

GENERAL PRODUCT SAFETY ACT

12.11.2003

I. GENERAL PROVISIONS

Article 1

(content and purpose of this Act)

(1) This Act shall lay down requirements to be met by the products to be placed on the market, the obligations of producers and distributors, the content and the methods of providing information to the European Union, as well as the types of product safety surveillance; it shall also regulate establishing of the Advisory Board and its tasks in the area of general product safety. Thus this Act partially transposes the content of EC Directive on general product safety (2001/95/EC) and it completely transposes the content of EEC Directive concerning products which, appearing to be other than they are, endanger the health or safety of consumers (87/357/EEC).

(2) The purpose of this Act is to ensure that only safe products are placed on the market.

Article 2

(relation to other regulations)

(1) This Act shall apply to the products not covered by other specific regulations harmonized with the European Community law and aimed at ensuring safety of products.

(2) Where the products are covered by the regulations, referred to in previous paragraph, this Act shall apply in its entirety to the aspects of risks or categories of risks not covered by those regulations.

The provisions of items 2 and 3 of Article 4 and Articles 5 to 8 of this Act shall not apply to the aspects of risks or categories of risks covered by those regulations. Other provisions of this Act shall apply if

the regulations referred to previously do not include equivalent provisions.

(3) Fulfilment of the requirements of this Act shall not affect the responsibility of the producers or distributors with regard to defective products pursuant to the regulations relating to their liability for the products and/or to the general regulations relating to contractual obligation.

Article 3

(publicity principle)

(1) Information available to the competent authorities relating to risks to consumer health and safety posed by products, shall be available to the public. The competent authorities are obliged to supply the applicant with such information of public interest 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 taken.

(2) Without prejudice to the previous paragraph, the information covered by professional secrecy according to valid regulations, shall not be disclosed to the general public. Pursuant to this Act the information related to the safety characteristics of the products shall not be deemed professional secrecy and shall be disseminated to the general public to ensure protection of the consumers health and safety.

(3) Protection of professional secrecy referred to in previous paragraph shall not prevent the dissemination of information between various competent authorities in the Republic of Slovenia or between the competent authorities in Slovenia and the competent authorities in the EU Member States (hereinafter referred to as the Member States) and the Commission of the European Union (hereinafter referred to as the Commission). The competent authorities in the Republic of Slovenia 12.11.2003 having received an information declared as professional secrecy, shall ensure the protection of such information.

Article 4 (definitions)

For the purposes of this Act:

1. "product" shall mean any product - including products in the context of providing a service - which is supplied or made available 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. "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 persons, taking into account in particular:

- 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 reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any 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 constitute grounds for considering a product to be “dangerous” ;

3. “dangerous product” shall mean any product which does not meet the definition of “safe product” in previous item;

4. “products appearing to be other than they are” shall mean any products which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size resembling foodstuffs (e.g. a perfumed rubber) such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be dangerous to their health and life by causing suffocation, poisoning, the perforation or obstruction of the digestive tract;

5. “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;

6. “producer” shall mean:

- the manufacturer of the product, when he is established in the European Union and any other legal 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;

– the manufacturer's representative, when the manufacturer is not established in the European Union, or if there is no representative established in the European Union, the importer of the product;

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

7. "distributor" shall mean any legal or natural person, professionally included in the supply chain

whose activity does not affect the safety properties of a product;

8. "recall" shall mean any measure aimed at achieving permanent or temporary return of a dangerous

product that has already been supplied or made available to consumers by the producer or

distributor; 12.11.2003

9. "withdrawal" shall mean any measure aimed at preventing the distribution, display and offer of a

product dangerous to the consumer.

10. "RAPEX" shall mean the European Union rapid information system.

II. SAFETY REQUIREMENTS

Article 5

(restriction and prohibition)

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

(2) The manufacture, import, export or placing on the market of the products appearing to be other

than they are presenting danger to the consumers, especially children, shall be prohibited.

Article 6

(compliance with the regulations and standards published)

(1) A product shall be deemed safe as far as the aspects or risk categories are concerned, which are

covered by special regulations not harmonized with the European Community law, which are aimed at

ensuring safety of products, provided that it conforms to the respective health and safety

requirements of those regulations.

(2) A product shall be presumed safe as far as the risks and risk categories covered by relevant

Slovenian national standards drawn up on the basis of European standards are concerned, the

references of which have been published as specified in paragraph 3 of this Article, when it meets the

requirements of those standards.

(3) In the Official Gazette of the Republic of Slovenia the minister in charge of economy (hereinafter referred to as the Minister) shall publish the references of the standards applied to establish presumption of safety of a product.

Article 7

(other safety assessment criteria)

In the absence of the regulations or standards referred to in previous article, the conformity of a

product to the requirements of this Act shall be assessed by taking into account the following elements:

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

Article 8

(measures taken by the inspecting authority) 12.11.2003

(1) The competent inspecting authority referred to in Article 17 of this Act shall take appropriate measures to impose restrictions on placing the product on the market or to require its withdrawal

from the market or recall where there is evidence that despite its conformity with the criteria

referred to in Articles 6 and 7 of this Act it is dangerous to consumers safety and health.

(2) 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 of the

Republic of Slovenia shall, within 20 days from official publication of the Decision, at the latest,

adopt a decree specifying the rules of conduct for producers or distributors.

In their monitoring the

implementation of the Decree the competent inspecting authority shall have all the powers as

defined in Article 17 of this Act.

III. OBLIGATIONS OF PRODUCERS AND DISTRIBUTORS

Article 9

(provision of warnings)

(1) Within the limits of their respective activities producers shall provide consumers 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.

(2) The presence of warnings referred to in previous paragraph does not exempt any person from compliance with the other requirements laid down in this Act and in adequate regulations based on this Act.

Article 10

(other obligations of producers)

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

- ensure the information of risks which these products might pose;
- choose to take appropriate action aimed at avoiding these risks, which may include adequate and effective warning of consumers, withdrawal of the product from the market or recall from consumers.

(2) The measures referred to in the previous paragraph must include in particular:

- an indication (on the product or its packaging) of the identity and details of the producer and the product reference or the batch of products, unless it is justified for such indication to be omitted ;
- 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.

(3) Action such as that referred to in the second indent of the first paragraph of this article shall be undertaken by the producers at their discretion or at the request of the competent inspecting authority referred to in Article 17 of this Act.

(4) Recall shall take place only, when the producers or the competent inspecting authority find other measures not sufficient to prevent the risks involved. Recall may be effected within the framework of codes of good practice on the matter concerned, where such codes exist.

Article 11

(obligations of distributors) 12.11.2003

(1) 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. In particular they must not supply products which they know or should have presumed – on the basis of information in their possession and of their professional activity – do not comply with those requirements.

(2) Within the limits of their respective activities the distributors shall participate in monitoring the safety of products placed on the market by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products and cooperating in the action taken by producers and the competent national authorities to avoid the risks.

Article 12

(obligation to provide information)

(1) 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 inform the competent inspection authority to that effect.

(2) If the producers and the distributors assess that serious risks are involved, the information referred to in the previous paragraph shall at least contain:

- the details, enabling exact identification of the product or the batch it belongs to;

- complete details of risks posed by the product concerned;
- all information available, necessary for tracing the product;
- all the details of action taken to prevent risk to the consumer.

(3) The Minister shall prescribe the form and content for the notifications referred to in this article.

Article 13

(obligation to cooperate)

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

(2) If within the reasonable time, which, as a rule, shall not exceed 10

working days from the request for cooperation, the producers or the distributors do not take adequate action aimed at completion of their obligations, the competent inspecting authority shall immediately take the required action referred to in paragraph 3 of Article 17 of this Act.

IV. PROVIDING INFORMATION TO THE EU

Article 14

(informing the Commission)

(1) Where the competent inspecting authority takes measures which restrict the placing on the market of products, requires their withdrawal or recall as provided for in Article 17 of this Act, it shall after informing the ministry in charge of general safety of products (hereinafter referred to as the Ministry) 12.11.2003

inform the Commission of the measures taken, specifying its reasons for adopting them. It shall also inform the Commission of any modification or withdrawal of such measures.

(2) If the competent inspecting authority considers that the effects of the risk do not or cannot go beyond the territory of the Republic of Slovenia, it shall inform the Commission of the measures taken insofar as they are likely to be of interest to other Member States and in particular if they have been adopted in response to a new risk which has not yet been reported in other notifications.

(3) The information pursuant to the first and second paragraphs of this article shall be provided, unless such information has been given pursuant to Article 15 of this Act or under other regulations covering product safety requirements.

Article 15

(notification through RAPEX)

(1) Where with respect to the products presenting serious risk the competent inspection authority adopts or recommends adequate measures or agrees with producers and distributors to adopt measures or actions to prevent, restrict or comply with specific conditions on the marketing or use of

such products, it shall after informing the Ministry immediately notify the Commission through iRAPEX of the measures and actions adopted. It shall also inform the Commission of any modification or withdrawal of any such measures or voluntary actions.

(2) If the competent inspection authority considers that the effects of the

identified serious risk do not or cannot go beyond the territory of the Republic of Slovenia, it shall notify the Commission of the adopted measures insofar as they are likely to be of interest to other Member States, and in particular if they have been taken in response to a new risk which has not yet been reported in other notifications.

(3) Without prejudice to the first paragraph of this article before deciding to adopt adequate measures or to take voluntary action the competent inspection authorities may pass on to the Commission any information in their possession regarding the existence of a serious risk.

Article 16

(governmental regulation)

The Government of the Republic of Slovenia shall specify the form and content of the notifications referred to in Articles 14 and 15 of this Act.

V. SURVEILLANCE

Article 17

(inspection surveillance)

(1) Compliance with the provisions of this Act shall be controlled by the inspection authorities within the limits of their responsibilities for individual types of products based on the rules relating to the organization of national administration or on other rules defining their respective responsibilities and obligations.

(2) The implementation of the provisions of this Act applicable to the products of fraudulent appearance, shall be monitored by the Health Inspectorate of the Republic of Slovenia. 12.11.2003

(3) In addition to the powers to take appropriate measures based on the rules referred to in the first paragraph of this article, for the purposes of this Act the competent inspecting officers shall be entitled to take the following measures:

(a) for any product:

- to organize, even after its being placed on the market as being safe, 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;
- to require all necessary information from the producers or distributors;
- to take samples of products and subject them to safety checks;

- (b) for any product that could pose risks in certain conditions:
- to require that it be marked with suitable, clearly worded and easily comprehensible warnings in the Slovenian language 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 risks 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 in the media;
- (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 marketing and introduce the accompanying measures required to ensure the ban is complied with;
- (f) for any dangerous product already on the market:
- to order or organize its immediate withdrawal and alert consumers to the risks it presents;
 - to order or coordinate and, if appropriate, organize with producers and distributors its recall from consumers and its destruction in suitable conditions;
 - to order delivery of the type of product, the sample of which has caused damage; the product must be delivered in unchanged condition with respect to the sample in dispute
- (4) When taking measures, in particular those referred to in items (d) to (f) of the previous paragraph, the competent inspecting authorities shall act in such a way as to implement the measures in a manner proportional to the seriousness of the risk and taking due account of the state of the art in view of possible direct or indirect risks to the health and safety of consumers, which have immediate or delayed effects (the precautionary principle).
- (5) When the competent inspecting authority is not provided with adequate know-how or equipment required for carrying out the checks and inspections referred to in paragraph 3 of this article, it shall entrust the performance of such professional actions within the limits of the surveillance activity to a qualified institution or individual.
- (6) Appeals against the administrative decision imposing the measures referred to in paragraph 3 of this article or the measures referred to in Article 8 of this Act shall not

suspend the enforcement of the administrative decision. The appeals against the administrative decision shall be lodged within eight days from the day when they have been served.

Article 18

(addressees of the measures taken by the inspection authorities)

The measures to be taken by the competent inspection authorities under the previous article shall be addressed, as appropriate, to:

- the producer; 12.11.2003
- the distributors within the limits of their respective activities and in particular the distributor responsible for the first stage of distribution in the territory of the Republic of Slovenia;
- other legal or natural persons, where necessary, with a view to cooperation in action taken to avoid risks arising from a product.

Article 19

(customs surveillance)

(1) In clearing the goods and implementing other actions within the limits of their responsibilities,

before releasing the products to the market, the Customs Authorities shall suspend release of the

products and/or the batches/series of products in question for three working days and immediately

inform the competent inspection authority to that effect, if they find:

- that individual products or batches of products show certain characteristics causing reasonable

doubt that they may pose serious risk to consumer health and safety when placed on the market

and used under stipulated or reasonably foreseeable conditions;

- that individual products or batches/series of products are not accompanied with the legally required

documents or are not adequately marked or that the stipulated mark is affixed unjustifiably. ,

(2) When within three working days the competent inspection authority does not implement any of the

measures referred to in Article 17 of this Act or if within this time they do not inform the Customs

Authorities of the implementation of such measures, the latter shall release the product or the batch of

products, the release of which was suspended, provided that all other conditions for its release have

been met.

VI. ADVISORY BOARD

Article 20

(the Advisory Board)

(1) At the Ministry the Advisory Board shall be established to deal with the issues related to the general product safety.

(2) The Advisory Board shall include the representatives of the competent administrative authorities, interested consumers organizations, entrepreneurial chambers and associations, as well as eminent experts in the field of technical safety of products and consumer protection.

(3) The Advisory Board shall address any notifications sent or received pursuant to Chapter IV of this Act and propose adoption of adequate measures aimed at elimination or reduction of risks related to products. For this purpose it shall in particular enhance and support voluntary actions of producers and distributors in ensuring the product safety and shall participate in forming codes of good practice in individual product safety areas.

(4) The number of members and the composition of the Advisory Board shall be specified by the minister.

VII. PENALTY PROVISIONS

Article 21

(major infringements) 12.11.2003

(1) A fine of 500,000 SIT to 10,000,000 SIT shall be imposed on any legal person or proprietorship for:

- placing on the market a dangerous product (paragraph 1 of Article 5);
- manufacturing, importing, exporting or placing on the market a product of fraudulent appearance (paragraph 2 of Article 5);
- not providing consumers with the relevant information to enable them to assess the risks inherent in a product and to protect themselves against such risks (paragraph 1 of Article 9);
- not adopting measures commensurate with the characteristics of the products (paragraph 1 of Article 10);
- supplying products which they know or should have presumed do not comply with safety requirements (paragraph 1 of Article 11).

(2) A fine of 50,000 SIT to 500,000 SIT shall be imposed on the responsible person of the legal person or of the proprietorship for the infringement referred to in the previous

paragraph.

Article 22

(other infringements)

(1) A fine of 250,000 SIT to 5,000,000 SIT shall be imposed on a legal person or a proprietorship for:

- not providing information on product risks, not keeping or providing the documentation necessary for tracing the origin of products or not cooperating in the action taken by producers and the competent national authorities to avoid the risks (paragraph 2 of Article 11),

- not informing the competent inspection authorities that a product that they have placed on the market poses risks to the consumer that are inconsistent with the general safety requirement (paragraphs 1 and 2 of Article 12),

(2) A fine of 25,000 SIT to 250,000 SIT shall be imposed on the responsible person of the legal person or of the proprietorship for the infringement referred to in the previous paragraph.

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 23

(time frame for issuing regulations)

(1) The implementing regulations referred to in paragraph 3 of Article 12 and in Article 16 of this Act shall be issued within three months from entering into force of this Act.

(2) The legal act referred to in paragraph four of Article 20 of this Act shall be issued by the minister within six months from entering into force of this Act.

Article 24

(completion of inspection authorities procedures)

The procedures of inspecting authorities started before entering into force of this Act, shall be completed pursuant to the regulations valid before its entering into force.

Article 25

(expiration of validity and application of the regulations) 12.11.2003

(1) As from the date of entry into force of this Act the General Safety of Products Act (U.1 RS 23/99) and the Rules governing products appearing to be other than they are (U.1. RS 5/00) shall cease to be valid.

(2) Until the commencement of the application of this Act provisions of the regulations referred to in the previous paragraph shall apply.

Article 26

(application of fines and imposing penalties)

(1) The amounts of fines specified in Articles 21 and 22 of this Act shall be applied at the commencement of the application of General Offences Act (U.1. RS 7/03).

(2) Until the time specified in the previous paragraph penalties shall be imposed as follows:

1. for the infringements referred to in Article 21 of this Act:

a fine of 500,000 SIT to 5,000,000 SIT shall be imposed on legal persons or proprietorships,

a fine of 50,000 SIT to 500,000 SIT shall be imposed on the responsible person of the legal person;

2. for the infringements referred to in Article 22 of this Act:

a fine of 250,000 SIT to 2,500,000 SIT shall be imposed on legal persons or proprietorships,

a fine of 25,000 SIT to 250,000 SIT shall be imposed on the responsible person of the legal person.

Article 27

(bringing into force and commencement of application of this Act)

This Act shall enter into force on the fifteenth day from its publication in the Official Gazette of the

Republic of Slovenia and shall be applicable as from the date of the accession of the Republic of Slovenia to the European Union.

Done in Ljubljana, on