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REPUBLIC OF CROATIA

ACT

ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND CONFORMITY ASSESSMENT

PART ONE
GENERAL PROVISIONS

Subject of the Act

Article 1.

This Act regulates the way of prescribing technical requirements for products, obligations of economic entities, prescribing requirements that must be fulfilled by conformity assessment bodies, contact point for products, single liaison office and cross-border mutual assistance, inspection supervision and misdemeanor provisions.

Transposition of European Union regulations

Article 2.

This Act ensures the implementation of the following European Union acts:

– Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance) (OJ L 218, 13.8.2008) (hereinafter: Regulation (EC) No 765/2008)

– Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and conformity of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (Text with EEA relevance) (OJ L 169, 25.6.2019) (hereinafter: Regulation (EU) 2019/1020) and

– Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods Actfully placed on the market in another Member State and repealing Regulation (EC) No 764/2008 (Text with EEA relevance) (OJ L 91, 29.3.2019) (hereinafter: Regulation (EU) 2019/515).

Concepts

Article 3.

Certain terms within the meaning of this Act have the same meaning as the terms defined in:

– Regulation (EC) no. 765/2008, except for the term "harmonised norm" which has the same meaning as the term defined in Regulation (EU) no. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision 1673/2006/EC of the European Parliament and of the Council (Text with EEA relevance) (OJ L 316, 14. 11. 2012) (hereinafter: Regulation (EU) No 1025/2012)

– Regulation (EU) 2019/1020

– Regulation (EU) 2019/515

– “international standard” as defined in Regulation (EU) No. 1025/2012

– "Croatian standard" is a standard available to the public that has been accepted by the Croatian national standardization body.

PART TWO
PRESCRIBING TECHNICAL REQUIREMENTS FOR PRODUCTS

Article 4.

For the purpose of safety, protection of life and health of humans, domestic animals and plants, protection of the environment and nature, protection of consumers and other users, the heads of state administration bodies, in accordance with their scope of activity, adopt ordinances prescribing technical requirements for products and conformity assessment procedures for individual products or groups of products, including, where necessary, regulations on regular and extraordinary inspections and testing of products in use.

Article 5.

(1) The regulations referred to in Article 4 of this Act shall regulate in more detail at least one of the following elements:

– technical requirements that must be met by products placed on the market or made available on the market

– conformity documentation necessary to demonstrate the conformity of the product with the prescribed requirements, which must be available to the competent authorities

– method of product labeling.

(2) When adopting the ordinance referred to in Article 4 of this Act, international principles and obligations assumed under international treaties shall be taken into account in order to prevent unnecessary obstacles to international trade.

(3) The regulations referred to in Article 4 of this Act shall prescribe that a product shall be presumed to comply with the prescribed technical requirements if it complies with the relevant harmonised standards, international standards, national standards or other technical specifications.

Prior consent

Article 6.

(1) The regulations referred to in Article 4 of this Act shall be adopted with the prior consent of the minister responsible for the economy.

(2) By way of exception to paragraph 1 of this Article, when the adoption of the ordinance referred to in Article 4 of this Act is exclusively within the scope of the ministry responsible for the economy, the consent referred to in paragraph 1 of this Article is not required.

Relationship to other Acts

Article 7.

This Act does not apply to the prescription of technical requirements and the implementation of conformity assessment procedures for products regulated by special Acts.

PART THREE
OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

(1) A product that is placed on the market or available on a market that includes distance sales in accordance with Article 6 of Regulation (EU) 2019/1020 must comply with the prescribed requirements relating to that product.

(2) An economic operator who places a product on the market or makes it available on the market shall be responsible for the compliance of the product with the prescribed requirements relating to that product within the framework of the obligations imposed on it by this Act and the regulations referred to in Article 4 of this Act.

(3) An economic entity that places a product on the market or makes it available on the market, within the framework of its obligations set out in this Act and regulations from Article 4 of this Act, is responsible for the accuracy and completeness of data on its products and must ensure that this data is in accordance with the prescribed requirements relating to that product.

Manufacturer's obligations

Article 9.

(1) When placing his product on the market, the manufacturer shall ensure that his product is designed and manufactured in accordance with the requirements laid down in the regulations relating to that product.

(2) When so prescribed by the regulations referred to in Article 4 of this Act, the manufacturer shall be obliged to draw up the prescribed technical documentation and carry out or ensure the carrying out of the applicable product conformity assessment procedure.

(3) When the conformity assessment procedure referred to in paragraph 2 of this Article has demonstrated the conformity of the product with the prescribed requirements, the manufacturer shall be obliged to draw up an EU declaration of conformity and affix the conformity marking when prescribed by the regulations referred to in Article 4 of this Act.

(4) The manufacturer shall be obliged to keep the technical documentation and the EU declaration of conformity after placing the product on the market, for the period specified in the regulations referred to in Article 4 of this Act.

(5) The manufacturer shall ensure that procedures are in place to maintain the conformity of the production series, taking into account changes in the design or characteristics of the product and changes in the applied harmonised standards or technical specifications referred to in the EU declaration of conformity of the product.

(6) The manufacturer is obliged, with regard to the risks posed by the product, and in order to protect the health and safety of consumers, to conduct testing of product samples that are placed on the market, to investigate and, if necessary, keep a book of complaints about non-conforming products and product recalls, and must inform the distributor about this.

(7) The manufacturer shall ensure that his product bears a type, batch or serial number or other information allowing its identification or, where the size or nature of the product does not permit this, that the required information is provided on the packaging or in the documents accompanying the product.

(8) The manufacturer shall indicate on the product or, where that is not possible, on its packaging or in a document accompanying the product his name, registered trade name or registered trade mark and the address which must indicate a single point at which the manufacturer can be contacted.

(9) When so prescribed by the regulations referred to in Article 4 of this Act relating to the product, the manufacturer must ensure that the product is accompanied by instructions and safety information in the Croatian language and Latin script.

(10) Where a manufacturer considers or has reason to believe that a product which he has placed on the market is not in conformity with the provisions of the regulations applicable to that product, he shall take the necessary corrective measures without delay to bring that product into conformity or to withdraw it from the market or to prevent its distribution, if more appropriate.

(11) If the product poses a risk, the manufacturer must notify the competent inspection bodies without delay, specifying the information, especially about the non-conformity of the product and all the corrective measures taken.

(12) The manufacturer is obliged, at the request of the competent inspector:

– provide all data and documents necessary to prove the conformity of the product in a language easily understood by the competent inspector

– cooperate in any action taken to eliminate the risks posed by the product it has placed on the market.

(13) In addition to the obligations referred to in paragraphs 1 to 12 of this Article, the manufacturer shall also fulfil the obligations set out in the regulations referred to in Article 4 of this Act for individual products adopted pursuant to this Act.

(14) The provisions of this article are also applied accordingly to the obligations of the installer during the design, manufacture, installation and placing of the product on the market when this is prescribed by the regulations from Article 4 of this Act.

Obligations of an authorized representative

Article 10.

(1) The manufacturer may, on the basis of a written mandate, designate a natural or legal person established in the European Union as its authorised representative.

(2) Obligations from Article 9, Paragraph 1 of this Act and the compilation of technical documentation do not refer to the obligations of an authorized representative.

(3) The authorized representative is obliged to carry out the tasks specified in the authorization referred to in paragraph 1 of this Article, in particular:

– make the EU declaration of conformity and the technical documentation available to the competent inspectors within the period specified in the regulation relating to that product

– at the request of the competent inspector, provide all data and documents necessary to prove product conformity

– cooperate with the competent inspector at his request in any action taken to eliminate the risks posed by the product covered by his authorization.

(4) The authorized representative is also obliged to fulfill the obligations set out in the regulations referred to in Article 4 of this Act for individual products.

Importer obligations

Article 11

(1) The importer shall place on the European Union market only a product that complies with the provisions of the regulations applicable to that product.

(2) Before placing a product on the market, the importer is obliged to establish that the manufacturer has carried out the appropriate conformity assessment procedure, has drawn up the technical documentation, that the product bears the prescribed conformity marking or other markings, that it is accompanied by the prescribed documents and that it has fulfilled the requirements set out in Article 9, paragraphs 7 and 8 of this Act.

(3) Where an importer considers or has reason to believe that a product is not in conformity with the provisions of the regulations applicable to that product, he shall not place the product on the market until it has been brought into conformity.

(4) If the product from paragraph 3 of this article represents a risk, the importer is obliged to inform the manufacturer and the competent inspection authorities thereof.

(5) The importer shall indicate his name, registered trade name or registered trade mark and the address at which he can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

(6) When prescribed by the regulations referred to in Article 4 of this Act, the importer is obliged to ensure that the product is accompanied by instructions and safety information in the Croatian language and Latin script.

(7) The importer shall ensure that, while the product is under his responsibility, storage or transport conditions do not jeopardise the product's compliance with the prescribed requirements.

(8) When deemed appropriate with regard to the risks presented by the product, the importer shall, in order to protect the health and safety of consumers, carry out sample testing of the products which he intends to place on the market, investigate and, if necessary, keep a register of complaints of non-compliant products and product recalls, and shall keep distributors informed thereof.

(9) Where an importer considers or has reason to believe that a product which he has placed on the market is not in conformity with the provisions of the regulations applicable to that product, he shall immediately take the necessary corrective measures to bring that product into conformity or to withdraw it from the market or to prevent its distribution.

(10) If the product referred to in paragraph 9 of this article represents a risk, the importer is obliged to immediately inform the competent inspection authorities about it, providing information about the non-conformity of the product and all corrective measures taken.

(11) Where the regulations referred to in Article 4 of this Act so require, the importer shall, for the period specified in the regulation applicable to that product, keep a copy of the EU declaration of conformity at the disposal of the competent inspectors and ensure that the technical documentation is available to the competent inspectors upon request.

(12) The importer is obliged, at the request of the competent inspector:

– provide all data and documents necessary to demonstrate product conformity in a language easily understood by the inspector and

– cooperate with the competent inspector in all actions taken to eliminate the risks posed by the product he has placed on the market.

(13) The importer is also obliged to fulfill the obligations set out in the regulations referred to in Article 4 of this Act for individual products.

Distributor obligations

Article 12

(1) When making the product available on the market, the distributor must act with due care in relation to the prescribed requirements.

(2) Before making a product available on the market, the distributor must check whether the product is marked with the prescribed conformity mark or other markings, whether it is accompanied by the prescribed documents, instructions and safety information in the Croatian language and Latin script, and whether the manufacturer and the importer have fulfilled the requirements referred to in Article 9, paragraphs 7 and 8, and Article 11, paragraph 5, of this Act.

(3) Where a distributor considers or has reason to believe that a product is not in conformity with the provisions of the regulations applicable to that product, he shall not make the product available on the market until it has been brought into conformity.

(4) When the product from paragraph 3 of this article represents a risk, the distributor must inform the manufacturer or importer, as well as the competent inspection authorities.

(5) While the product is under his responsibility, the distributor must ensure that storage or transport conditions do not jeopardise the product's compliance with the prescribed requirements.

(6) Where a distributor considers or has reason to believe that a product which he has made available on the market is not in conformity with the provisions of the regulations applicable to that product, he shall immediately ensure that the necessary corrective measures are taken to bring that product into conformity, to withdraw it from the market or to prevent its distribution, if appropriate.

(7) When the product referred to in paragraph 6 of this article represents a risk, the distributor must immediately notify the competent inspection authorities and the competent inspection authorities of the member state in which the said products are made available in this sense, providing information in particular about the non-compliance of the product and all corrective measures taken.

(8) The distributor is obliged, upon request of the competent inspector:

– provide all data and documents necessary to prove the conformity of the product and

– cooperate with the competent inspector in all actions taken to eliminate the risks posed by the product which he has made available on the market.

(9) The distributor is also obliged to fulfill the obligations set out in the regulations referred to in Article 4 of this Act for individual products.

Owner and user obligations

Article 13.

(1) Where the owner considers, or has reason to believe, that a product does not comply with the provisions of the regulations applicable to that product, including the requirements for periodic inspections, the product may not be made available or used until it has been brought into compliance.

(2) When the product from paragraph 1 of this article represents a risk, the owner must inform the manufacturer or importer or distributor and the competent inspection bodies.

(3) The user may only use those products that comply with the provisions of the regulations applicable to that product.

(4) When the product from paragraph 3 of this article poses a risk, the user must inform the owner and the competent inspection authorities about it.

(5) The owner or user of the product is also obliged to fulfill the obligations set out in the regulations referred to in Article 4 of this Act for individual products.

Tasks of economic operators with regard to products pursuant to Article 4 of Regulation (EU) 2019/1020

Article 14.

The manufacturer, importer, authorised representative and fulfilment service provider are also obliged to carry out tasks in accordance with Article 4 of Regulation (EU) 2019/1020.

Cases where the manufacturer's obligations apply to importers and distributors

Article 15

Where an importer or distributor places a product on the market under his own name or trademark or modifies a product already placed on the market in such a way that compliance with the requirements applicable to that product may be affected, he shall be considered to be the manufacturer and shall be subject to the obligations of the manufacturer in accordance with Article 9 of this Act.

Identification of economic entities

Article 16

Each economic operator must, within the period specified in the regulation applicable to the individual product, at the request of the competent inspector, provide information on the identity of:

– any economic operator who has delivered the product to him

– any economic operator to whom the product was delivered.

PART FOUR
CONFORMITY ASSESSMENT BODIES AND REQUIREMENTS THEY MUST MEET

Prescribing requirements for conformity assessment bodies

Article 17.

(1) The regulations referred to in Article 4 of this Act may prescribe requirements that must be met by conformity assessment bodies.

(2) The minimum requirements that must be met by conformity assessment bodies are:

– the professional competence of the personnel in the relevant field for which the conformity assessment body is authorised

– necessary equipment and space

– independence and impartiality in the conformity assessment procedure

– keeping a trade secret

– liability insurance, unless their liability is assumed by the state.

(3) A conformity assessment body shall not be an economic operator for the products it assesses, nor shall it be directly involved in the design, manufacture or construction, the placing on the market or making available on the market, the installation, use or maintenance of those products.

Article 18

The head of the state administration body referred to in Article 4 of this Act may, by ordinance, prescribe the procedure for monitoring the work of conformity assessment bodies and the measures to be taken in the event of failure to meet the prescribed requirements referred to in Article 17 of this Act.

Authorization to perform conformity assessment tasks

Article 19

(1) A conformity assessment body may perform conformity assessment activities only on the basis of an authorisation decision (hereinafter: authorisation) issued by the head of the state administration body referred to in Article 4 of this Act.

(2) When a conformity assessment body demonstrates its competence in accordance with the requirements laid down in Croatian standards that have adopted the corresponding harmonised European standards, it shall be presumed to meet the requirements referred to in Article 17 of this Act.

(3) The accreditation certificate issued by the Croatian national accreditation body shall be considered proof of the competence of the body to assess conformity with the requirements set out in Croatian standards that have adopted the corresponding harmonised European standards.

(4) The authorization referred to in paragraph 1 of this Article may be limited in time or valid until revoked.

(5) The conformity assessment body must meet the requirements referred to in Article 17 of this Act for the entire duration of its authorisation.

(6) If it is determined that during the period of authorisation, a conformity assessment body has ceased to meet the prescribed requirements, the head of the competent state administration body referred to in Article 4 of this Act shall revoke the authorisation in the part in which the body has ceased to meet the requirements.

(7) No appeal is permitted against the decision referred to in paragraphs 1 and 6 of this Article, but an administrative dispute may be initiated.

(8) The state administration body responsible for the adoption of regulations referred to in Article 4 of this Act shall notify the European Commission of the conformity assessment bodies it has authorised to carry out conformity assessment procedures.

(9) The notification procedure referred to in paragraph 8 of this Article, as well as the requirements relating to the bodies carrying out the notification and the requirements relating to the notified bodies, shall be prescribed by an ordinance by the head of the state administration body competent for the economy.

Conducting the conformity assessment procedure

Article 20

(1) The conformity assessment body referred to in Article 19 of this Act shall carry out conformity assessment procedures based on the request of the manufacturer or his authorised representative.

(2) The conformity assessment body referred to in Article 19 of this Act and the applicant referred to in paragraph 1 of this Article shall regulate their mutual rights and obligations in relation to the implementation of conformity assessment procedures by means of a contract concluded in writing.

PART FIVE
PRODUCT CONTACT POINT

Article 21

The state administration body responsible for the economy shall be designated as the Product Contact Point (PCP) in accordance with Article 9 of Regulation (EU) 2019/515.

PART SIX
SINGLE OFFICE FOR LIAISON AND CROSS-BORDER MUTUAL ASSISTANCE

Article 22

(1) The State Inspectorate, in accordance with Article 10, paragraph 3 of Regulation (EU) 2019/1020, is designated as a single liaison office responsible for coordinating the implementation of Regulation (EU) 2019/1020, which coordinates all necessary activities between inspections responsible for the supervision of products placed on the market of the Republic of Croatia.

(2) The Single Liaison Office referred to in paragraph 1 of this Article shall, in the implementation of Regulation (EU) 2019/1020, perform tasks in accordance with the obligations referred to in Article 10, paragraph 4, and Article 34, paragraph 3, of Regulation (EU) 2019/1020.

(3) In implementing Regulation (EU) 2019/1020, market surveillance authorities, each within their respective scope of competence, as determined by the regulations transposing the regulations set out in Annex I to Regulation (EU) 2019/1020:

– perform tasks in accordance with the obligations referred to in Article 34(4) and (5) of Regulation (EU) 2019/1020

– cooperate directly with the market surveillance authorities of the Member States in cases of cross-border mutual assistance in accordance with Articles 22, 23 and 24 of Regulation (EU) 2019/1020 and

– cooperate with the single liaison office referred to in paragraph 1 of this Article.

(4) By way of derogation from paragraph 3, subparagraph 2 of this Article, if the single liaison office receives a request referred to in Articles 22 and 23 of Regulation (EU) 2019/1020, it shall forward it without delay for action to the competent authority referred to in paragraph 3 of this Article, which shall be obliged to act on that request in accordance with the prescribed tasks.

PART SEVEN
INSPECTION SUPERVISION

Article 23

(1) Inspection supervision over the implementation of Chapter IV of Regulation (EC) No. 765/2008, Regulation (EU) 2019/1020 in the part relating to products to which this Act applies, Regulation (EU) 2019/515, this Act and the ordinance referred to in Article 4 of this Act, each within its scope, shall be carried out by: market inspectors, pressure equipment inspectors, electricity inspectors, construction inspectors and agricultural inspectors, in accordance with the powers granted by this Act and special regulations.

(2) By way of derogation from paragraph 1 of this Article, inspection supervision over the implementation of Chapter IV of Regulation (EC) No. 765/2008 in the part relating to the affixing of the CE marking, Regulation (EU) 2019/1020 and Regulation (EU) 2019/515, this Act and the regulations referred to in Article 4 of this Act which regulate the technical requirements for:

– radio equipment, carried out by electronic communications inspectors of the Croatian Regulatory Agency for Network Industries (HAKOM)

– measuring instruments and non-automatic scales, performed by metrological inspectors

– hazardous substances in electrical and electronic equipment, carried out by market inspectors, sanitary inspectors and pharmaceutical inspectors, each within their own scope of work

– equipment and protective systems intended for use in potentially explosive atmospheres, are carried out by electrical power inspectors

– elevator safety, each carried out within their own scope by market inspectors, construction inspectors and electrical energy inspectors.

Inspector's powers

Article 24.

(1) Competent inspectors have powers from Article 14, paragraph 4 of Regulation (EU) 2019/1020.

(2) The powers referred to in paragraph 1 of this Article shall be exercised in accordance with Article 14, paragraph 3 of Regulation (EU) 2019/1020.

(3) The exercise of the powers referred to in paragraph 1 of this Article must be in accordance with the principle of proportionality, proportionate to the nature of the non-compliance and the total actual or potential damage resulting from the non-compliance.

(4) Competent inspectors have the authority under this Act to:

– carry out appropriate examinations and tests of products to determine their conformity with the prescribed technical requirements even after they have been placed on the market or made available on the market and

– take product samples free of charge and submit them for testing and assessment of compliance with the prescribed technical requirements.

(5) If the competent inspection body does not have the necessary expertise or equipment to carry out the inspection or testing referred to in paragraphs 1 and 4 of this Article, it may entrust the implementation of individual actions within the framework of inspection supervision to a professional institution that was not involved in the testing and conformity assessment of the same product before it was placed on the market or made available on the market.

Administrative measures

Article 25

(1) If the competent inspector, while carrying out an inspection, determines that a product placed on the market or made available on the market does not comply with the requirements of this Act and the regulations referred to in Article 4 of this Act, which relate to formal non-compliance:

- the product is not labeled in accordance with the requirements of this Act and the regulations from Article 4 of this Act

– the conformity documents have not been drawn up or have not been drawn up correctly, or are incomplete, or are not available

– instructions and safety information do not accompany the product or are not included with the product or are incomplete or

– any other requirement relating to formal non-compliance as defined in the regulations adopted pursuant to this Act has not been met,

and the same non-conformities do not pose a risk to the health and safety of the user, the inspector will without delay, through the inspection record, require the economic entity that placed the product on the market or available on the market to implement corrective measures in order to eliminate formal non-conformities within the framework of its obligations under this Act and the regulations adopted on the basis of this Act, and will determine an appropriate deadline for the execution of the corrective measure.

(2) If the economic operator fails to implement the corrective measures referred to in paragraph 1 of this Article within the specified period, the competent inspector shall issue a decision prohibiting the economic operator from placing the product on the market or making it available on the market or ordering the withdrawal of the product from the market.

(3) If the competent inspector, when carrying out an inspection, determines that a product placed on the market or made available on the market does not comply with the requirements of this Act and the regulations referred to in Article 4 of this Act and/or that the non-compliance poses a risk to the health and safety of users, including formal non-compliance that poses a risk, the inspector shall, in proportion to the assessment of the nature of the risk, issue a decision ordering the economic operator that placed the product on the market or made available on the market to take one or more of the following corrective measures within the framework of the obligations imposed on it by this Act and the regulations referred to in Article 4 of this Act:

– order the elimination of identified non-conformities and set an appropriate deadline for their elimination

– prohibit the placing of the product on the market or making it available on the market

- to order the immediate withdrawal or recall of the product from the market for end users and to order the familiarization and notification of the public on the risks it presents

- to order the destruction of the product if it is necessary to protect the health or safety of the user

– temporarily prohibit the placing of a product on the market or making it available on the market, the delivery of a product, the offer to deliver a product, the advertising of a product or the display of a product during the time necessary for various inspections and tests if there is a reasonable suspicion that the product does not comply with the requirements of this Act and the regulations referred to in Article 4 of this Act

– order that clearly formulated and easily understandable warnings in the Croatian language and Latin script be placed on the product about the risks that the product may pose and/or order that end users be immediately warned in an appropriate manner by publishing special warnings in the Croatian language and set an appropriate deadline for implementation.

(4) If the economic entity does not eliminate the non-conformities within the period referred to in paragraph 3, sub-paragraph 1 and sub-paragraph 6 of this article, the inspector will issue a decision prohibiting the placing of products on the market or available on the market and order the withdrawal of products that have already been placed on the market or available on the market.

(5) With the decision from paragraph 4 of this article, the inspector will cancel the decision from paragraph 3, subparagraph 1 and subparagraph 6 of this article.

(6) Before taking corrective measures referred to in paragraphs 1 and 3 of this Article, the inspector shall inform the economic operator of the measures to be taken and shall be given the opportunity to comment within an appropriate period, not shorter than ten working days, unless this is not possible due to the urgency of taking the measure for the purpose of protecting health and safety or for some other reason related to the public interest.

(7) In the case of products sold online or by other means of distance selling, as defined in Article 6 of Regulation (EU) 2019/1020, and in addition to taking the corrective measures referred to in paragraph 3 of this Article, there are no other effective means to eliminate the serious risk, the inspector shall determine by decision any measure that achieves the purpose of eliminating the serious risk, in particular:

– order public communications service operators and/or internet access service providers and/or hosting service providers to remove content or restrict access to the internet interface or to clearly display to end-users, when accessing the internet interface, an explicit warning indicating a non-compliant product

- order all domain registries or domain registrars to delete the fully qualified domain name and allow the competent authority to register it.

(8) If damage has been caused to public communications service operators, internet access service providers and accommodation service providers based on the decision referred to in paragraph 7 of this Article, they have the right to claim compensation from the economic operator in accordance with the general rules for compensation for damage.

(9) Operators of public communications services, providers of internet access services and providers of accommodation services shall be obliged to cooperate with the competent inspection authorities in accordance with Article 7(2) of Regulation (EU) 2019/1020.

(10) An appeal filed against the inspector's decision referred to in paragraphs 2, 3, 4 and 7 of this Article shall not postpone the execution of the decision, unless otherwise provided for by special regulations.

RAPEX system

Article 26

In the event of measures under Article 19 of Regulation (EU) 2019/1020 being taken for products presenting a serious risk, a notification procedure is carried out through the RAPEX system in accordance with the regulation governing the rapid exchange of official notifications on products presenting a risk to the health and safety of consumers (RAPEX).

Costs of the inspection procedure

Article 27.

The costs of the inspection procedure, which include the costs of testing and checking the conformity of the product, transport costs related to the inspection, the costs of purchasing product samples, including under a secret identity, shall be borne by the economic operator who has placed on the market or made available on the market, including distance selling, in accordance with Article 6 of Regulation (EU) 2019/1020, a product that does not comply with the technical requirements for that product.

Inspection of products upon import for placing on the European Union market

Article 28.

The inspection of products upon import for placing on the European Union market is performed by the Customs Administration of the Ministry of Finance in accordance with Articles 25 to 28 of Regulation (EU) 2019/1020.

PART EIGHT
MINORITY PROVISIONS

Manufacturer and authorized representative

Article 29

installer and authorized representative – shall be fined from 50,000.00 to 1,000,000.00 kuna for a misdemeanor if:

– places on the market a product that is not designed and manufactured in accordance with the requirements laid down in the regulations applicable to that product (Article 9, paragraph 1)

– fails to carry out or ensure the implementation of the applicable conformity assessment procedure when prescribed by the regulations referred to in Article 4 of this Act (Article 9, paragraph 2)

- does not prepare the prescribed technical documentation for the product that he has placed on the market when this is prescribed by the regulations from Article 4 of this Act (Article 9, paragraph 2)

– fails to draw up an EU declaration of conformity when the conformity assessment procedure referred to in Article 9, paragraph 2 of this Act has demonstrated the conformity of the product with the prescribed requirements (Article 9, paragraph 3)

– fails to affix the conformity marking to the product when this is prescribed by the regulations referred to in Article 4 of this Act (Article 9, paragraph 3)

– fails to keep the technical documentation and the EU declaration of conformity for the period specified in the regulations referred to in Article 4 of this Act after placing the product on the market (Article 9, paragraph 4)

– fails to ensure procedures to maintain the conformity of the production batch (Article 9, paragraph 5)

– fails to carry out sample testing of products it places on the market in relation to the risks posed by the product in order to protect the health and safety of consumers (Article 9(6))

- does not keep a book of complaints about non-compliant products (Article 9, paragraph 6)

- does not inform distributors about non-compliant products and withdrawal of products from the market (Article 9, paragraph 6)

– places a product on the market without ensuring that the product bears a type, batch or serial number or any other element allowing its identification or, where the size or nature of the product does not allow this, fails to indicate the same information on the packaging or in the documents accompanying the product (Article 9, paragraph 7)

– does not indicate on the product or, where that is not possible, on its packaging or in a document accompanying the product its name, registered trade name or registered trade mark and the address at which it can be contacted (Article 9(8))

– places a product on the market without ensuring that it is accompanied by instructions and information in the Croatian language and Latin script when this is prescribed by the regulations referred to in Article 4 of this Act relating to the product (Article 9, paragraph 9)

– places on the market a product which is not in conformity with the provisions of the regulations applicable to that product and does not take the necessary corrective measures voluntarily to bring that product into conformity, withdraw it from the market or prevent its distribution (Article 9, paragraph 10)

- places a product that represents a risk on the market, and does not inform the competent inspection authorities about it, stating information about the non-compliance of the product and the corrective measures taken (Article 9, paragraph 11)

– fails to provide the competent inspector with all the data and documents necessary to prove the conformity of the product (Article 9, paragraph 12, subparagraph 1)

- he does not cooperate with the competent inspectors in all the actions he undertakes to eliminate the risks posed by the product he has placed on the market (Article 9, paragraph 12, subparagraph 2)

- does not perform the tasks specified in the authorization given by the manufacturer (Article 10, paragraph 3)

– does not act in accordance with the regulations referred to in Article 4 of this Act

- does not put the prescribed "CE" mark and/or mark the products with marks that are similar to the "CE" mark to the extent that they could create confusion on the market or mislead consumers in accordance with Article 30 of Regulation (EC) no. 765/2008

– does not perform tasks in accordance with Article 4(3) of Regulation (EU) 2019/1020

– does not perform tasks in accordance with Article 4(4) of Regulation (EU) 2019/1020

- does not act in accordance with the executive decisions of the competent inspector from Article 25 of this Act.

(2) For the violations referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from 20,000.00 to 50,000.00 kuna.

(3) For the offenses referred to in paragraph 1 of this article, a physical person - a craftsman and a person who performs other independent activities will be fined from HRK 20,000.00 to HRK 50,000.00.

(4) For misdemeanors referred to in paragraph 1, subparagraphs 3, 4, 5, 10, 11 and 12 of this article, the competent inspector shall not file an indictment or issue a misdemeanor order if the business entity acts within the deadline and implements the corrective measures referred to in Article 25, paragraph 1 of this Act, except in the case of re-establishment of the same misdemeanor.

Importer

Article 30

(1) A legal entity – importer shall be fined from 25,000.00 to 500,000.00 kuna for a misdemeanor if:

– places on the market a product that does not comply with the provisions of the regulations applicable to that product (Article 11, paragraph 1)

– places on the market a product for which the appropriate conformity assessment procedure has not been carried out (Article 11(2))

– places a product on the market for which technical documentation has not been drawn up (Article 11, paragraph 2)

– places on the market a product that does not bear the prescribed conformity marking (Article 11, paragraph 2)

– places a product on the market that does not bear other prescribed markings (Article 11, paragraph 2)

– places a product on the market without product identification data and information about the manufacturer in accordance with Article 9, paragraphs 7 and 8 of this Act (Article 11, paragraph 2)

– does not indicate its name, registered trade name or registered trade mark and the address at which it can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product (Article 11(5))

– places a product on the market that is not accompanied by instructions and information in the Croatian language and Latin script when so prescribed by the regulations referred to in Article 4 of this Act (Article 11, paragraph 6)

– does not carry out tests on samples of products that it intends to place on the market with regard to the risks posed by the product in order to protect the health and safety of consumers (Article 11(8))

- does not keep a book of complaints about non-compliant products (Article 11, paragraph 8)

- does not inform distributors about non-compliant products and withdrawal of products from the market (Article 11, paragraph 8)

– places on the market a product which is not in conformity with the provisions of the regulations applicable to that product and does not take the necessary corrective measures voluntarily to bring that product into conformity, withdraw it from the market or prevent its distribution (Article 11, paragraph 9)

- places a product that represents a risk on the market, and does not inform the competent inspection bodies about it, providing information about the non-conformity of the product and the corrective measures taken (Article 11, paragraph 10)

– does not keep a copy of the EU declaration of conformity for the purpose of making it available to the competent inspectors in accordance with the regulations referred to in Article 4 of this Act (Article 11, paragraph 11)

- does not ensure that the technical documentation is available to the competent inspectors in accordance with the regulations from Article 4 of this Act (Article 11, paragraph 11)

– fails to provide the competent inspector with all the data and documents necessary to prove the conformity of the product (Article 11, paragraph 12, subparagraph 1)

- he does not cooperate with the competent inspectors in all actions he undertakes to eliminate the risks posed by the product he has placed on the market (Article 11, paragraph 12, sub-paragraph 2)

– does not perform tasks in accordance with Article 4(3) of Regulation (EU) 2019/1020

– does not perform tasks in accordance with Article 4(4) of Regulation (EU) 2019/1020

– does not act in accordance with the regulations referred to in Article 4 of this Act

- does not act in accordance with the executive decisions of the competent inspector from Article 25 of this Act.

(2) For the violations referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from 15,000.00 to 50,000.00 kuna.

(3) For the offenses referred to in paragraph 1 of this article, a physical person - a craftsman and a person who performs other independent activities will be fined from HRK 15,000.00 to HRK 50,000.00.

(4) For misdemeanors referred to in paragraph 1, subparagraphs 3, 4, 5, 6, 7 and 8 of this article, the competent inspector shall not submit a charge proposal or issue a misdemeanor order if the business entity acts within the deadline and implements the corrective measures referred to in Article 25, paragraph 1 of this Act, except in the case of re-establishment of the same misdemeanor.

Distributor

Article 31

(1) A legal entity – distributor shall be fined from 15,000.00 to 100,000.00 kuna for a misdemeanor if:

– makes a product available on the market contrary to the prescribed requirements (Article 12, paragraph 1)

– makes available a product that does not bear the conformity mark or other prescribed markings (Article 12, paragraph 2)

– makes a product available on the market that is not accompanied by the prescribed documents, instructions and safety information in the Croatian language and Latin script (Article 12, paragraph 2)

– makes a product available on the market without product identification data and information about the manufacturer and importer in accordance with Article 9, paragraphs 7 and 8 and Article 11, paragraph 5 of this Act (Article 12, paragraph 2)

– makes available on the market a product which is not in conformity with the provisions of the regulations applicable to that product and does not take the necessary corrective measures voluntarily to bring that product into conformity, withdraw it from the market or prevent its distribution (Article 12(6))

- makes available on the market a product that represents a risk, and does not inform the competent inspection bodies about it, providing information about the non-conformity of the product and the corrective measures taken (Article 12, paragraph 7)

– fails to provide the competent inspector with all the data and documents necessary to prove the conformity of the product (Article 12, paragraph 8, subparagraph 1)

- he does not cooperate with the competent inspectors in all the actions he undertakes to eliminate the risks posed by the product he made available on the market (Article 12, paragraph 8, sub-paragraph 2)

– does not act in accordance with the regulations referred to in Article 4 of this Act

- does not act in accordance with the executive decisions of the competent inspector from Article 25 of this Act.

(2) For the violations referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from 10,000.00 to 50,000.00 kuna.

(3) For the offenses referred to in paragraph 1 of this article, a physical person - a craftsman and a person who performs other independent activities will be fined from HRK 10,000.00 to HRK 50,000.00.

(4) For the misdemeanors referred to in paragraph 1, subparagraphs 2, 3 and 4 of this article, the competent inspector shall not file an indictment or issue a misdemeanor order if the business entity acts within the deadline and implements the corrective measures referred to in Article 25, paragraph 1 of this Act, except in the case of re-establishment of the same misdemeanor.

Order fulfillment service provider

Article 32

(1) A legal entity – a provider of order fulfillment services – shall be fined HRK 25,000.00 to HRK 500,000.00 for a misdemeanor if:

– does not perform tasks in accordance with Article 4(3) of Regulation (EU) 2019/1020

– fails to carry out tasks in accordance with Article 4(4) of Regulation (EU) 2019/1020.

(2) For the violations referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from 15,000.00 to 50,000.00 kuna.

(3) For the offenses referred to in paragraph 1 of this article, a physical person - a craftsman and a person who performs other independent activities will be fined from HRK 15,000.00 to HRK 50,000.00.

Owner and user

Article 33.

(1) A legal entity – owner, user – shall be fined from 5,000.00 to 100,000.00 kuna for a misdemeanor if:

– makes available or uses a product that does not comply with the provisions of the regulations applicable to that product, including the requirements for periodic inspections before its compliance is carried out (Article 13(1))

– makes available or uses a product that presents a risk and fails to inform the competent inspection authorities thereof (Article 13, paragraph 2)

– uses a product that does not comply with the provisions of the regulations applicable to that product (Article 13(3))

– uses a product that poses a risk and fails to inform the competent inspection authorities thereof (Article 13, paragraph 4)

– does not act in accordance with the regulations referred to in Article 4 of this Act

- does not act in accordance with the executive decisions of the competent inspector from Article 25 of this Act.

(2) For the violations referred to in paragraph 1 of this Article, the responsible person in the legal entity shall also be fined from 1,000.00 to 15,000.00 kuna.

(3) For the offenses referred to in paragraph 1 of this article, a physical person - a craftsman and a person who performs other independent activities will be fined from HRK 1,000.00 to HRK 15,000.00.

PART NINE
TRANSITIONAL AND FINAL PROVISIONS

Ongoing procedures

Article 34.

Procedures initiated under the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, Nos. 80/13, 14/14 and 32/19) until the date of entry into force of this Act shall be completed in accordance with the provisions of that Act.

Article 35

(1) Until the entry into force of the by- Acts adopted on the basis of this Act and on the basis of special Acts, the following shall remain in force:

a) subordinate legislation adopted on the basis of the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, No. 80/13), namely:

– Rulebook on technical standards for the protection of low-voltage networks and associated transformer stations ("Official Gazette of SFRY", No. 13/78.)

– Rulebook on technical measures for the operation and maintenance of power plants ("Official Gazette of the SFRY", No. 19/68.)

– Rulebook on technical standards for the construction of overhead power lines with rated voltages from 1 kV to 400 kV ("Official Gazette of the SFRY", No. 65/88, "Official Gazette", No. 24/97)

- Rulebook on technical norms for the construction of overhead power lines ("Official Gazette of the SFRY", no. 51/73, 69/73. - correction, 11/80. - amendment, article 10 of the Rulebook on technical norms for the installation of power lines and telecommunications cable lines - No. 36/86, article 333 of the Rulebook on technical norms for the construction of overhead power lines of nominal voltages from 1 kV to 400 kV - No. 65/88.), only the provisions relating to low-voltage power lines and connections of rated voltage up to 1 kV are in force.

– Rulebook on technical norms for the installation of overhead power lines and telecommunication cable lines ("Official Gazette of the SFRY", no. 36/86.)

b) subordinate legislation adopted on the basis of the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, Nos. 158/03 and 79/07), which were left in force by the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, No. 20/10), namely:

– Ordinance on crystal glass products (Official Gazette, No. 135/05 and 32/09)

– Ordinance on requirements for efficiency levels of new hot water boilers using liquid and gaseous fuels (Official Gazette, Nos. 135/05 and 140/12)

c) subordinate legislation adopted on the basis of the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, No. 20/10), namely:

– Ordinance on the marking of materials of the main parts of footwear intended for sale to consumers (Official Gazette, No. 41/10)

– Ordinance on the placing on the market of personal protective equipment (Official Gazette, No. 89/10)

– Rulebook on technical requirements for electric power plants with nominal alternating voltages above 1 kV ("Narodne novine", no. 105/10.)

– Ordinance on Machinery Safety (Official Gazette, No. 28/11)

– Ordinance on the notification of conformity assessment bodies (Official Gazette, No. 34/11)

d) subordinate legislation adopted pursuant to the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, Nos. 80/13, 14/14 and 32/19), namely:

– Ordinance on mobile pressure equipment (Official Gazette, No. 91/13)

– Ordinance on aerosol dispensers (Official Gazette, No. 45/14, 140/14 and 117/17)

– Ordinance on the implementation of Regulation (EU) No. 1007/2011 of the European Parliament and of the Council on textile fibre names and related labelling and marking of the raw material composition of textile products (Official Gazette, No. 18/15.)

– Ordinance on the implementation of Regulation (EC) No. 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters (Official Gazette, No. 14/16)

– Ordinance on Elevator Safety (Official Gazette, No. 20/16)

– Ordinance on metrological and basic requirements for non-automatic weighing instruments (Official Gazette, No. 21/16.)

– Ordinance on technical and metrological requirements relating to measuring instruments (Official Gazette, No. 21/16)

– Ordinance on simple pressure vessels (Official Gazette, No. 27/16)

– Ordinance on Electromagnetic Compatibility ("Narodne novine", no. 28/16 and 88/19)

– Ordinance on equipment and protective systems intended for use in potentially explosive atmospheres (Official Gazette, No. 33/16)

– Ordinance on electrical equipment intended for use within certain voltage limits (Official Gazette, No. 43/16)

– Ordinance on Radio Equipment (Official Gazette, Nos. 49/16 and 88/19)

– Rulebook on pressure equipment ("Narodne novine", no. 79/16.)

– Ordinance on common provisions for measuring instruments and methods of metrological supervision (Official Gazette, No. 112/16)

– Ordinance on the implementation of Regulation (EU) 2016/426 on appliances burning gaseous fuels (Official Gazette, No. 66/18.)

– Ordinance on the safety of elevators in use (Official Gazette, No. 5/19)

– Ordinance on limiting the use of certain hazardous substances in electrical and electronic equipment ("Narodne novine", no. 20/20, 87/20 and 104/21)

– Ordinance on inspections and testing of high-hazard pressure equipment (Official Gazette, No. 75/20).

of the subordinate legislation falls are responsible for repealing the regulations referred to in paragraph 1 of this Article , as follows:

– the head of the state administration body responsible for the economy for the regulations referred to in paragraph 1, point b), sub-items 1 and 2 of this Article, paragraph 1, point c) , sub- items 1, 4 and 5 of this Article, paragraph 1, point d), sub-items 1, 2, 3, 5, 8, 11, 13, 15, 16 and 18 of this Article

– the head of the state administration body competent for energy for the regulations referred to in paragraph 1, point a), sub-points 1 to 5 of this Article, in paragraph 1, point c) , sub-point 3 of this Article and point d), sub-point 4 of this Article

– the head of the state administration body responsible for the environment and waste management for the regulation referred to in paragraph 1, item d), subitem 17 of this Article

– the head of the state administration body competent for electronic communications for the regulations referred to in paragraph 1, item d), subitems 9 and 12 of this Article

– the head of the state administration body responsible for occupational safety for the regulation referred to in paragraph 1, item c), subitem 2 of this Article

– the head of the state administration body responsible for internal affairs for the regulation referred to in paragraph 1, item d), subitem 10 of this Article

– the head of the state administration body responsible for metrology matters for the regulations referred to in paragraph 1, item d), subitems 6, 7 and 14 of this Article.

(3) By- Acts from paragraph 1 of this Article shall be adopted within one year from the date of entry into force of this Act.

Article 36

The Regulation on the procedure for official notification of technical regulations and regulations on information society services (Official Gazette, No. 105/15) remains in force until the entry into force of the

Act prescribing the procedure for notification of technical regulations and regulations on information society services (TRIS).

Expiration of regulations

Article 37.

On the date of entry into force of this Act, the Act on Technical Requirements for Products and Conformity Assessment (Official Gazette, Nos. 80/13, 14/14 and 32/19) shall cease to be valid.

Entry into force

Article 38.

This Act shall enter into force on the eighth day following the date of its publication in the Official Gazette.

Class: 022-03/21-01/114
Zagreb, November 12, 2021.

CROATIAN PARLIAMENT

President
of the Croatian Parliament
Gordan Jandroković, mp