# THE CROATIAN PARLIAMENT

2259

Pursuant to Article 88 of the Constitution of the Republic of Croatia, I hereby pass the

# **DECISION**

## PROMULGATING THE ACCREDITATION ACT

I hereby promulgate the Accreditation Act, adopted by the Croatian Parliament at its session on 25 September 2003.

No.: 01-081-03-3245/2 Zagreb, 1 October 2003

> President of the Republic of Croatia **Stjepan Mesić**, m. p.

# **ACCREDITATION ACT**

## I. GENERAL PROVISIONS

## Article 1

This Act shall regulate the establishment and activities of the body that performs the tasks of the national accreditation agency and determine the scope of accreditation, as well as the relation between accreditation and conformity assessment regulations.

### Article 2

For the purposes of this Act, accreditation means a procedure by which an independent accreditation body formally recognises that a legal or natural person is competent to carry out specific tasks.

## Article 3

For the purposes of this Act, the following definitions apply:

- conformity assessment means any activity concerned with determining, directly or indirectly, that certain requirements are fulfilled,
- accreditation certificate means a document stating that competence for performing specific conformity assessment tasks has been confirmed,
- technical inspection means the examination of product technical documentation, the testing of a product, process or installation, and determination of their conformity to specific requirements or, on the basis of professional judgment, general requirements.

### II. ACCREDITATION BODY

#### Article 4

- (1) For the permanent and unhindered performance of tasks of the national accreditation agency, the Government of the Republic of Croatia shall establish, by means of a regulation, an independent accreditation body (hereinafter referred to as: Accreditation Body) as a public institution.
- (2) The Accreditation Body shall perform the following tasks:
  - accreditation of testing and calibration laboratories,
  - accreditation of legal and natural persons performing the certification of products, management systems and personnel,
  - accreditation of legal and natural persons conducting technical inspection or similar activities,
  - other assessments and confirmation of the competence for carrying out conformity assessment procedures, including determining whether legal and natural persons meet conformity assessment requirements set by conformity assessment regulations.
- (3) The Accreditation Body shall participate in the work of European and international accreditation organisations and represent the Republic of Croatia in those organisations. Within the framework of its activities, the Accreditation Body shall also perform other tasks laid down by the Founding Charter and the Statute unless the goal of these tasks is profit making.
- (4) The Accreditation Body has the sole right to carry out the tasks referred to in paragraph 2 of this Article unless otherwise provided for by another law.
- (5) The organisation, authorities and the decision-making process, as well as other issues relevant for the operation and performance of the tasks of the Accreditation Body shall be regulated by the Statute in line with the law and the Founding Charter of the Accreditation Body.
- (6) The Accreditation Body shall perform its activities in accordance with the regulations relating to public institutions unless specific issues are otherwise regulated by this Act.

#### Article 5

- (1) The Accreditation Body shall acquire funds by performing its activities, from the state budget and other sources in the manner and under the conditions laid down in the Founding Charter.
- (2) The amount of funds to be obtained from the state budget shall be determined by the scope of activities referred to in paragraph 2 of Article 4 of this Act, as laid down in the annual work program, and by taking into account the anticipated amount of funds to be provided from other sources referred to in paragraph 1 of this Article.

(3) The membership fees of the Accreditation Body paid to international and European accreditation organisations shall also be funded from the state budget.

### III. SCOPE OF ACCREDITATION

#### Article 6

In the accreditation procedure, the competence of legal and natural persons for the performance of tasks for which the accreditation is being granted shall be verified with regard to the requirements set by regulations, relevant international and European standards, or equivalent national standards, as well as documents issued by European and international accreditation organisations.

### Article 7

- (1) The accreditation procedures performed by the Accreditation Body shall be regulated by the Founding Charter, the Statute and other general acts, and must be based on international and European standards, or equivalent national standards, as well as documents issued by the European and international accreditation organisations.
- (2) Accreditation shall be performed on the basis of the application submitted by a legal or natural person.
- (3) Mutual rights and obligations concerning the obtaining of the accreditation certificate and maintaining of accreditation shall be regulated by the Accreditation Body and a legal or natural person in a contract.
- (4) The Accreditation Body shall be obliged to conclude a contract with every legal or natural person applying for accreditation. When concluding the contract, the Accreditation Body has to inform the legal or natural person in an unambiguous and transparent manner about the requirements for obtaining the accreditation and about the accreditation procedure itself. The contract shall regulate the rights and obligations of the signatories and the performance of the accreditation procedure in accordance with the standards and documents referred to in Article 6 of this Act.
- (5) If the Accreditation Body determines that a legal or natural person complies with the requirements set by the standards or documents referred to in Article 6 of this Act, it shall grant the accreditation certificate to the legal or natural person.
- (6) The validity of the accreditation certificate shall be time-limited. The accredited body must comply with the accreditation requirements during the period in which the accreditation certificate is valid.
- (7) The Accreditation Body shall pass a decision on the withdrawal of accreditation if it determines that the accredited body does not comply with any of the accreditation requirements.
- (8) A complaint may be filed against the decision referred to in the previous paragraph with the body determined by the Statute of the Accreditation Body.

# IV. ACCREDITATION AND CONFORMITY ASSESSMENT REGULATIONS

#### Article 8

- (1) Conformity assessment regulations may determine the manner in which the Accreditation Body shall participate in the process of designating conformity assessment bodies.
- (2) Conformity assessment regulations may determine that, on the basis of the accreditation certificate, a body is presumed competent to perform conformity assessment.
- (3) The competence of the body referred to in the previous paragraph may also be proved in other ways.

# V. TRANSITIONAL AND FINAL PROVISIONS

## Article 9

- (1) The Government of the Republic of Croatia shall adopt the Founding Charter of the Accreditation Body and appoint a temporary director of the Accreditation Body by 30 September 2004.
- (2) Funds for the initiation of the activities of the Accreditation Body shall be provided from the state budget of the Republic of Croatia.
- (3) The Accreditation Body shall start work on 1 January 2005.

# Article 10

- (1) The founder shall provide the Accreditation Body with the necessary facilities, and the Accreditation Body shall take over from the State Office for Standardisation and Metrology tangible assets and equipment intended for the performance of tasks relating to accreditation as well as the employees performing these tasks.
- (2) The amount of tangible assets and equipment referred to in paragraph 1 of this Article shall be regulated in more detail by the Founding Charter of the Accreditation Body.

## Article 11

Regulations determining the status and salaries of employees in public services shall apply to the employees of the Accreditation Body.

#### Article 12

The State Office for Standardisation and Metrology shall perform the activities of the Accreditation Body until the Accreditation Body starts work.

## Article 13

- (1) The accreditation procedures begun before the date of the entry into force of this Act shall be concluded in accordance with the regulations effective until the date of entry into force of this Act.
- (2) Accreditations granted according to the provisions of the Standardisation Act (Official Gazette 55/96) shall remain in force until their expiry.

### Article 14

The provisions of Articles 24 to 31 of the Standardisation Act (Official Gazette 55/96) shall cease to be valid on the date of entry into force of this Act.

## Article 15

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette and shall be applied from 1 January 2005.

Class: 383-01/03-01/04 Zagreb, 25 September 2003

> President of the Croatian Parliament **Zlatko Tomčić,** m. p.