ACT

No. 264 of 7 September 1999

on technical requirements for products and on conformity assessment and on change and amendment of some Acts in the wording of Act No. 436/2001 Coll. and Act No.254/2003 Coll.

The National Council of the Slovak Republic resolved upon this Act:

ARTICLE I General provisions

§ 1 Subject of the Act

By this Act governed are:

- a) the method for determination of technical requirements related to products which would endanger the health, safety or property of persons, or environment (hereinafter referred to as "the justified concern"),
- b) rights and obligations of legal entity entitled to carry out activities under this Act related to development, approval and issuance of Slovak technical standards,
- c) procedures for conformity assessment of products to technical requirements (hereinafter referred to as "conformity assessment"),
- d) rights and obligations of enterprisers¹ and other legal entities established according to specific regulation² and designated to carry out activities under this Act related to conformity assessment.
- e) the rights and obligations of enterprisers¹ who manufacture, import or place the products on the market.
- f) the competence of central body of state administration and other state administration bodies in the field of standardisation and conformity assessment.
- g) surveillance over observance of the Act including infliction of fines.

§ 2 Specification of basic terms

- (1) For the purpose of this Act the following terms apply:
 - a) product means any thing that has been manufactured, mined or otherwise acquired irrespective of the degree of its processing, and is intended to be placed on the market or put into service;

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^{1 § 2} clause 2 of Commercial Code

² § 22 of Act No. 303/1995 Coll. on budget rules in the wording of later regulations

- b) manufacturer means an enterpriser who has mined, manufactured or by other procedure obtained the product, or who presents himself as the manufacturer by affixing to the product his trade name, trade mark or other identification code which identifies him as manufacturer or distinguishes him from other manufacturer; manufacturer can be also importer,
- c) importer means an enterpriser who places on the market a product made in other state or who intermediates placing of such product on the market,
- d) authorised representative the legal person, or physical person ^{2b}), who is entrusted by the manufacturer to stand for on the merits concerning responsibilities resulting from this Act,
- e) distributor means an enterpriser who sells the products, intermediates their sale, or by other means provides products to users, but does not influence directly product's properties by this operation (hereinafter "distributes"); a supplier also is distributor,
- f) notified body means an enterpriser¹⁾ or legal person²⁾ who was by a member state of the European Union or by the Slovak Republic notified to the European Communities and all member states of the European Union as a body authorised to perform conformity assessment,
- g) placing the product on the market when the product for the first time passes for payment or free of charge from the phase of manufacturing or import into a phase of distribution namely for the case when it is determined for one's own need,
- h) putting the product into service means the moment when the product for the first time passes - for payment or free of charge - from the phase of manufacturing or import into a phase of operation, namely after its finished installation, or into a phase of use, whether for the need of other persons or for one's own need,
- i) technical requirements for product mean technical specifications contained in a technical regulation or technical standard; technical specification stipulates required characteristics of product that are technical specifications, namely:
 - 1. quality level,
 - 2. utility properties,
 - 3. safety,
 - 4. dimensions,
 - 5. name under which it is sold,
 - 6. marks,
 - 7. testing of product and test methods,
 - 8. packaging,
 - 9. marking or labelling of the product,

³ § 2 sub-paragraph 1 item e) of Act No 634/1992 Coll. on consumer protection in the wording of Act No. 220/1996 Coll. and Act No. 137/1998 Coll.

^{2b}) § 10 sub-paragraph 3 of Act No. 455/1991 Coll. on crafts entrepreneuring, as amended by later regulations.

- 10. procedures for conformity assessment of product to legal regulations or technical standards,
- 11. manufacturing methods and processes having influence on characteristics of the product,
- j) other requirements necessary for the purposes of justified concern or consumer protection4 that apply to life cycle of use or damage of the product or changes of its scope of use, in case where the conditions of its use can substantially influence the composition or characteristics of the product or its placing on the market, or its putting into service (hereinafter referred to as "putting on the market").
- (2) For the purpose of this Act also a service is considered as a product if it is provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of service; the radio and television broadcasting services are not considered as services under this Act^{4a)}.

§ 3 The Slovak Office of Standards, Metrology and Testing

- (1) The Slovak Office of Standards, Metrology and Testing (hereinafter referred to as "Office") is a central body of state administration in the field of technical standardisation and conformity assessment that:
 - a) elaborates and submits to the government conceptions in the field of technical standardisation and conformity assessment,
 - b) co-operates with the ministries and other central bodies of state administration in the competence of which there is the issuance of a technical regulation (hereinafter referred to as "ministry") and with other legal entities at the process of assurance of uniform application of technical requirements, conformity assessment and surveillance execution,
 - c) ensures in co-operation with the ministries international exchange of information in the field of Slovak technical standards, technical regulations and conformity assessment according to international agreements by which the Slovak Republic is bound,
 - d) designates a legal entity to provide for the development, approval and issuance of the Slovak technical standards
 - e) designates a Slovak technical standard suitable for conformity assessment,
 - f) announces the changes in the lists of European standards harmonised with technical regulations of European Communities,
 - g) grants and withdraws the authorisation and regularly checks the existence and fulfilment of conditions given in the decision on authorisation by authorised body under this Act,
 - h) publishes information on Slovak technical standards, on Slovak technical

 $^{^4}$ Act No. 634/1992 Coll. in the wording of later regulations

^{4a)} Act No. 308/2000 Coll on broadcasting and retransmission and on the changes of Act No. 195/2000 Coll., on telecommunication in the wording of Act No. 147/2001Coll.

standards harmonised with technical regulation and Slovak technical standards suitable for conformity assessment; information on authorisation granting and withdrawal to authorised body, including the contents of authorisation,

- i) keeps register of the identification codes.
- (2) The Office, at execution of surveillance over conformity assessment is entitled to:
 - a) place the obligation on authorised body to remove ascertained imperfection in its work and determine adequate time limit for its removal,
 - b) inflict fines.

Technical regulations and standards

§ 4 Technical regulations

Technical regulation for the purpose of this Act means a generally binding legal regulation⁵, which includes technical requirements for products, observance of which is compulsory in introducing the product on the market, by its use or, which ban or restrict on the manufacture, import, sale or use of certain product.

§ 5 Standards

- (1) The standard contains rules, guidelines, characteristics or the results of activities aimed at achieving the optimal degree of their arrangement in given field and at general and repeated use. Standard means:
 - a) international standard that is adopted by an international standardisation organisation and made available to the public,
 - b) European Standard that is adopted by an European standardisation organisation and made available to the public,
 - c) Slovak technical standard that is made available to the public,
 - d) foreign standard that was adopted by foreign national standardisation organisation and made available to the public.
- (2) Slovak technical standard is created and approved under § 6 and its issuance is announced in the Official Journal of the Slovak Office of Standards, Metrology and Testing (hereinafter referred to as "the Official Journal").
- (3) Slovak technical standard is marked with lettering symbol STN. The name Slovak technical standard and STN marking must not be used for other type of documents.
- (4) International and European Standards under sub-paragraph 1 are issued in the Slovak Republic only as Slovak technical standards and they are a part of the Slovak Technical Standards' system. For adoption thereof all methods determined for this purpose by international and European standardisation organisations can be used.
- (5) The Slovak technical standard becomes a harmonised one when it adopts a harmonised European Standard, which creates the assumption of conformance with technical requirements of relative European Communities Directives, and for this purposes it has been published in

⁵ § 1 of the Act NC SR No 1/1993 Coll. on Collection of Laws of the Slovak Republic in the wording of Act No 44/1998 Coll.

the Official Journal of the European Communities. The Office announces in its bulletin that the harmonised technical standard can be used for the assessment of fulfilment of technical requirements for products, stipulated by the Slovak Republic Government (hereinafter referred as "Government") by its ordinance transposing the relative EC Directive, or for assessment of meeting the requirements for products laid down by specific regulation. ⁶.

- (6) The Office, after proceeding with the competent ministry and if necessary after approval by the appropriate bodies of the European Communities, will designate the technical standards as suitable for conformity assessment, the designation of technical standard suitable for conformity assessment will be applied only then when the relative Directive is transposed into the Slovak Republic legislation, when it allows the application of national standards for meeting the conformity requirements until there do not exist any harmonised standards, or in non-harmonised sector. The Office notifies the designated technical standards suitable for conformity assessment in its Official Journal.
- (7) The Office informs the ministry on changes in the lists of European Standards harmonised with technical regulations of European Communities.
- (8) The proposal for cancellation of determination of harmonised Slovak technical standard and proposal for cancellation of determination of other Slovak technical standard suitable for conformity assessment are entitled to submit the surveillance bodies given in § 30 on the basis of their own ascertainment or on other initiative.
- (9) The Office announces in the Official Journal which Slovak technical standards it has determined as suitable for conformity assessment, including changes in such determination or withdrawal of such determination, and harmonised Slovak technical standards. In the announcement there will also be given the title of the technical regulation the harmonised standard relates to. If the Office cancels the determination of Slovak technical standard suitable for conformity assessment, at the same time it announces which harmonised Slovak technical standard it has determined.

§ 6 Development, approval and issuance of Slovak technical standards

- (1) The development, approval and issuance of Slovak technical standards under this Act is guaranteed by the Office.
- (2) The Office can designate a sole legal entity to provide for the development, approval and issuance of the Slovak technical standards (hereinafter referred to as "designated legal entity"). Decision on designation of the legal person, as well as decision on discharge of designation, the Office shall announce by publication in the Collection of Laws of the Slovak Republic.
- (3) The Office can designate a legal entity under sub-paragraph 2 on the basis of its application. The decision regarding designation shall be issued by the Office only to the legal entity capable to fulfil the following conditions:
 - a) the timely publication in the Official Journal of announcement on the prepared drafts of Slovak technical standards and on issued standards;
 - b) mutual conformity of Slovak technical standards and their compliance with legal regulations;
 - c) application of the attained state of development in science and technology;
 - d) protection of the justified concern;

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⁶ For example Act No. 90/1998 Coll. on construction products, as amended by Act No.413/2000 Coll.

- e) voluntary character with regard to the participation in standardisation activities;
- f) independence and existence of mechanisms making impossible the predominance of any individual interest;
- g) the fulfilment of obligations arising from the international agreements binding the Slovak Republic, from the membership in international and European standardisation organisations and making use of the results from international cooperation;
- h) discussion of the draft standard with any one who will report within the period determined in the public announcement, or with any one who will submit his opinion on the published draft standard within the time limit determined in the announcement;
- i) distribution of the published Slovak technical standards within two weeks from the delivery of the order or as agreed upon with the customer.
- (4) There is no legal title for designation of legal entity granting under sub-paragraph 2.
- (5) If the designated legal entity fails to satisfy the conditions given in the decision on designation, the Office shall withdraw the designation.
- (6) Decision regarding designation as well as withdrawal of designation shall be published by the Office in the Official Journal.
- (7) The production costs for writing the harmonised Slovak technical standards and the Slovak technical standards <u>suitable</u> for conformity assessment are to be born by the Office. In other cases, the production costs on writing the Slovak technical standards are to be born by the entity, which is requesting their processioning
- (8) The expenses linked with membership of a designated legal entity in international and European standardisation organisations shall be covered by the Office.
- (9) The Slovak technical standards published on any type of carrier can be copied and distributed only with consent of the designated legal entity.
- (10) In case of Slovak technical standards, which are quoted directly in the technical regulations, the Office, after agreement with designated legal entity, shall publicise in the Official Journal the title for duplication thereof.

§ 7 Conformity with Slovak technical standards

- (1) Conformity with Slovak technical standards is voluntary, except the cases when conformity is required by this Act or other technical regulation. Reference to Slovak technical standards conformity to which is mandatory is quoted directly in the technical regulation. Slovak technical standards cited in technical regulations shall be made in the official language⁷ and shall be available to the public under § 6 sub-paragraph 3 item i) and subparagraph 10.
- (2) Observance of harmonised Slovak technical standard or Slovak technical standard suitable for conformity assessment is considered as observance of technical requirements stipulated by technical regulation.
- (3) Observance of Slovak technical standard is voluntary.

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 $^{^{7}}$ \S 8 sub-paragraph 3 Act of the National Council of the Slovak Republic No. 270/1995 Coll. on official language in the wording of later regulations.

Notification obligations

- (1) The notification place responsible for the mediation of information on draft technical regulations, their proposals for changes and amendments, as well as on draft Slovak technical standards is the Office.
- (2) The Office being the notification centre ensures:
 - a) information for abroad on draft technical regulations, draft Slovak technical standards and procedures for conformity assessment,
 - b) information on authorised entities,
 - c) information on similar foreign drafts of technical regulations by publishing in the Official Journal.
- (3) The Office announces to European Communities bodies in the scope stipulated by international agreements
 - a) standpoints about the fact that in the Slovak Republic there has been demonstrable
 ascertained that the harmonised technical standard does not meet essential
 requirements given by the technical regulations issued by the bodies of European
 Communities, or other facts related to standards,
 - b) authorised entities entrusted with fulfilment of tasks of notified bodies operating within European Union,
 - c) decision on placing protective measure in case of determined products including those products having origin in states by which relevant international agreement is signed.
 - d) issuing of technical regulations if they adopt the European Communities Directives, moreover it sends their text to the European Communities bodies.
- (4) The technical regulation or Slovak technical standard notified according to sub-paragraph 2 shall not be adopted before expiring the standstill period for commenting laid down by international agreement by which the Slovak Republic is bound.
- (5) The Office informs relevant ministry on notifications of draft foreign technical regulations, draft technical standards and conformity assessment procedures. The Office coordinates and assures notifications of draft technical regulations, drafts of changes thereof, draft Slovak technical standards, changes thereof and conformity assessment procedures for abroad. Relevant ministry is obliged to submit to the Office draft of the technical regulation, its change, or amendment prepared.

Products, determined products and their placing on the market

§ 9 Determined products

- (1) Determined products are such products that represent higher risk of jeopardy to justified concern and for mitigation or elimination of which are stipulated technical requirements given in § 2 sub-paragraph 1 items i) and j) and conformity assessment according to § 12 if not determined by specific regulation⁶.
- (2) Determined products must not be placed on the market, until the conformity of their properties with technical requirements is assessed, details of which are laid down in the technical regulations.

- (3) The Government through its ordinance shall stipulate details on technical requirements given in § 2 sub-paragraph 1 items i) and j), that is:
 - a) on groups of determined products,
 - b) on elimination or mitigation of risk that can be represented by determined products, through specification of technical requirements for determined products if they are not regulated by specific regulations⁶,
 - c) on the way of marking of determined products that at placing on the market are marked with Slovak conformity mark or other mark, if it follows from international agreement by which the Slovak Republic is bound.
 - d) on the procedure of conformity assessment of the determined products and the way of preservation, treating and placing the documentation at other subjects' disposal which relates to the procedure of conformity assessment and declaration of conformity
- (4) Determined products which are placed on the market as used or reconditioned are considered as products placed on the market for the first time under § 2 sub-paragraph 1 items f) and g), unless otherwise stipulated by the Ordinance of the Government.
- (5) The Office, based on the request of the ministry can decide on placing of the determined product on the market, even if conformity assessment procedures pursuant to § 12 were not used, as long as it is demanded for the sake of protection of the justified concerns (e.g. accidents, experimental purposes etc.). Such decision will not be put into effect at the determined products included in the Protocol to the European Agreement on affiliation between the European Communities and their member states on the one hand, and the Slovak Republic on the other hand, on conformity assessment and recognition of industrial products except for the cases as it is provided by the Directive which is given in the Annex to the given product and is transposed into the legislation of the Slovak Republic by the form of Government Ordinance.
- (6) Decision in accordance with sub-paragraph 5, as well as on withdrawal of such a decision, is announced by the Office in its Official Journal.
- (7) The Office, after proceeding with the competent ministry can, for a transition period classify the product within the determined products or, at the determined product to determine an assessment of the specific technical requirement or, at the determined product temporarily set-up a conformity assessment procedure. The Office announces such measure by the publication in the Collection of Laws of the Slovak Republic.

§ 10

Obligations of manufacturers, importers and distributors in placing products on the market

- (1) The manufacturer, his authorised representative or importer (hereinafter referred to as "manufacturer or importer") is allowed to place on the market only safe products⁸, irrespective of whether they are designed for personal need or for professional use. If it is impossible to identify the manufacturer or importer, the distributor is responsible for fulfilment of the conditions of placing the product on the market.
- (2) The manufacturer or importer of determined product assesses before placing this products on the market conformity of properties of determined product with technical requirements stipulated by technical regulations.

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⁸ § 6a of Act No 634/1992 Coll. in the wording of later regulations.

- (3) Determined the manufacturer or importer before the assessment of conformity of their properties to technical requirements for their safety under this Act and technical regulations may not place products on the market that is in a way corresponding to conformity assessment under § 12.
- (4) The manufacturer or importer of the determined product can place on the market only such a product that satisfies all technical requirements, which apply to the determined product. Before placing the determined product on the market he is obliged to draw up a written declaration of conformity with technical regulations (hereinafter referred to as "Declaration of Conformity"), providing that § 13, sub-paragraph 6 does not apply to it.
- (5) The manufacturer or importer has to provide the distributor on demand with Declaration of Conformity.
- (6) The distributor shall not distribute a product about which he knows on the basis of his own information or his professional knowledge, or he can assume that the product is able to endanger justified concern.
- (7) The distributor shall not distribute determined products for which the manufacturer or importer failed to issue the declaration of conformity (§ 13) or at which he has no written acknowledgement that the manufacturer or importer has issued the declaration of conformity, or if the manufacturer failed to mark determined product with conformity mark.

Authorisation and conformity assessment of determined products

§ 11 Authorisation

- (1) Authorisation shall mean the entrusting of an enterpriser¹ or other legal entity² with performance of conformity assessment; the Office or respective ministry through decision shall issue the authorisation. The holder of authorisation (hereinafter referred to as "authorised body") in accordance with the scope of authorisation and range of activity in the conformity assessment procedures can be authorised for: certification, conformity assessment, assessment of activities related to manufacture of determined product, performance of inspection and testing of determined products.
- (2) There is no legal title for authorisation under sub-paragraph 1.
- (3) In the decision on authorisation there shall be laid down the conditions and scope of maintenance of uniform proceeding of authorised entities.
- (4) If on authorisation decides the ministry in accordance with specific regulations⁹, the Office regulates methodically the co-operation of authorised entities.
- (5) The Office or the ministry can decide on authorisation on the basis of application of an entity given in § 1 item d), and evidence of fulfilment of the following conditions:
 - a) it employs persons having professional prerequisites and personal competence to perform activities in the process of conformity assessment, and the duty to keep confidential facts they come to know in the activities of authorised body,
 - b) it has technical means and equipment necessary for performance of conformity assessment procedures, or access to such facilities,
 - c) it is able to assure organisationally the impartiality of performance of activities at conformity assessment, objectivity and neutrality of check-up operations, matter of

 $^{^9}$ For example Act of the National Council of the Slovak Republic No. 152/1995 Coll. on foodstuffs in the wording of Act NC SR No 290/1996 Coll., Act No. 90/1998 Coll.

factness and impartiality of elaborated written reports and protocols, the same from the part of management as from the part of technical employees, to summarise and impartially evaluate the announced and own findings and proposals of all interested subjects,

- d) it is able to take impartial decisions in relation to interests of manufacturers and other subjects which could derive benefit from certain result of conformity assessment,
- e) it is able to assure protection of data representing business secret, and data that could be misused,
- f) it has contractual assurance of those operations that it cannot perform itself at conformity assessment,
- g) it has insurance for the case of liability for damage caused by the activity of authorised body,
- h) it has residence or domicile in the territory of the Slovak Republic.
- (6) Authorised body shall keep the documentation and evidence, which proves the fulfilment of the above-mentioned conditions for authorisation.
- (7) In the decision process on authorisation, the certificate of accreditation can be recognised, as well as other findings testifying the fulfilment of the conditions for authorisation.
- (8) In the decision on authorisation, the Office shall quote about the authorised body:
 - a) business name and address,
 - b) identification number,
 - c) identification code
 - d) technical regulation according to which the authorised body will carry out conformity assessment, conformity assessment procedures and scope of determined products the authorisation applies to,
 - e) legal form,
 - f) name and address of the person or persons that are the statutory body or its members stating the way by which they act on behalf of the authorised body,
 - g) validity period of authorisation.
- (9) Authorised body ensures the activities related to conformity assessment of products with requirements of technical regulations. It is obliged namely:
 - a) to perform technical findings objectively and on the level of the knowledge of development in science and technology in the period when findings are performed,
 - b) to issue on the basis of technical findings certificates or other documents,
 - c) to inform immediately the Office about all changes in conditions prescribed for authorisation,
 - d) to grant, on the basis of application, original copies of issued certificates and other documents including related documents to the Office, and if necessary, also to other authorised entities and in case when required by international agreement by which the Slovak Republic is bound, also to foreign entities,
 - e) to co-operate with the market surveillance bodies,
 - f) based on the Decision of the Office to finish the conformity assessment process

- (10) Authorised body is entitled:
 - a) to annul the validity of the certificate or other document it issued, if it finds out that conditions for certificate granting have not been met,
 - b) at performance of its activity, to have a look into relevant technical, production, commercial and other documents concerning conformity assessment, to enter working, storage and commercial sites,
 - c) to use the impress of the stamp with state symbol, registered by the Office, on documents, which it issues in accordance with this Act.
- (11) The Office is entitled to carry out supervision whether the entities authorised by it act in compliance with the provisions of this Act, and with the conditions laid down in the decision on authorisation.
- (12) If the authorised body has stopped to observe conditions laid down by this Act and in authorisation decision, or in the process of its activity it has broken a legal regulation related to the scope of authorisation and contents of activity or if requested by the authorised body or the need for authorisation ceases to exist, the Office shall change or withdraw the authorisation after discussion with the respective ministry. In case the authorised body asks for withdrawal of an authorisation, it shall do it at least 6 months before proposed date of withdrawal.
- (13) Considering that the Office will make decision on withdrawal of an authorisation of the authorised body in compliance with sub-paragraph 13, shall appoint the authorised person, who will finish the conformity assessment process.
- (14)The decisions on authorisation change of authorisation, withdrawal of authorisation or extinction of the authorised body shall be published by the Office in the Official Journal.
- (15)If no authorised body has been authorised to perform conformity assessment of a determined product, the conformity assessment will be provided by the Office. At this activity it utilises technical findings performed by accredited entities or technical findings of foreign subjects.
- (16) Authorised body by notification according to § 8 sub-paragraph 3 item b) becomes a notified body.

§ 12 Conformity assessment

- (1) Conformity assessment means ascertaining whether the real properties of determined product meet stipulated technical requirements for determined product, through procedures listed in sub-paragraph 3.
- (2) Conformity is considered to be proved when the product meets all technical requirements applying for determined product.
- (3) Conformity assessment procedures are:
 - a) conformity assessment by the manufacturer or by the importer,
 - b) conformity assessment of a sample of type (prototype) of product by authorised body and issuance of certificate by authorised body (certification of product type),
 - c) conformity assessment of the product with certified product type,
 - d) assessment of quality system for manufacture or its components in an enterprise by authorised body and performance of surveillance over its proper functioning,
 - e) assessment of quality system for final product inspection in an enterprise by

- f) verifiying of conformity of the product with certified product type or with stipulated conditions, which is carried out by the manufacturer, importer, authorised body on every product or on a sample chosen by statistical method,
- g) verifiying of conformity of every product with technical requirements by an authorised body,
- h) surveillance over proper functioning of the quality system in an enterprise by authorised body and in case of necessity checking of conformity of the product with requirements of technical regulations in the stage of design of the product,
- i) other procedures for conformity assessment, in case it is necessary for adoption of the contents of technical regulation issued by bodies of European Communities.
- (4) At conformity assessment there can be used the certificate or conclusions and results of inspection.
- (5) Costs linked to conformity assessment shall be borne by the enterpriser who applies for conformity assessment
- (6) Conformity assessment procedures can be used also for proving conformity of other than determined product.
- (7) Conformity assessment procedures can be used also at voluntary declaration of conformity with Slovak technical standards.
- (8) To technical requirements given in § 2 sub-paragraph 1 item h) will stipulate the Government through its ordinance details on:
 - a) placing individual groups of determined products on the market in dependence from their technical complexity and the degree of possible risk linked to the use thereof.
 - b) procedures and operations that must be met at conformity assessment (hereinafter referred to as "conformity assessment procedures"). It shall be done by their specification or, by combination.
 - c) contents of an appropriate documentation in dependence from groups of determined products, technical complexity thereof, the degree of possible risk to justified concern and the method for conformity assessment,
 - d) contents of conformity assessment in dependence from used method for conformity assessment.

§ 13 Declaration of conformity

- (1) The manufacturer or importer of determined product is responsible for the content of the written declaration of conformity with the technical requirement, inclusive the conformity assessment procedure used.
- (2) The manufacturer or importer has the right to mark with Slovak conformity mark the determined product for which a declaration of conformity has been issued.
- (3) The documentation about the applied procedure in the course of the conformity assessment and the Declaration of Conformity and the documents related to it, the manufacturer or importer is obliged to keep up in the Slovak Republic territory and provide it at any time, on demand to the surveillance bodies for a period ending 10 years after the last product has been manufactured, imported or placed on the market. Liability to assure the

storage of these documents passes from the manufacturers and importers, who have closed down in consequence of liquidation, bankruptcy or settlement, on the bankruptcy trustee or the liquidator. To the imported product marked according to sub-paragraph 6 with the CE marking, the importer is not obliged to keep the documentation on the applied method of conformity assessment in the Slovak Republic territory, but he is obliged to submit it to the surveillance body according to the conditions stipulated by separate regulation ^{9a)}.

- (4) The declaration of conformity shall not exempt the manufacturer or importer from their liability for a defective product nor for the damage caused by a defective product.
- (5) The declaration of conformity or written acknowledgement that the manufacturer or importer issued the declaration of conformity, the distributor is obliged to everybody by its request:
 - a) submit for examination,
 - b) issue its verified copy within 20 days from delivery of application at expense of the applicant.
- (6) The manufacturer or importer can replace the declaration of conformity by CE marking (§ 21) if this is stipulated in the international agreement by which the Slovak Republic is bound, and in accordance with the conditions stipulated by separate regulation ^{9a)}

§ 14 Certification

Certification under this Act means activity of an authorised body that by issuing a certificate confirms that the properties of determined product and activities related to its manufacture, or the properties of determined product or activities related to its manufacture are in conformity with the technical requirements for determined products quoted in technical regulations.

§ 15 Inspection in the processes of conformity assessment

- (1) Inspection means the activity of an authorised body related to the conformity assessment procedures which examines whether the design of a determined product, product, equipment, or quality system are in compliance with technical requirements. The authorised body also checks professional level of employees, level of technical equipment, level of technology and other processes and applied methodics.
- (2) Inspection for the purpose of conformity assessment does not mean the activity of surveillance bodies (§ 30).

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^{9a)} For example, Government Ordinance of the Slovak Republic No 391/1999 Coll. which lays down details on technical requirement for machinery in the wording of later regulations, Government Ordinance of the Slovak Republic No 392/1999 Coll. which lays down details on technical requirements and procedures of conformity assessment for electrical equipment which are used within the certain voltage limits, in the wording of later regulations, Government Ordinance of the Slovak Republic No 393/1999 Col. which lays down details on technical requirements for appliances burning gaseous fuels in the wording of Government Ordinance of the Slovak Republic No 394/1999 Coll. which lays down details on technical requirements for products from the point of view of electromagnetic compatibility (EMC) in the wording of later regulations, Government Ordinance of the Slovak Republic No 395/1999 Coll. which lays down details on technical requirements for toys...

§ 16 Testing

Testing of the determined product is an activity of the authorised body, accredited body, the manufacturer or importer, at which are examined properties, or characteristics of the intended product aimed at assessment the conformity with technical requirements.

Marks of conformity and marking § 17 Marks of conformity

- (1) Determined product that underwent the conformity assessment process under § 12 can be marked by conformity mark.
- (2) Conformity marks are:
 - a) Slovak conformity mark,
 - b) other conformity marks
 - c) CE marking,
 - c) foreign conformity marks.
- (3) Under § 2 sub-paragraph 1 items b) and d) the enterpriser is obliged to mark the determined product with conformity mark prior to its placing on the market (hereinafter referred to as "marker") if so stipulated by technical regulation.

§ 18 Slovak mark of conformity for determined products

- (1) Slovak mark of conformity C_{SK} consists of stylised letter marking given in the annex.
- (2) Slovak mark of conformity $C_{SK \text{ of}}$ determined products demonstrates that:
 - a) properties of determined product meet technical requirements for product and in case of construction products also requirements laid down under specific regulation⁶
 - b) conformity assessment procedures stipulated by this Act or by other specific regulation⁶ have been observed.
- (3) The marker accompanies the Slovak conformity mark C_{SK} by identification code of the authorised body in case when required by applied procedure for conformity assessment.
- (4) Determined product with which the conformity of properties in accordance with \S 12 subparagraph 2 has not been proved shall not be marked by the marker with conformity mark C_{SK} .
- (5) The Office shall publish in the Official Journal identification codes of the authorised bodies.

§ 19 Affixing the Slovak mark of conformity of determined product

(1) Slovak conformity mark of determined product shall be affixed preferably on the product. The Slovak conformity mark has to be placed on such part of the product, as to be visible. In case the Slovak mark of conformity of determined products cannot be placed on the product,

it can be placed on the packaging and quoted in accompanying documentation or, in case it cannot be placed even on the packaging, it can be quoted in the accompanying documentation.

- (2) Slovak conformity mark of determined products can be realised by the marker through:
 - a) printing on the packaging or on the product or in accompanying documentation,
 - b) label or self-adhesive foil,
 - c) relief or imprint on a product or casting to the product,
 - d) if it is not possible according to items a) c), by other way specified by the authorised body.
- (3) Slovak conformity mark of determined product in dependence from the way it is made must be
 - a) produced with contrast colours resistant to abrasion,
 - b) produced in such a way as to withstand the conditions of outer environment, secured against attrition,
 - c) secured against repeated usage.
- (4) The size and the way of placing of conformity mark of determined products shall be chosen so as the mark not to be shadowed nor doubt could be cast by other marking of the product, in such a way that confusion of other marking with the Slovak conformity mark can not happen, nor misrepresentation.
- (5) Dimensions of Slovak conformity mark of determined products must be such, as the mark of determined products to be easy identifiable and legible.

§ 20 Withdrawn by Act No.436/2001 Coll.

§ 21 CE marking

- (1) A particular status has the CE marking. It can be affixed to the product only if there has been issued the Declaration of Conformity with the technical regulations of European Communities on the product or if each product has been accompanied by it.
- (2) CE marking consists of stylised letter marking given in the annex.
- (3) At producing and placing of the CE marking, the marker proceeds similarly as at placing the Slovak conformity mark. Provision of § 19 shall be used adequately.
- (4) The Government by its Ordinance will stipulate the details of the usage of the CE marking as well as of the Declaration of Conformity
- (5) If the marker marks the products with the CE marking, the Slovak mark of conformity cannot be affixed to such marked product.
- (6) The CE marking can be replaced with other conformity mark if it is stipulated in a separate regulation $^{9a)}$

Accreditation activity § 22
Accreditation

- (1) Accreditation means the activity through which there is confirmed the competence for performance of testing of products, calibration of measuring instruments, execution of certification, inspection and similar technical activity.
- (2) Subjects of accreditation are:
 - a) accreditation body and
 - b) accredited entity.
- (3) Accreditation body is a legal entity that based on its application as the only one is determined by the decision of the Ministry of Economy of the Slovak Republic (hereinafter referred to as "Ministry of Economy") for the issuance of certificates of accreditation under sub-paragraph 1 and for performance of activities under § 23 in case he meets the following conditions:
 - a) impartiality of activity performance towards applicants for accreditation, namely objectivity and neutrality of check-up operations, matter of factness and impartiality of written reports and protocols the same from the part of management as from the part of technical employees, the ability to summarise and impartially evaluate the announced and own findings and proposals of all interested subjects in the process of decision on accreditation granting,
 - b) protection of data representing commercial secret, which could be misused, and protection of confidential information attained during the accreditation process;
 - c) harmonisation of requirements and assessment procedures with the rules of relevant international organisations engaged in the accreditation area given in European and International standards (hereinafter referred to as "accreditation rules");
 - d) fulfilment of obligations arising from the membership in international organisations active in accreditation field;
 - e) assurance of financial resources necessary for the accreditation operation;
 - f) employment of personnel being in permanent labour relation and having professional prerequisites and personal competence for performance of activities in relation to accreditation and having the obligation to keep secret on the facts they come to know during their operation.
- (4) Accredited entity means an enterpriser or legal entity (§ 1 item d) that performs activities under sub-paragraph 1 on the basis of certificate of accreditation (§ 26) issued to it by the accreditation body.

§ 23 Operation of the accreditation body

(1) The accreditation body

- a) on the basis of applications of the applicants for accreditation issues certificates of accreditation,
- b) provides by request the information on principles, conditions and procedure for accreditation, and on the way of covering the costs of accreditation,
- c) in due time informs accredited entities about the changes in requirements for accreditation that it intends to do,
- d) keeps the register of the issued certificates of accreditation; issued certificates and

- e) performs surveillance over the obeying the accreditation rules by the accredited entities. If the accreditation body finds deficiencies in fulfilment of these rules, according to severness of ascertained deficiencies, it suspends the accreditation till removal of deficiencies or it withdraws the accreditation certificate,
- f) ensures the exchange of experience among entities it accredited and it takes part in the exchange of experience with other foreign accreditation entities.
- (2) Expenses of the accrediting body connected with membership of the accreditation organisations are covered by the Ministry of Economy only within the range of the membership dues.
- (3) The Ministry of Economy shall withdraw the decision on determination of accreditation body if the accreditation body fails to satisfy the conditions given under § 22 sub-paragraph 3 items a) to f), or if it asks for it itself,
- (4) The Ministry of Economy shall inform the Office about its decision on determination of accreditation body as well as on withdrawing it. The Office shall publish this information in the Official Journal.

§ 24 Obligations of the accredited entity

- (1) The accredited entity during the validity of accreditation certificate shall fulfil conditions under which it has been accredited.
- (2) The accredited entity shall notify without delay the accreditation body essential changes related to its accreditation. Such changes are the changes in the subject and scope of activity, organisation changes, changes in the area of staff members in direct relation to the accreditation subject or changes in ownership form.
- (3) The accredited entity shall make possible for the persons authorised by the accreditation body the access to premises and equipment, to provide all information necessary for checking the accreditation rules fulfilment and necessary co-operation at the performance of their work.
- (4) The accredited entity shall cover the expenses linked to accreditation.

§ 25 Accreditation proceedings

- (1) Proceeding on accreditation begins on a day when the written application of the accredited entity for accreditation (hereinafter referred to as "applicant") has been delivered to an accreditation body.
- (2) In accordance with sub-paragraph 1 the application must contain:
 - a) identification data of the applicant,
 - b) information about the legal form or status of the applicant,
 - c) type of accreditation he asks for,
 - d) subject and scope of requested accreditation listing relevant technical specifications,
 - e) name of a person responsible for technical correctness of results from the activities of the applicant,
 - f) data on qualification, professional knowledge, training and experience of technical staff of the applicant,

- g) list of technical equipment,
- h) documentation describing the Quality System.
- (3) If the application for the beginning of proceedings does not have essentials under subparagraph 2 or it has other imperfection, the accreditation body invites the applicant in written to complete the application in appointed time or to retrieve its other imperfection. In case the applicant fails to complete it in this time or fails to retrieve the imperfection, the accreditation body shall stop the proceedings and it shall return the application to the applicant.
- (4) The accreditation body on the basis of application shall deliver to the applicant within 10 days from the day when the application is complete, the draft of contract on conditions for accreditation performance. To contents and form of the contract apply adequately provisions of specific regulations ¹⁰.
- (5) The accreditation body shall stop the proceedings and it shall return the application to the applicant if:
 - a) the applicant after having submitted the application lapsed without successor in title,
 - b) the applicant refuses the draft contract according to sub-paragraph 4 or the contract fails to be signed from other reason,
 - c) it stopped being accreditation body.
- (6) If the accreditation body is inactive, namely if it fails to deliver the draft contract on accreditation conditions within one month from the beginning of proceedings, the applicant can retract the application. The applicant can retract the application also from other reason or without giving the reasons, but only before signing the contract on accreditation conditions.
- (7) If the proceedings prove that the applicant has met all conditions or he diverges from them only in unimportant details, the accreditation body shall issue for the applicant the accreditation certificate (§ 26); otherwise it shall inform him that such certificate will not be issued because he failed to meet accreditation rules. The information thereabout shall be delivered in written to the applicant; the information must contain reasons for non-issuance of accreditation certificate.
- (8) The accreditation certificate is in force from the day, which is given therein as the day of entering into force.

§ 26 Certificate of accreditation

The accreditation certificate shall contain:

- a) the name of accreditation body granting the certificate and its residence,
- b) the business name and residence or enterprising place of the accredited entity,
- c) the subject and scope of the accreditation quoting the relevant technical specifications related to accreditation,
- d) the name of the person or persons that are its statutory body or members of the statutory body quoting the way how they act on behalf of the accredited entity,
- e) the number of the accreditation certificate and the date of its entering into force,
- f) data on conditions and validity of the accreditation certificate.

^{10 §§ 591} to 600 Commercial Code.

g) other data if necessary.

§ 27 Withdrawal of certificate of accreditation

- (1) If the accreditation body ascertains disagreement between accreditation rules and accreditation certificate, it shall request the accredited entity to remove it in adequate time that must not be longer than one month. If it does not happen, it shall send to accredited entity a notice on the beginning of proceedings on accreditation withdrawal; it shall notify thereabout the accredited entity.
- (2) The proceedings begin on the day of delivery of the notification about its start to accredited entity.
- (3) The accreditation body shall withdraw the certificate of accreditation under § 26 if there is proved in the proceedings that:
 - a) accredited entity in appointed time failed to remove the disagreement between accreditation rules and accreditation certificate,
 - b) quality system at accredited entity does not assure permanently required level of checking,
 - c) operation of accredited entity has been stopped for more than six months,
 - d) accredited entity entered into liquidation.
- (4) Communication of the accreditation body about withdrawal of certificate of accreditation shall be delivered to the accredited entity.
- (5) Within 14 days from the delivery of communication under sub-paragraph 3 the accredited entity is obliged to return the certificate of accreditation-to-accreditation body.

§ 28 Proceedings on traverses

- (1) The accreditation body has the right to submit in written traverses against the proceeding of accreditation body in proceedings on accreditation and its individual acts. Traverses shall be submitted to accreditation body within 10 days from the day of realisation of the act against which they are directed, if in the contract on conditions of accreditation performance there is not agreed a longer term. The traverses have no postponing effect.
- (2) The accreditation body is obliged to deal with the traverses without delay and to examine challenged proceeding or act.
- (3) If the accreditation body ascertains that the traverses are well founded, it shall assure the removal of this imperfection at expenses of that who caused this imperfection. It shall inform in written the applicant within 3 days about removal of imperfections.
- (4) If the accreditation body ascertains that the traverses are not well founded, it shall communicate it in written to accredited entity within three days from the end of examination of traverses.

§ 29 Proceedings on examination

(1) The applicant is entitled to apply the Ministry of Economy for examination of proceeding and acts of the accreditation body if it presumes that they are inconsistent with this Act. For examination can be applied within 15 days from delivery of communication of accreditation

body on cessation of proceedings and thereby on refusal of accreditation certificate issuance or on its withdrawal.

- (2) The application shall be submitted in written and shall contain:
 - a) data on accredited entity and on accreditation body,
 - b) the circumstance which is seen by the accredited entity as infringement of law,
 - c) proposal for decision of the Ministry of Economy.
- (3) The Ministry of Economy in proceedings shall examine the rightness of the procedure and operations carried out by the accreditation body and their harmony with the law; it shall examine namely the neutrality of evaluation of attained data, whether the conclusions proceed from the proposal of accredited entity, from the contract on accreditation conditions, from test reports, from written reports and performed inspections. If it ascertains that the application is well founded, it shall cancel contested operations of the accrediting body; else it shall dismiss the application.
- (4) The decision of the Ministry of Economy is final and there is no possibility to appeal therefrom.

Surveillance § 30 Surveillance bodies

- (1) Surveillance bodies under this Act are the bodies of state administration established according to specific regulations¹¹.
- (2) Surveillance bodies perform surveillance over:
 - a) whether on the determined products placed on the market had been issued the Declaration of Conformity and if the technical regulation requests it, whether these are marked by the conformity mark.
 - b) whether the properties of determined products placed on the market and the method for conformity assessment correspond to determined conditions of issued declaration of conformity,
 - c) whether the conformity marks are used legally and are not modified or counterfeited.
- (3) Manufacturer or importer that has placed products on the market is obliged to allow the surveillance bodies at the execution of their function to have a look into relevant technical, production, commercial and other documents concerning assessed products, to make them possible to check these products and namely to allow them to enter working, storage and commercial sites.
- (4) Procedure under sub-paragraph 3 is applied also in case when the product is not a determined one but there arises justified suspicion that it can endanger the justified concern.
- (5) Distributor is obliged to make possible for the surveillance bodies at the execution of their function to enter storage and commercial sites.

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For example Act of the National Council of the Slovak Republic No. 71/1986 Coll. on Slovak Trade Inspection in the wording of later regulations; Act of the National Council of the Slovak Republic No. 272/1996 Coll. on protection of people's health, in the wording of later regulations Act No. 140/1998 Coll. on medicinal products and medical devices in the wording of later regulations, on change of Act No. 455/1991 Coll. on crafts entrepreneuring in the wording of later regulations, on change and amendment of the Act of the National Council of the Slovak Republic No. 220/1996 Coll. on advertising in the wording of later regulations, Act No.95/2000 Coll. on labour inspection and on change and amendment of some Acts in the wording of its amendments, Act No 142/2001 Coll. on Metrology and on change and amendment of some Acts, Act No 195/2000 Coll. on Telecommunications in the wording of Act 308/2000 Coll..

- (6) If the surveillance body finds out the breaking of this Act or of regulations issued for its execution, it shall inflict protective measure or a fine in accordance with this Act.
- (7) By this Act are not affected the rights and obligations of surveillance bodies following for them from specific regulations¹¹.

§ 31 Safeguard provisions

- (1) The surveillance body may impose on enterpriser:
 - a) the suspension of placing products on the market for a specified period of time in case of well-founded suspicion of menace to justified concerns,
 - b) the prohibition of marketing the products or decision on withdrawal of these products from the market or also from the use in case that products evidently menace the justified concern,
 - c) the stipulation of the duty to inform immediately and efficiently about this menace persons that might be exposed to a danger using such product, namely in cases where protective measure according to item a) or b) has been imposed.
- (2) An appeal submitted against safeguard provision has no postponing effect.
- (3) The expenses linked to a safeguard provision are born by the one who places on the market products that endanger justified concern.

§ 32 Fines

- (1) The surveillance body shall inflict a fine of up to a 5 000 000. Slovak Crowns (SKK) on anyone who:
 - a) has used the conformity mark or certificate or declaration of conformity illegally or deceptively,
 - b) has placed on the market or distributed determined product without declaration of conformity under § 10 sub-paragraph 4, without certificate of conformity or without the prescribed marking of products with the Slovak conformity mark under § 17 sub-paragraph 3, or has placed the product on the market without authority.
 - c) has failed to comply with the decision on protective measure.
- (2) The Office shall, based on an initiative from outside or on its own findings, inflict a fine of up to 1 000 000. Slovak Crowns on anyone who without authority:
 - a) has used on the document the denomination "STN",
 - b) has duplicated or distributed a Slovak technical standard,
 - c) has declared himself as an authorised body,
 - d) has issued a certificate.
- (3) The Ministry of Economy shall, based on an initiative or on its own findings, inflict a fine of up to 1 000. Slovak Crowns on anyone who has declared himself without authority as an accreditation body or an body for which accreditation certificate has been issued, or failed to return the accreditation certificate (§ 27 sub-paragraph 5).
- (4) In case of repeated unlawful action there can be inflicted a fine under sub-paragraphs 1 -3 up to the double of inflicted fine.

- (5) In the process of the infliction of fines there shall be taken into account the price of the product, seriousness, way, duration and consequences of the unlawful action.
- (6) The fine may be inflicted within one year from the date the body authorised for infliction of fines has learned about the breach of duty, but not later than three years from the date on which such breach of duty has occurred.
- (7) The fine shall be payable within 30 days from the date of maturity of the decision on the infliction of the fine.
- (8) The money received from fines is the income of the state budget.

Common provisions

§ 33 Recognition of foreign documents and marks

- (1) Also foreign mark can be considered the Slovak conformity mark in compliance with this Act. Foreign document can be document of conformity, test report, certificate of conformity, certificate of conformity of a type or declaration of conformity in compliance with this Act if so stipulated in international agreement by which the Slovak Republic is bound.
- (2) The Office can, on the reciprocity principle, recognise foreign documents which evidence conformity assessment, or foreign mark as Slovak conformity mark under this Act, or as basic documents for conformity assessment, as far as the level of justified concern corresponding to requirements of relevant technical regulations is ensured.
- (3) If not otherwise stipulated by international agreement by which the Slovak Republic is bound and if the Office according to sub-paragraph 2 did not decide on mutual recognition of basic documents for conformity assessment, the authorised body can, on a basis of application, recognise the results of tests, certificates and inspections and other operations related to conformity assessment carried out abroad. The application for recognition of a foreign document shall be accompanied also by its translation into official language.
- (4) The Office publicises the facts under sub-paragraph 1 and 2 by publishing in the Official Journal.
- (5) Provisions of sub-paragraphs 2 4 do not apply for products regulated by specific regulation⁶.

§ 34 Proceedings

General regulations on administration proceedings¹² do not apply to proceedings under § 9 sub-paragraph 5, § 22 and §§ 26 to 29.

Transitory and final provisions

§ 35

(1) The decisions issued for execution of state testing under previous regulations are considered under this Act being the decisions on authorisation till 31 December 2000, unless in singular case their validity expires before.

¹² Act No. 71/1967 Coll. on administrative proceedings (administrative order).

- (2) The products determined for obligatory certification under previous regulations are considered determined products under this Act till 31 December 2002 at the latest.
- (3) The decisions on approval of products and certificates of products issued under previous regulations are considered certificates of determined products under this Act until the date of expiry of their validity or until otherwise stipulated by technical regulation.
- (4) The proceedings on approval of product and procedures on certification of product that have started before this Act is in force, shall be completed under this Act as certification of type of determined product in the case of a determined product, or in other cases when it is specially applied for by the applicant.
- (5) This Act does not apply for products placed on the market before its force nor for products placed on the market under specific regulations⁶.
- (6) The proceedings on infliction of fines that have started before this Act is in force shall be completed in accordance with the Act effective in time when the proceedings started.
- (7) Slovak technical standards marked as "STN" adopted before this Act entering into force are considered to be Slovak technical standards under this Act.
- (8) Enterprisers and bodies of state administration are obliged until 31 December 2000 to obey those provisions of the Slovak technical standard which are determined as compulsory according to regulations in force till now.

§ 36

- (1) For foodstuffs, cosmetics and tobacco products do not apply provisions of § 30 subparagraph 2 item b) and sub-paragraphs 3 and 4, §§ 31 and 32 sub-paragraph 1 item c).
- (2) In case of foodstuffs, cosmetics and tobacco products, the custom authorities shall inform without delay the bodies of food inspection ¹³.

§ 37 Repealing provision

Repealed are:

- Act No. 30/1968 Coll. on state testing in wording of Act No. 54/1987 Coll., Act No 194/1988 Coll., Act 479/1992 Coll. and Act No 539/1992 Coll. and Act No. 148/1995 Coll.;
- 2. Act No. 142/1991 Coll. on Czecho-Slovak technical standards in wording of Act No. 632/1992 Coll. and Act No 143/1995 Coll.;
- 3. § 28 and Annex No. 2 of Act No. 90/1998 Coll. on construction products;
- 4. Regulation of the Federal Office for Standardisation and Measurements No. 585/1992 Coll. by which Act No. 30/1968 Coll. on state testing, in wording of later regulations, is executed;

Regulation of the Slovak Office of Standards, Metrology and Testing No. 246/1995 Coll. on certification of products.

Enter into force

This Act is in force from 1 January 2000. This Act is in force from 1 November 2001. This Act is in force from 1 August 2003.

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^{\$ 23} of the Act of National Council of the Slovak Republic No. 152/1995 Coll. on foodstuffs in wording of Act of National Council of the Slovak Republic No. 290/1996 Coll.