

LAW ON PRODUCT SAFETY

(Directive 2001/95/EC)

GENERAL PROVISIONS

Contents Article 1

With this Law shall regulate the general product safety requirements, the manner of prescribing the technical regulations and principles of mutual recognition of the documents and conformity marks of foreign origin.

Objective Article 2

The purpose of this Law shall be safety of products when placed on the market, put into service or in use, in particular concerning:

- providing and protection of the public interest;
- protection of the life and health of people, animals and plants and
- environment and nature protection, and consumer and other users protection, and protection of the property.

Application and Relation with other Regulations Article 3

(1) This Law shall only apply to non-food products.

(2) The provisions of this Law regarding prescribing the requirements and implementation of procedures of the conformity assessment shall not apply to the products regulated by other specific laws, except for the provisions referred to in Articles 24, 25, 26, 28, 29, 30 and 31 of this Law, unless otherwise is determined by a specific law.

(3) This Law shall not apply to products produced in the Republic of Macedonia or in the European Union, and are intended for export in non-Member States or countries that are not members of the European Economic Area (hereinafter referred to as: the EEA).

Principle of Publicity Article 4

(1) The data available to the competent authorities referred to in Article 33 paragraphs (2) and (3) of this Law, relating to health hazard and consumer and other user protection shall be public. The competent authorities shall be bound, upon the request of the interested legal and natural persons, to submit all necessary detailed information describing a particular product, the types of hazards related to its use as well as the measures adopted in accordance with the regulations regarding information access.

(2) As an exception from paragraph (1) of this Article, the data that according to the regulations on information access are not public, must not be disclosed.

(3) **Professional** secret, within the meaning of this Law, may not refer to information concerning the safety product characteristics that must be disclosed to the public in order to protect the health and safety of the consumers and other users and to protect the public interest.

(4) Keeping **of the professional** secret may not impede the transmission of information among the competent authorities in the Republic of Macedonia and among the competent authorities of the EU Member States and the Commission of the European Union. The competent authorities in the Republic of Macedonia having received information, designated as **professional** secret, shall be bound to provide its protection according to the law.

Acts Regulating Relations and Action

Article 5

(1) The Government of the Republic of Macedonia shall prescribe in details the manner of information exchange with the European Commission on to the measures adopted by the competent **state** inspection bodies regarding market restriction of products determined to threaten the health of the consumers and other users or any other justified interest by their use.

(2) When the European Commission shall reach a decision prohibiting, i.e. restricting the putting into circulation of a product, or prohibiting the export of a particular product or a group of products which represent a serious hazard, the Government of the Republic of Macedonia shall prescribe the manner of undertaking action of the manufacturers, i.e. distributors to execute the decision.

PART I

GENERAL PRODUCT SAFETY

CHAPTER I

EXPRESIONS USED AND RELATION WITH OTHER REGULATIONS

Definitions

Article 6

(1) Particular expressions used in this Law shall have the following meaning:

a) "user" shall mean a consumer, employee or employer;

b) "consumer" shall mean any natural person purchasing or using products or services for his/her own direct consumption for purpose not intended for his profession or for other business activities; and

c) "manufacturer" shall mean:

- the manufacturer of a product, when it had a seat in the Republic of Macedonia or in the European Community, or any legal or natural person representing himself/herself as a manufacturer, and applying its name, trade mark or other specific label on the products, or a person repairing the product,

- the manufacturer's representative, when the manufacturer does not have a seat in the Republic of Macedonia or in the European Community, or when it has not established a representative office in the Republic of Macedonia or in the European Community, the importer of the product; and

- other legal or natural person, who is professionally engaged in the supply chain as long as its activities may affect the product safety.

d) “competent state inspection bodies” are the State Market Inspectorate, State Labour Inspectorate, State Sanitary and Health Inspectorate, State Inspectorate for Technical Inspection, State Environment Inspectorate, Agency for Electronic Communications and other competent state inspection bodies in the field of transport and communications, Directorate for Protection and Salvage and other state inspection bodies,

(2) Particular expressions used in this part of the Law shall have the following meaning:

a) “product” shall mean any product included within service provision, which is intended for the consumers or is likely that, according to reasonably foreseeable conditions, it shall be used by the consumers, even though it is not intended for them, and it is purchased or available free of charge or not, within the frames of commercial activities, and whether new, used or repaired.

This expression shall not apply to second hand products in form of antiquities, or to products to be fixed or repaired before their use, assuming that the person to whom it is delivered is well informed by the supplier thereof;

b) “safe product” shall mean any product, which in common or reasonable conditions of use including its expiry date, even when applicable, upon the requests for putting in use, installation and maintenance, it does not impose a hazard or is of minimum danger compatible to the use of the product, is considered acceptable and consistent with a high level of protection regarding the safety and health of people, taking into consideration, in particular:

- the product characteristics including its composition, packaging, assembly instructions, and when applicable, installation and maintenance instructions,

- effects on other products, when it is reasonably foreseeable that it shall be used along with other products,

- product presentation, its marks, labelling, any warnings and manuals on usage, throwing away and/or removal, and any other marks or information on the same product; and

- consumer category, in particular children and elderly, who are exposed to hazard during its use.

The possibility to achieve a higher level of safety or availability of other products that have a lower degree of hazard shall not represent a basis to consider it as “hazardous”;

c) “hazardous product” shall mean any product that is not in compliance with the definition “safe product”;

d) “serious hazard” shall mean any serious hazard, including even direct effects, which require rapid intervention by the competent organs of the state administration;

e) “distributor” shall mean any legal or natural person, who as a professional cooperates in the supply chain and whose operation does not affect the safety of the product;

f) “complete withdrawal” shall mean any measure to return the hazardous products to the manufacturer or distributor, which have already been placed on the market or available to the consumers; and

g) “withdrawal” means any measure to prevent the distribution, presentation or offer of the product, hazardous to the consumer.

h) “recall” means any measures whose aim is to return dangerous products that was already distributed or made available to the consumers by the manufacturer or distributor

Application and Relation with other Regulations

Article 7

(1) This part of the Law shall entirely refer to the products determined in Article 6 paragraph (2) a) of this Law.

(2) The provisions provided for in this part of the Law shall apply to the products for which essential requirements exist regarding aspects or types of hazards, determined by the regulations regarding the requirements for products harmonized with the European Union law (hereinafter referred to as: technical regulations), if there are no actual provisions within the technical regulations to ensure product safety.

(3) Provided that the technical regulations regulate essential requirements for safety, this part of the Law shall only apply to those aspects of hazards, i.e. types of hazards that are not covered by those requirements, other than Articles 6 paragraph (1) a) and b) and 37 paragraph (2) of this Law that shall not apply. The other provisions provided for in this part of the Law shall apply, if provisions for this purpose are not provided for in the technical regulations.

CHAPTER II

GENERAL SAFETY REQUIREMENTS

Restriction and Prohibition

Article 8

Manufacturers shall be bound to put on the market only safe products.

Harmonization with Regulations and Published Standards

Article 9

(1) The products shall be considered safe if some aspects of hazard, i.e. types of hazard are regulated by specific regulations, whereas those regulations are not part of the harmonized area of the European Community and whose purpose is to ensure product safety, provided they meet health and safety conditions laid down by those regulations.

(2) A product shall be considered safe if the hazards or types of hazards are covered by appropriate national standards drawn up on the basis of the European standards and published in the list of standards referred to in paragraph (3) of this Article, and it is compatible with the general safety requirements provided for in those standards.

(3) The list of standards, whose application shall mean that the product is safe, shall be published by the Minister of Economy in the Official Gazette of the Republic of Macedonia.

Other Safety Measures

Article 10

In the cases when the regulations i.e. standards referred to in Article 9 paragraphs (1) and (2) of this Law do not exist, the conformity of the product with the general safety requirements shall be determined on the basis of:

- a) voluntary national standards prepared on the basis of the relevant European standards, and are not included in the list of standards referred to in Article 9 paragraph (3) of this Law;
- b) standards prepared by EU Member States in which the product is placed on the market;
- c) other standards adopted by the Institute for Standardisation of the Republic of Macedonia;
- d) recommendations of the European Commission determining the guidelines for establishing the product safety;
- e) rules of best experience regarding product safety valid in certain areas;
- f) condition of the technique and technology; and
- g) consumers' reasonable expectations regarding product safety.

CHAPTER III

MANUFACTURERS AND DISTRIBUTORS' RESPONSIBILITY

Provision of Manufacturers' Warnings

Article 11

(1) The manufacturers within the frames of their activities shall be bound to provide the consumers with all relevant information enabling them to assess the hazards of the product during the ordinary or reasonably foreseeable period of use and to undertake precaution measures concerning the hazards of the product even where such hazards are not obvious, immediately, without proper warning.

(2) The provision of information referred to in paragraph (1) of this Article shall not absolve the manufacturer from responsibility for conformity to the other requirements laid down in this part of the Law.

Other Manufacturers' Responsibility

Article 12

(1) The manufacturers within the frames of their activities shall be bound to undertake measures appropriate with the product characteristics they purchase, thus enabling:

- 1) to be informed on possible hazards caused by those products; and
- 2) to take certain actions, if necessary to avoid those hazards, including adequate and effective warning, withdrawal from the market or complete withdrawal.

(2) The measures referred to in paragraph (1) of this Article may include:

- a) Stating precise data on the manufacturer (firm, seat and web-site, if any) and on the product, if possible, the lot of the product it belongs to, whereas the data should be stated on the product itself or on its packaging, except in cases when it is justified not to provide such data; and
- b) Checks and testing of the products on the market, in all cases, when appropriate and necessary as well as keeping records on submitted requests and informing distributors on those activities.

Undertaking Measures

Article 13

(1) The manufacturers shall be bound to undertake the measures referred to in Article 12 paragraph (1) item 2 of this Law on their own assessment and need, or on the basis of the decision made by the competent inspection pursuant to Article 36 paragraph (1) item 5 of this Law. Complete withdrawal may be carried out by competent inspections only as a final measure, when it shall be determined that the other measures are not sufficient to prevent the hazard, or when the manufacturers consider it is necessary or upon obligation to do so, as addition to the measures undertaken by the competent inspections.

(2) The withdrawal referred to in paragraph (1) of this Article may be carried out according to the rules of best experience regarding the issue of withdrawal.

Distributors' Responsibility

Article 14

(1) The distributors within the frames of their activities shall be bound to act with the necessary professional care to ensure product conformity with the applicable safety requirements. The distributors may not purchase products for which they are aware or assume, and according to their professionalism and on the basis of the information they possess that the products are not in conformity with the safety requirements.

(2) The distributors within the frame of their activities shall be bound to contribute to monitoring the safety of the products put into circulation, whereas, they shall be bound to forward the information on hazards every product might bear; they are bound to keep and submit the documents necessary for determining the origin of the product and to cooperate regarding the measures undertaken by the manufacturers and the competent state authorities (organs) in order to avoid hazards. Within their operation, the distributors shall be bound to undertake measures to enable effective cooperation.

Obligations on Notification

Article 15

(1) When the manufacturers and distributors are aware or assume, on the basis of information they possess and according to their professionalism, that the product they have put into circulation represents a hazard to the consumer, which is incompatible with the general safety requirements, they shall be bound, within the time period laid down by the regulation referred to in paragraph (2) of this Article, but not later than ten days, to inform the State Market Inspectorate, stating details on the actions undertaken in order to protect the consumers from hazards.

(2) The manner, procedure and time periods for notification as well as the manner, procedure, criteria and methods of assessing the hazard by the manufacturers and distributors and the form and contents of the notification form referred to in paragraph (1) of this Article shall be prescribed by the Minister of Economy.

(3) The regulation referred to in paragraph (2) of this Article shall be published on the web-site of the Ministry of Economy.

(4) The Minister of Economy shall inform the European Commission on the notification referred to in paragraph (1) of this Article in cases when it is determined that the hazard may affect the EU Member States.

Obligation for Cooperation

Article 16

(1) The manufacturers and distributors, within the frames of their activities, shall be bound to cooperate upon the request of the competent inspection bodies regarding all actions undertaken to avoid hazards imposed by the products they purchase or have already purchased.

(2) If the manufacturer or distributor within a reasonable time period, determined by the competent inspection body, but not later than ten days, does not act upon the request for cooperation by the competent authority, and does not undertake all necessary measures to avoid hazards imposed by the products, the competent inspection body shall immediately undertake the measures referred to in Article 36 paragraph (1) of this Law.

CHAPTER IV

PROVIDING INFORMATION TO THE

EUROPEAN UNION

Notification

Article 17

(1) In case when the competent inspection bodies restrict the supply of products or adopt measures imposing product withdrawal or its complete withdrawal pursuant to Article 36 of this law, they shall be bound to notify the Ministry of Economy, stating the reasons for the adopted measures.

(2) The Ministry of Economy shall be bound to inform the European Commission on the measures referred to in paragraph (1) of this Article, and that do not refer to Article 18 of this law, and thereto state the reasons for the adopted measures. The Ministry of Economy shall also be bound to inform the European Commission on any change or termination of the measures.

(3) When the Ministry of Economy considers that the effects of the hazards determined do not have or may not have scope out of the territory of the Republic of Macedonia, it shall inform the European Commission on adopted measures, if they contain information of interest to the EU Member States, from the point of product safety, and in particular provided that those measures have been taken as a response to a new hazard not being covered by other notifications.

(4) The notification in accordance with paragraphs (2) and (3) of this Article shall be forwarded unless notification pursuant to Article 18 of this law has not been forwarded, i.e. in accordance with the technical regulations and other regulations.

(5) The Government of the Republic of Macedonia shall prescribe the contents of the notification in details as well as the procedure for notification referred to in this Article.

Registering through the Rapid Alert System for Non-Food Products which represent a serious hazard

Article 18

(1) Contact point of the Rapid Alert System for Non-Food Products which represent a serious hazard (hereinafter: RAPEX) in the Republic of Macedonia shall be the Ministry of Economy.

(2) In cases when the competent inspection bodies, due to the products which represent a serious hazard, will adopt or plan to adopt measures, or will agree with the manufacturers and distributors on compulsory or voluntary base for prevention, limiting or previously meeting the conditions for placing on the market or putting the products into use, they shall be bound to notify the Ministry of Economy of this.

(3) The competent inspection body shall be bound to notify the Ministry of Economy on time, without delay, on the changes or termination of some measure referred to in paragraph 2 of this Article.

(4) In case of serious hazard the competent inspection body shall be bound to forward the information pursuant to this Article and the voluntary measures provided for in Chapter III of this part of the law, undertaken by the manufacturers and distributors.

(5) The Government of the Republic of Macedonia shall prescribe the contents of the notification in detail, as well as the procedure for notification referred to in this Article.

PART II

MANNER OF PRESCRIBING THE TECHNICAL REGULATIONS

Definitions

Article 19

Some expressions used in the second and third part of this Law shall have the following meaning:

- “product” shall mean any product or a group of products which is a result of separate production activities, is intended for the users, and is closely determined with a technical regulation;
- “conformity assessment procedure” shall mean any procedure that directly or indirectly confirms that the essential requirements to be met by the products are fulfilled;
- “conformity assessment body” shall mean an authorised body performing services for conformity assessment and that may be subject to accreditation;
- “conformity document” shall mean a document confirming that the product, process or service are in accordance with the essential requirements laid down in the technical regulation, and which may be a statement of conformity, certificate of conformity or other document;
- “conformity mark” shall mean a mark that is used or issued in accordance with the rules of the certification system, proving that a particular process, product or service are in conformity with a particular standard or a technical regulation;
- “placing on the market” shall mean an activity with which the products becomes available for the first time in the Republic of Macedonia or in the European Union due to its use or further distribution with or without financial contribution; and
- “put **into service or** in use” shall mean first use of the product by the **final** user in the Republic of Macedonia or in the European Union.
- **“manufacturer” means a natural or legal person who has a seat in the Republic of Macedonia or in the European Community, who designs and manufacturers’ a product or who has such a product designed or manufactured, under his name or trademark and who places it on the market; this includes any legal or natural persons who applies his name, his trademark, or some other distinguishing mark on a product for business purpose and therefore presents himself as the manufacturer, and any person bringing product into circulation after having influences the conformity of a product;**

- “**distributor**” means any natural or legal person in the supply chain other than the manufacturer or the importer, who makes a product available on the market;
- “**importer**” means any natural or legal person who has a seat in the Republic of Macedonia or in the European Community, who imports the product and places it on the market;
- “**recall**” means any measures whose aim is to return dangerous products that was already distributed or made available to the consumers by the manufacturer or distributor
- “**withdrawal**” shall mean any measure aimed at preventing the making available on the market of a product in the supply chain;
- “**non-harmonized area**” means area for which there is not a harmonized regulation in the European Community

Contents of the Technical Regulations Article 20

(1) Technical regulations shall be adopted for particular products intended for the **consumers or other** users, in particular, including at least one of the following **requests**:

- 1) essential requirements to be met by the products;
- 2) the procedure, manner and conditions under which the conformity assessment of the product is carried out according to the prescribed requirements;
- 3) the conditions to be met by the bodies participating in the conformity assessment procedure;
- 4) the type of documents accompanying the product when it is placed on the market or is put in use;
- 5) obligation and manner **of applying a conformity mark** product marking;
- 6) reference to application of standards and other technical specifications;
- 7) form and contents of technical documentation as well as the manner and duration of its keeping;
and
- 8) protective clause and notification procedure.

(2) The technical regulations shall determine the product essential requirements proportional to the product level of risk. Within the technical regulations regarding particular products or a group of products depending on the technical complexity of the product or the group of products, the conformity assessment procedure or an adequate combination of procedures for conformity assessment (modules) may be determined.

(3) The conformity assessment procedures may be **regulated** directly determined by use of **with** the technical regulation, or indirectly with the standards or the technical specifications.

(4) The technical regulations shall be adopted by the Minister for Economy, or by the minister within which competence, laid down by law, fall matters connected with the production, market and putting in use the particular products or groups of products.

Application of Standards Article 21

(1) If the technical regulation **for certain products or group of products** refers to application of national standards, the Minister for Economy, or the minister competent for adoption of technical regulations, shall publish the list of standards in the Official Gazette of the Republic of Macedonia.

(2) The appropriate application of the standards from the List of Standards referred to in paragraph 1 of this Article shall create an assumption on the product's conformity with the essential requirements laid down in the technical regulations, in view of the aspects covered by the standards.

Restriction and Prohibition

Article 22

(1) The products or groups of products for which technical regulations exist, cannot be placed on the market or put in use if they are not in conformity with the prescribed essential requirements **laid down in** the technical regulations, if a conformity assessment has not been carried out according to the prescribed procedure, if they are not marked in a prescribed manner and if they are not accompanied by documents **prescribed** in the technical regulations.

(2) The products or groups of products determined as not being in conformity with the prescribed essential requirements determined by the technical regulations must not be marked with conformity marks and with other marks similar to the conformity marks to the extent of misleading the consumers.

(2) Products or group of products that are not in compliance with the relevant technical regulations must not be marked with conformity marks.

Obligations Arising from the Technical Regulations

Article 23

The technical regulations **prescribe** the products with which placing on the market or putting in use, the manufacturer shall be obliged to:

- 1) ensure application of the conformity assessment procedures **as prescribed in the technical regulations** under the prescribed requirements;
- 2) issue and/or provide a conformity document;
- 3) prepare a technical documentation in a prescribed form and contents and keep it in a prescribed manner and duration;
- 4) apply prescribed conformity marks;
- 5) forward all necessary information on the product conformity, conformity documents and technical documentation upon request from the competent **state** inspection bodies; and
- 6) carry out the **other** tasks laid down in the technical regulations.

Conformity Assessment Bodies

Article 24

(1) The technical regulations on particular products **prescribe** the conditions to be met by the legal persons for carrying out a conformity assessment, and which in particular, shall refer to:

- appropriate expert staff, **premises** and technical equipping,
- **indipendence** and impartiality in view of the entities directly or indirectly connected with the product being assessed for conformity,
- confidentiality regarding work,
- responsibility regarding the work performed,
- insurance of professional accountability; and
- other conditions necessary for appropriate execution of the prescribed procedure.

(2) If established that all conditions referred to in paragraph 1 of this Article are met, as well as the **other** conditions for carrying out conformity assessment laid down in the **relevant** technical regulations, upon previous consent of the minister competent for adoption of the regulations from the appropriate field, the Minister for Economy shall authorise the legal person with a decision to carry out a conformity assessment within 15 days from the day of receiving the application.

If the decision of paragraph 2 of this Article is not enacted within the prescribed deadline, it would be considered that the application of the legal person has been approved.

(3) The conformity assessment body shall be deemed to have met the conditions for carrying out a conformity assessment, established in the technical regulations, provided that his/her ability has been proven by a previously implemented accreditation procedure. The certificate for accreditation issued by the Institute for Accreditation of the Republic of Macedonia shall be considered as a proof for the technical capability of the conformity assessment body.

(4) The Decision referred to in paragraph 2 of this Article shall authorize the legal person to carry out a conformity assessment, and it shall determine the date for validity of the authorisation, the scope and tasks **performed by** of the conformity assessment body.

(5) Against the Decision referred to in paragraph 2 of this Article an appeal may be lodged, within 15 days, to the Commission of the Government of the Republic of Macedonia for settlement of administrative matters of second instance in the field of economy.

(6) Conformity assessment bodies shall be bound to constantly fulfil the conditions referred to paragraphs 1 and 3 of this Article.

(7) In accordance with the regulation referred to in paragraph 10 of this Article, the Minister for Economy may designate (notify) the conformity assessment bodies in the European Commission, and if necessary, **as well upon request** in the Member States of the European Economic Area.

(8) The Ministry of Economy shall keep a register of the conformity assessment bodies.

(9) Upon request from the competent authorities, the conformity assessment bodies shall be bound to cooperate.

(10) The Government of the Republic of Macedonia shall provide for, in details, the procedure of the state bodies and institutions for enacting the Decision referred to in paragraph 2 of this Article, the manner of authorization for termination of the decision referred to in Article 25 paragraph 1 of this law, the form and contents of the register referred to in paragraph (8) of this Article, the manner of notification for acquiring capacity of the conformity assessment bodies and the manner of designation (notification) of the conformity assessment bodies within the European Commission.

Revoking the Decision for Authorisation

Article 25

(1) If the Minister for Economy **it is determined** that a conformity assessment body ceases to meet a particular condition referred to in Article 24 paragraphs 1 and 3 of this law or any other condition laid down with **in the relevant** technical regulation, he/she **the Minister of Economy** shall reach a decision terminating the decision for authorisation, **within 15 days from the day of determining the case.**

(2) Against the Decision referred to in paragraph 1 of this Article an appeal may be lodged, within 15 days, to the Commission of the Government of the Republic of Macedonia for settlement of administrative matters of second instance in the field of economy.

(3) The appeal referred to in paragraph 2 of this Article shall not delay the execution of the Decision.

(4) The Minister for Economy shall inform the European Commission on reaching the Decision referred to in paragraph 1 of this Article, if the conformity assessment body is designated (notified).

Conformity Certificates

Article 26

(1) In accordance with the technical regulations for particular products or groups of products, the conformity assessment bodies shall be authorised to issue conformity certificates on the basis of a request submitted by the interested legal and natural persons.

2) The Ministry of Economy shall publish a list of authorised conformity assessment bodies in the Official Gazette of the Republic of Macedonia.

(3) The conformity assessment bodies shall conclude a contract in writing with any legal and natural person willing **the manufacturer that shall** obtain a conformity document.

Commission for Product Safety

Article 27

(1) For reviewing the issues with respect to product safety from the aspect of application of the technical regulations and conformity of the products with the technical regulations, upon proposal from the Ministry of Economy, the Government of the Republic of Macedonia shall establish a Commission (hereinafter: Commission). The commission shall comprise representatives of the competent administrative bodies, consumer organisations and other associations of citizens, chambers of commerce as well as prominent experts from the field of technical safety of the product and consumer safety.

(2) The Commission shall be chaired by a President designated by the Minister for Economy.

(3) The Commission shall review all provided information regarding the safety and conformity of the products from the aspect of application of the technical regulations according to the types of products or types of hazards and shall propose the adoption of appropriate measures for elimination or reducing the hazard in connection with the products.

(4) The Commission shall also encourage and support the voluntary activities of the manufacturers and distributors with regard to product safety and shall cooperate when determining the codes of acceptable behaviour in particular areas, taking into consideration the scientific and technical knowledge regarding product safety.

(5) The Commission shall adopt its rules of procedure.

(6) The Ministry of Economy shall carry out the professional and administrative affairs of the Commission.

PART THREE

PRINCIPLES OF MUTUAL RECOGNITION

Validation of Documents and Marks for Conformity of Foreign Origin

Article 28

In the Republic of Macedonia shall be valid only documents and marks for conformity of foreign origin that have been issued in accordance with international agreements that the Republic of Macedonia has concluded and ratified, i.e. has acceded to.

Validation of Documents and Marks for Conformity of Foreign Origin upon Exception

Article 29

(1) The Minister for Economy, or the Minister in charge of adoption of regulations, for the products laid down with the provisions in force in the Republic of Macedonia, and which are not part of the harmonised area of the European Communities (hereinafter: non-harmonised provisions) shall, with exception to the Article 28 of this law, adopt a decision in which the validity of the documents and the marks for conformity of foreign origin will be recognised **and will determine same level of protection**, if:

- the conformity documents and the marks confirm the conformity with the requirements laid down with the non-harmonised regulations, and

- the conformity assessment bodies that issue the documents, i.e. the conformity marks referred to in indent 1 in this Article meet the conditions prescribed with the non-harmonised regulations.

(2) The Minister for Economy, or the minister in charge of adoption of non-harmonised provisions, shall closely stipulate the procedure for recognition of the validity of conformity documents and marks.

Non-harmonised Area

Article 30

(1) The prescribed requirements for the products laid down with the non-harmonised provisions shall not apply to the products which pursuant to the law and other provision are produced, i.e. **and are intended for placing** on the market or **putting** in use in the Member States of the European Community and EEA.

(2) If the competent **state** inspection body, on the basis of the conformity documents and additional data, determines that the product referred to in paragraph 1 of this Article does not meet an equal level of protection of the public interest laid down with a non-harmonised provision, shall be bound to reach a Decision which it will prohibit its placement on the market or putting in use, or will reach a Decision for withdrawal of the product from the market or use.

(3) The competent **state** inspection body shall be bound to reach a Decision referred to in paragraph 2 of this Article provided that the following conditions are met, if:

- It has previously informed in writing the manufacturer about the legal basis for adoption of a Decision which can impede the placing or the withdrawal of the product on the market and/or the use,

- On the basis of available facts and evidence, as well as data on the condition of the technique or

technology, it has identified that there are reasons for protection of the public interest, and provided that the adoption of a Decision for removing the shortcomings as a mild measure, it will not provide equal level of protection of the public interest,

- It gave an opportunity to the manufacturer to respond upon the written notification referred to in indent 1 of this Article within a period of at least 30 days, and

- Prior to reaching the Decision, it has taken into consideration the declaration of the manufacturer and additional facts and evidence it has found.

(4) An appeal can be lodged against the Decision referred to in paragraph 2 of this Article within a period of 15 days to the Commission of the Government of the Republic of Macedonia for Administrative Disputes of second instance in the field of economy.

(5) The appeal referred to in paragraph 4 of this Article shall not delay the enforcement of the Decision.

Examination Article 31

(1) Provided, in accordance with the stipulated requirements about the products laid down by non-harmonized regulations, it has been laid down that the products, prior to the placement on the market, need to be examined, these can be placed on the market in the Republic of Macedonia, only if these were examined in the conformity assessment bodies in the Member States of the European Union, EEA and/or in the Republic of Macedonia, and the results of those examinations are available to the competent **state** inspection bodies.

(2) The bodies that carry out the conformity assessment referred to in paragraph (1) of this Article are considered to meet the conditions for carrying out conformity assessment, laid down in the non-harmonized regulations provided their capacity was proved by an accreditation procedure that was previously carried out .

Procedure for Enacting Technical and Non-harmonized Regulations Article 32

The procedure for notification in the European Commission for enacting technical and non-harmonized regulations, technical specifications and standard, would be closely prescribed by the Government of the Republic of Macedonia.

The Ministry of Economy is the contact point for notification in the European Commission for enactment of the technical and non-harmonized regulations.

The Standardization Institute is the contact point for notification in the European Commission for enactment of the standards and the technical specifications.

PART FOUR

SURVEILLANCE

Surveillance and Inspection Surveillance Article 33

(1) The surveillance over the implementation of provisions of this Law and the technical provisions adopted on the basis of this Law shall be done by the Ministry of Economy, i.e the Ministry in charge of adoption of technical provisions within the relevant area.

(2) The inspection surveillance over the implementation of the provisions of this Law that refer to

products from Article 6, paragraph (2) a) of this Law shall be done by the State Market Inspectorate and the State Sanitary and Health Inspectorate.

(3) The inspection surveillance over the implementation of the provisions of this Law that refer to the products from Article 19, paragraph (1), indent 1 of this Law, the technical regulations and the non-harmonized regulations adopted on the basis of this Law shall be done by the **competent state inspection bodies**. State Market Inspectorate, the State Labour Inspectorate, the State Sanitary and Health Inspectorate, the State Inspectorate for Technical Inspection, the State Environment Inspectorate, the Agency for Electronic Communications and other competent inspection bodies in the area of transport and communications, the Protection and Rescue Directorate and other inspection bodies in accordance with the law and other regulations.

Competences for Inspection Surveillance

Article 34

On the basis of this law and beside the competences laid down with other laws, the competent **state** inspection bodies shall have the following competences:

- to overtake or organize, even when the product referred to in this law is placed on the market as being safe, appropriate checkups for the product properties that have an effect on its safety. The checkups should be within the necessary scope and to be carried out until the final phase of usage, i.e. the use of the product,
- to ask for all the necessary data about the product referred to in this Law from the manufacturer and the distributor,
- to take samples of the products referred to in this Law for conducting safety checkups,
- to ask for all the necessary documents for the product conformity referred to in Article 19, paragraph (1), indent 1 of this Law and the technical documentation, and
- to destroy the products referred to in the Article 19, paragraph (1), indent 1 of this Law that are not in conformity with the requirements laid down, provided this is necessary for protection of the health and safety of consumers and other users and for protection of the environment and nature.

Guidelines for the Activities of the Competent State Inspection Bodies

Article 35

(1) During the implementation of measures by the adoption of a decision, the competent **state** inspection bodies are bound to act in the manner that their measures are compatible with the seriousness of the hazard, and to respect the current situation in the science and technology at the largest scale, in terms of possible direct and indirect moments or further hazards for the health and the safety of the consumers and the other users of the product.

(2) Provided the competent **state** inspection body does not have the necessary expert knowledge about the product or a group of products or equipment for carrying out inspection surveillance, it can entrust the performing of the expertise within the frames of the inspection surveillance, to an institution that has adequate premises, equipment, professional staff, and is unbiased and independent in its operations in accordance with the law.

(3) The competent **state** inspection bodies shall give an opportunity to the parties involved to deliver their opinion and comments prior to the adoption of measures with a decision in accordance with this law, except in cases when there is a serious hazard for the life and health of the consumers.

Measures for the Products Referred to in this Law

Article 36

(1) If the inspector in charge of carrying out the surveillance determines that:

1) for every product referred to in this Law that can represent a hazard in certain conditions, the inspector will take measures by adopting a decision:

- by which he/she shall order to mark the product with appropriate and clearly written and easily understandable warnings in Macedonian language, which does not exclude the use of other languages officially used within the European Union, with regard to the hazards it can provoke, and
- by which he/she shall condition every trading of the product with prior fulfilment of the conditions ensuring product safety;

2) for every product referred to in this Law that can represent a hazard for certain individuals, he/she will take measures by adopting a decision ordering timely warnings on the possible hazards for the individuals, including announcements of specific warnings through the media;

3) for every product referred to in this Law that may not fulfil the conditions of this Law, he/she will take measures by adopting a decision temporarily prohibiting any supply, offers for purchase or placements on the market, or advertising within a period necessary to perform every checkup for its safety, controls and assessments;

4) for every hazardous product referred to in this Law, he/she will take measures by adopting a decision prohibiting its trade and shall take all the appropriate measures necessary to ensure implementation of the prohibition, and

5) for **each** hazardous product referred to in this Law that is already placed on the market, he/she shall:

- take measures by adopting a decision ordering or organizing its real and urgent withdrawal and warn the consumers about the hazards it has, and

- take measures by adopting a decision ordering or coordinating or, if appropriate, organizing, together with the manufacturers and distributors, its complete withdrawal from the consumers, and its destruction in appropriate circumstances.

(2) Prior to the implementation of measures by the adoption of a decision referred to in paragraph (1) of this Article, and in particular those referred to in item 3, 4 and 5, the competent **state** inspection bodies are bound to encourage and promote voluntary activities on behalf of the manufacturers and distributors, in accordance with the duties determined by this Law.

(3) The measure referred to in paragraph (1), item 5, indent 2 of this Article shall be adopted by the Director of the competent **state** inspection body.

Measures for the Products Referred to in the Article 19 of this Law

Article 37

(1) If while carrying out the inspection surveillance of the products referred to in the Article 19, paragraph (1), indent 1 of this Law, for which technical regulations are provided, the inspector identifies violation of the provisions of this Law and technical regulations, he/she shall take measures by adopting a decision:

a) ordering:

- 1) to overcome the identified non-conformities, setting a period for their removal;
- 2) to mark the products with the determined markings or removal of the prohibited markings;
- 3) to destroy the products that are not in conformity, if this is necessary for the protection of the health and safety of the people and for protection of the environment and the nature, and
- 4) to withdraw the products that are not in conformity from the markets, and

b) prohibiting:

- 1) to place on the market the products that are not in conformity and restrict the market with the same;

- 2) to put in use or restrict the use of the products that are not in conformity;
- 3) temporarily any supply, supply or exposure of the products, while carrying out the appropriate checkups, and
- 4) the use of products that are not in conformity.

(2) If there are evidences that beside the compliance with the provision of this Law, the product endangers the safety and the health of the consumers and the other users, the inspectors in charge are bound to adopt appropriate measures pursuant to paragraph (1) of this Article, by which they can restrict the placement of the product referred to in this Law on the market, i.e. determine its withdrawal from the market or complete withdrawal.

Competency Article 38

The competent inspection bodies, while carrying out the inspection surveillance of the implementation of the provision in the Article 5, paragraph (2) of this Law, can take all the authorities and measures in accordance with the Articles 34 and 36 of this Law.

Right to Complaint Article 39

(1) A complaint can be lodged against each measure taken by the competent **state** inspection bodies within a period of 15 days to the Commission for solving Administrative Disputes at second instance in the field of economy within the Government of the Republic of Macedonia.

(2) The complaint against the decision referred to in paragraph (1) of this Article shall not delay its enforcement.

Subjects Against which Inspection Measures Can be Taken Article 40

The competent **state** inspection body shall take the measures of this Law, appropriately against:

- the manufacturer,
- the distributors within the frames of their activities, in particular against the distributor that carries out or has carried out the first step of market distribution, and
- other legal and natural persons when it is necessary to provide for their cooperation in the actions for avoiding and impeding the hazards from the product.

Costs Article 41

If, according to the results of the checkups carried out it is determined that the products referred to in the Article 19, paragraph (1), indent 1 of this Law are not in conformity with the determined essential requirements laid down with the technical regulations, the costs for the checkup carried out shall be covered by the entities the inspection was carried out at.

PART FIVE MISDEAMEANOURS SANCTIONS

^1en 41-a

For misdemeanours of Article 43-a of this Law, the State Market Inspectorate, a body of state administration, (hereinafter: misdemanour body) performs a dismenaour procedure and delivers a misdemeanour sanction.

The misdemeanour procedure of paragraph 1 of this Article implemented at the misdemeanour body is performed by a commission for deciding upon misdemeanour (hereinafter: misdemeanour commission) established by the Minister of Economy.

Against the decisions of a misdemeanour body, delivering a misdemeanour sanctions pursuant to the provisions of this Law, a complaint may be filed for starting an administrative dispute at the competent court.

^1en 42

(1) Fine in amount of 3.500 to 5.000 EUR in denars counter value shall be declared to a legal entity for a misdemenour, if:

- 1) places unsafe products referred to in this Law contrary to the Article 8 of this Law;
- 2) does not provide the consumers with all the appropriate information of the hazards the product referred to in this Law and does not take measures of precaution against hazards (Article 11, paragraph (1));
- 3) does not take measures appropriate to the characteristics of the product referred to in this Law (Article 12, paragraph (1), items 1 and 2);
- 4) supply products referred to in this Law about which knows or assumes and in accordance with its professionalism on the basis of the information he/she possesses that the products are not in accordance with the safety requirements (Article 14, paragraph (1));
- 5) does not forward information on the hazards that a certain product referred to in this Law might have, does not keep and deliver the documents necessary for identification on the origin of the products referred to in this Law and does not collaborate in the measures taken by the manufacturers and the competent state bodies (Article 14, paragraph (2));

(2) Fine in amount between 700 up to 1.000 EUR in denar counter value shall be declared for a misdemeanour to the responsible person in the legal entity for the activities of paragraph 1 of this Article.

(3) Fine in amount between 300 up to 500 EUR in denar counter value shall be declared for a misdemeanour to the oficial person in the legal entity for the activities of paragraph 1 of this Article.

(4) Fine in amount of 500 EUR in denar counter value shall be declared for a misdemeanour to the natural person for the activities of paragraph 1, point 2 of this Article.

(5) When a misdemeanour of paragraph 1 of this Article was done with the aim that the doer acquires for himself/herself or other person a material gain or the misdemeanour is done by organised group of persons or in the course of the calendar year the doer repeats the misdemeanour of paragraph 1 of this Article, the competent court may declare a fine in amount of 15.000 EUR in denar counter value.

(6) If there is a risk that a legal person for activities of paragraph 1, points 1, 2 and 4 of this Article, may repeat the misdemeanour, it may be declared a sanction of temporary prohibition for performing certain activity in duration of three to five years.

(7) For the misdemeanour of paragraph 1, point 1 of this Article the material gain made by performing the misdemeanour shall be deducted.

Article 43

(1) Fine in amount of 3.500 up to 5.000 EUR in denars counter value shall be declared to a legal entity, if:

1) places on the market or puts in use products referred to in the Article 19, paragraph (1), indent 1 of this Law, which are not in conformity with the determined essential requirements of the technical regulation, does not carry out the conformity assessment in accordance with the stipulated procedure in the technical regulation, does not mark them as determined and do not come accompanied by documents determined in the technical regulations (Article 22, paragraph (1));

2) marks products referred to in the Article 19, paragraph (1), indent 1 of this Law, which are not in conformity with the prescribed essential requirements of the technical regulation, with conformity markings or other markings close to the conformity markings to the level to manipulate the consumers (Article 22, paragraph (2));

3) for products referred to in the Article 19, paragraph (1), indent 1 of this Law, does not provide application of the procedures for conformity assessment in accordance with the prescribed requirements in the technical regulations (the Article 23, paragraph (1), item 1);

4) for products referred to in the Article 19, paragraph (1), indent 1 of this Law, does not provide a conformity document (Article 23, paragraph (1), item 2);

5) for products referred to in the Article 19, paragraph (1), indent 1 of this Law, does not develop technical documentation in stipulated form and content and does not keep the same in a prescribed manner and duration (Article 23, paragraph (1), item 3);

6) for products referred to in the Article 19, paragraph (1), indent 1 of this Law, does not use conformity markings (Article 23, paragraph (1), item 4);

7) does not submit all the necessary information on the conformity of the product referred to in the Article 19, paragraph (1), indent 1 of this Law, the technical documentation and the conformity documents upon a request by the competent **state** inspection body (Article 23, paragraph (1), items 5) and,

8) does not perform tasks laid down with the technical regulations (Article 23, paragraph (1), item 6).

(2) Fine in amount between 700 up to 1.000 EUR in denar counter value shall be declared for a misdemeanour to the responsible person in the legal entity for the activities of paragraph 1 of this Article.

(3) Fine in amount between 300 up to 500 EUR in denar counter value shall be declared for a misdemeanour to the official person in the legal entity for the activities of paragraph 1 of this Article.

(4) Fine in amount of 500 EUR in denar counter value shall be declared for a misdemeanour to the natural person for the activities of paragraph 1, point 2 of this Article.

(5) When a misdemeanour of paragraph 1 of this Article was done with the aim that the doer acquires for himself/herself or other person a material gain or the misdemeanour is done by organised group of persons or in the course of the calendar year the doer repeats the misdemeanour of paragraph 1 of this Article, the competent court may declare a fine in amount of 15.000 EUR in denar counter value.

(6) If there is a risk that a legal entity for activities of paragraph 1, points 1, 2 and 4 of this Article, may repeat the misdemeanour, it may be declared a sanction of temporary prohibition for performing certain activity with duration from three up to five years.

(7) For the misdemeanour of paragraph 1, point 1 of this Article the material gain made by performing the misdemeanour would be deducted.

^1en 43-a

Fine in amount of 1.000 EUR in denars counter value shall be declared to a legal entity for misdemeanour, if:

- doesn't notify the State Market Inspectorate, i.e it doesn't provide the details for the actions taken in order to protect the consumers from the dangers (Article 15 paragraph (1))
- don't cooperate with the competent state inspection bodies (Article 16).

Fine in amount of 300 in denar counter value shall be declared to the responsible person in the legal entity for misdemeanour for activities of paragraph 1 of this Article.

Fine in amount of 200 EUR in denar counter value would be declared to the official person in the legal entity for misdemeanour for activities of paragraph 1 of this Article.

Fine in amount of 300 in denar counter value would be declared to the natural entity for misdemeanour for activities of paragraph 1 of this Article.

The State Market Inspectorate may for the misdemeanours of this Article declare to the legal entity a mandatory fine in amount of 500 EUR in denar counter value, and to the responsible person in the legal entity in amount of 200 EUR in denar counter value, as well as to the natural entity in amount of 500 EUR in denar counter value.

^1en 43-b

For the misdemeanours determined in Articles 42 and 43 of this Law the State Market Inspectorate is obliged to the misdemeanour doer to propose a settlement procedure before filing a request for misdemeanour procedure.

The procedure from paragraph 1 of this Article is performed pursuant to the Misdemeanour Law and the Law on State Market Inspectorate.

The State Market Inspectorate in the settlement procedure for misdemeanours of Articles 42 and 43 of this Law may declare to the legal person a fine and issue a payment order.

^1en 43-c

For misdemeanours of Article 43-a of this Law the State Market Inspectorate may to the misdemeanour doer offer a mediation procedure and reaching an agreement by which the misdemeanour doer should pay the fine, other fees or to remove the consequences of the misdemeour.

The procedure of paragraph 1 of this Article is performed pursuant to the Misdemeanour Law.

PART SIX

TRANSITIONAL AND FINAL PROVISIONS

Article 44

Article 134, paragraph 1, items 5 and 6, Article 136, paragraph 1, item 9, Article 138, paragraph 1, item 19 and the Article 140 that refers to the penalty provision in Article 138, paragraph 1, item 19 in the Law on Protection of Consumers (Official Gazette of the Republic of Macedonia, No 38/2004) and the Law on Prescribing Technical Requirements for Products and Conformity Assessment” (Official Gazette of the Republic of Macedonia, No 55/2002) shall be cease to be valid from the date of entry into force of this Law.

Article 45

The procedures that are initiated pursuant to the Law on Protection of Consumers (Official Gazette of the Republic of Macedonia, No 38/2004) shall be terminated pursuant to the same from the date of entry into force of this Law.

Article 46

The by-laws on the basis of the first part of this Law shall be adopted within six months from the date of entry into force of this Law.

Article 47

The Decisions for authorization issued to the legal and natural persons prior to the date of entry into force of this Law shall cease to be valid with effect within a year from the date of entry into force of the technical regulation adopted on the basis of this Law.

Article 48

The Articles 28 and 29 of this Law shall cease to be valid from the date of accession of the Republic of Macedonia to the European Union.

Article 49

The provisions in Article 4, paragraph (4) in the part that refers to transfer of information with the European Union, the Article 5, paragraph (2), the Article 15, paragraph (4), the Article 17, paragraphs (2), (3) and (4), the Article 24, paragraph (7), the Article 25, paragraph (4) and the Article 27 of this Law shall enter into force upon the date of accession of the Republic of Macedonia to the European Union, except for the products for which relevant protocol on conformity assessment has been concluded introducing free movement of the products referred to in the Article 19 of this Law between the Republic of Macedonia and the European Union, upon the date of entry into force of the relevant protocol.

Article 50

The provisions in the Articles 30, 31 and 38 of this Law shall enter into force on the date of accession of the Republic of Macedonia to the European Union.

Article 51

The provisions regulating the technical requirements of the products, the procedures for their conformity with the technical requirements, the marking of the products, as well as the necessary documentation to accompany the products, and that are adopted or are applied on the basis of the Law on Standardization (Official Gazette of the Republic of Macedonia, No 23/95) or on the basis of the Law on Prescribing the Technical Requirements for Products and Conformity Assessment" (Official Gazette of the Republic of Macedonia, No 55/2002), or on the basis of other laws, shall continue to be applied until the adoption of the provisions on the basis of the second part of this Law.

Article 52

The by-laws that are into force to the date of entry into force of this Law, and which lay down the mandatory application of standards shall be in force no longer than 30 June 2006.

Article 53

(1) By the date of accession of the Republic of Macedonia to the European Union or upon entry into force of a relevant protocol for conformity assessment with the European Community, the expression "manufacturer or its authorized representative with a seat in the Republic of Macedonia or in the European Union" shall mean "manufacturer or its authorized representative with a seat in the Republic of Macedonia".

(2) Upon the date of accession of the Republic of Macedonia to the European Union or upon entry into force of a relevant protocol for conformity assessment with the European Community, the expression "manufacturer or its authorized representative with a seat in the Republic of Macedonia or in the European Union" shall mean "manufacturer or its authorized representative with a seat in the European Union".

(3) Provisions of paragraphs 1 and 2 of this Article shall be applied when enacting technical regulations of this Law.

Article 54

The provisions in the Article 24, paragraph (3) of this Law in the part “published by the Institute for Accreditation of the Republic of Macedonia” shall cease to be valid from the date of accession of the Republic of Macedonia to the European Union.

Article 55

This Law shall enter into force on the eighth day following its publication in the Official Gazette of the Republic of Macedonia