, the competent inspecting officers shall be entitled to take the following measures:

1) for any product:
   (1) to organize appropriate checks on its properties affecting safety; such checks shall be carried out on an adequate scale up to the final stage of use or consumption;
   (2) to require all necessary information from the producers, distributors or other persons;
   (3) to take samples of products and subject them to safety checks;
2) for any product that could pose risks in certain conditions:
   (1) to require that it be marked with suitable, clearly worded and easily comprehensible warnings in the language that is officially used in the Republic of Serbia, on the risks it may present;
   (2) to make its marketing subject to prior conditions so as to make it safe;
3) for any product that could pose risks for certain persons, to order that they be given warning of the risk in good time in an appropriate form, including the publication of special warnings in the media;
4) for any product that could be dangerous, for the period needed for the various safety evaluations, checks and controls, temporarily to ban its distribution, display and offer;
5) for any dangerous product, to ban its offer to distribution, display and offer, and introduce the accompanying measures required to ensure the ban is complied with;
6) for any dangerous product already on the market:

(1) to order or organize its immediate withdrawal and alert consumers and other users to the risks it presents;

(2) to order or coordinate and, if appropriate, organize with producers and distributors its recall from consumers and/or other users, including the forcefull recall, and its destruction in suitable conditions and at the expense of producers or distributors;

7) for any product of fraudulent appearance, to ban its manufacturing, import export or placement on the market.

Recall of the product, referred to in subitem (2) of item 6) of paragraph 1 of this Article, shall take place only when other measures and actions referred to in Articles 10, 11, 12 and 18 of this Act, taken by the producer and distributor, volunitarily or upon the order of the competent inspecting officer, are not sufficient to prevent the risks involved.

If the product is found to be unsafe, all costs of surveillance shall be covered by the producer.

Appeals against the administrative decision of the competent inspecting officer imposing the measure referred to in paragraph 1 of this Article shall be lodged to the minister in charge, within eight days from the day when the administrative decision has been served.

Appeals against the administrative decision on banning import or export of the products of fraudulent appearance referred to in item 7), paragraph 1 of this Article shall be lodged to the minister in charge of health within two days from the day when the administrative decision has been served.

The ministry in charge of health shall decide on the appeal referred to in paragraph 5 of this Article within two days from the day when the appeal has been served.

Appeals against the administrative decision referred to in paragraphs 5 and 6 of this Article shall not suspend the enforcement of the administrative decision.

Proportionality and Precautionary Principles

Article 19

When taking measures referred to in paragraph 1 of Article 18 of this Act, in particular those referred to in items 4), 5) и 6), the competent inspecting authorities shall act in such a way as to implement the measures in a manner proportional to the category and type of risk and its seriousness (the proportionality principle).

The competent inspecting officer may implement the measures referred to in paragraph 1 of Article 18 of this Act when there is no conclusive scientific evidence pertaining to the risk the product can pose, regardless whether the effects of that risk are immediate or delayed, where there are initial, and not conclusive, results of scientific research indicating the seriousness of risks and possible effects on the health and lives of consumers and other users (the precautionary principle).

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Article 20

The measures referred to in paragraph 1 of Article 18 of this Act to be taken by the competent inspecting officer shall be addressed, as appropreate, to the producer, distributor and/or other persons where necessary.

The competent inspecting officer can take several measures referred to in paragraph 1 of Article 18 of this Act, at the same time.

Obligation to Cooperate in Monitoring

Article 21

The competent authorities shall be obliged to cooperate in the surveillance with respect to the implementation of this Act.

VI. PENAL PROVISIONS

Major Infringements

Article 22

A fine of 500,000.00 to 3,000,000.00 RSD shall be imposed on a legal person – producer for:

1) placing on the market a dangerous product (Article 5);
2) manufacturing, importing, exporting or placing on the market a product of fraudulent appearance (Article 6);
3) not undertaking measures and actions that enable withdrawal of the product from the market or recall from customers in order to prevent or minimize the risk to the level considered to be acceptable (item 3), paragraph 3, Article 10).

A fine of 50,000.00 to 200,000.00 RSD shall be imposed on the responsible person of the legal person – producer, for the infringement referred to in paragraph one of this Article.

Article 23

A fine of 300,000.00 to 3,000,000.00 RSD shall be imposed on a legal person – distributor for:

1) importing, exporting or placing on the market a product of fraudulent appearance (Article 6);
2) supplying or making available a product that is inconsistent with item 1) of Article 11 of this Act;

A fine of 50,000.00 to 200,000.00 RSD shall be imposed on the responsible person of the legal person – distributor, for the infringement referred to in paragraph 1 of this Article.

Other Infringements

Article 24

A fine of 100,000.00 to 1,000,000.00 RSD shall be imposed on any legal person – producer for:

1) not providing consumers and other users with the relevant information/warning to enable them to assess the risks inherent in a product and to protect themselves against such risks (paragraph 1 of Article 10 1);
2) not undertaking measures and actions referred to in items 1) and 2) of paragraph 3 of Article 10 of this Act;
3) not providing the competent authority with the notification referred to in paragraph 1 of Article 12 of this Act and not cooperating with the competent autorities upon their request referred to in paragraph 3 of Article 12 of this Act.

A fine of 20,000.00 to 50,000.00 RSD shall be imposed on the responsible person of the legal person – producer for the infringement referred to in paragraph one of this Article.

A fine of 100,000.00 to 500,000.00 RSD shall be imposed on the entrepreneur - producer for the infringement referred to in paragraph one of this Article.

A fine of 10,000.00 to 50,000.00 RSD shall be imposed on the natural person - producer for the infringement referred to in paragraph one of this Article.

Article 25

A fine of 100,000.00 to 1,000,000.00 RSD shall be imposed on any legal person – distributor for:

1) not tracking and passing on the information about product risks (item 2) of Article 11);

2) not keeping and providing the documentation necessary for tracing the producer's identity and the origin of products (item 3) of Article 11);

3) not cooperating in the action taken by producers and competent authorities to prevent, avoid and minimize the risk to the level considered to be acceptable (item 4) of Article 11);

4) not providing the competent authority with the notification referred to in paragraph 1 of Article 12 and not cooperating with the competent autorities upon their request referred to in paragraph 3 of Article 12 of this Act.

A fine of 20,000.00 to 50,000.00 RSD shall be imposed on the responsible person of the legal person – distributor for the infringement referred to in paragraph one of this Article.

A fine of 100,000.00 to 500,000.00 RSD shall be imposed on the entrepreneur - distributor for the infringement referred to in paragraph one of this Article.

A fine of 10,000.00 to 50,000.00 RSD shall be imposed on the natural person - distributor for the infringement referred to in paragraph one of this Article.

Statute of Limitation for Bringing Summary Proceedings

Article 26

The infringement procedure may not be initiated upon the expiration of three years from the day the infringement was committed.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 27

The legal act referred to in paragraph 5 of Article 12 of this Act shall be issued by the minister within three months from entering into force of this Act.

The legal act referred to in paragraph 2 of Article 14 of this Act shall be issued by the Government within three months from entering into force of this Act.

The legal act referred to in paragraph 3 of Article 15 of this Act shall be issued by the Government within 30 days from the date of the accession of the Republic of Serbia to the RAPEX system.

Article 28

As of the date of the accession of the Republic of Serbia to the European Union, the wording of sub-item (1), item 7), Article 4, of this Act: "registered with the competent authority in the Republic of Serbia", shall mean "registered in the European Community", and the wording "have the residence in its territory", shall mean "have the residence in the European Community", and the wording of sub-items (2) and (3): "is not registered with the competent authority in the Republic of Serbia", shall mean: "is not registered in the European Community",

while the wording: “does not have residence in its territory”, shall mean: “does not have residence in the European Community”.

Article 29

This Act shall enter into force on the eight day from its publication in the Official Gazette of the Republic of Serbia and shall be applicable six months upon becoming effective.

The provision of Article 15 of this Act shall be applicable as of the date of the accession of the Republic of Serbia to the RAPEX system, and the provision of Article 16 of this Act shall be applicable as of the date of the accession of the Republic of Serbia to the European Union.