

DRAFT

**National strategy for harmonization of technical legislation
with the legislation of the European Union**

State Office for Standardization and Metrology
Ministry of Economy
Ministry of European Integrations

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1 Introduction

The goal of the harmonization of technical legislation, standardization, metrology, accreditation and conformity assessment is to build the appropriate national technical infrastructure to fit a contemporary market economy, as well as to facilitate the development of the competitiveness of the Croatian industry on the international market and its inclusion in the global trade in goods and services on an equal footing.

A strong tendency to the globalization of world trade, international cooperation in the production of goods, increased technological sophistication of the majority of products and services, as well as the increased concern for health, security and environmental issues intensify the need for the international uniformness of technical standards, measurements, tests and conformity assessment procedures and promote the importance of accreditation and their international recognition. This increasing importance attached to the equivalence of measurements, tests and conformity assessment procedures has far-reaching effects on trade and the involvement of national economies in the international trade. This is the reference against which future national needs in respect of technical infrastructure and future needs for international cooperation should be assessed.

A comprehensive national technical infrastructure has to cover several aspects or fields of responsibility: the system of enactment of technical regulations, voluntary standardization system, accreditation and conformity assessment system and a national metrological system. In some countries a separate organization is responsible for each aspect, while in others several aspects are covered by a single organization. Each of these systems can function in a satisfactory way if a coordination of all these aspects is ensured. Due to the nature of this system it is very desirable and often of the utmost importance to authorize one organization for each of these aspects to represent national interests in international discussions and negotiations on international and regional agreements.

The goal of harmonization is to develop legislation and technical infrastructure that will facilitate the improvement of product safety, protection of health and occupational safety, environmental protection and consumer protection and thus help the Republic of Croatia to fulfill international commitments it has assumed by acceding WTO (WTO/TBT and WTO SPS Agreements) and by signing the Stabilization and Association Agreement with the European Union.

By Article 73 of *the Stabilization and Association Agreement* referring to technical regulations, standardization, metrology, accreditation and conformity assessment, the Republic of Croatia has undertaken to "take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardization, metrology and accreditation and conformity assessment procedures". Under this Article, "to this end, the Parties shall start at an early stage to promote the use of Community technical regulations and European standards, tests and conformity assessment procedures, conclude, where appropriate, European Conformity Assessment Protocols, foster the development of the quality infrastructure: standardization, metrology, accreditation and conformity assessment, promote the participation of Croatia in the work of specialized European organizations, in

particular CEN, CENELEC, ETSI, EA, WELMEC, EUROMET etc.”. The Republic of Croatia must fulfill these obligations within 6 years.

The development of the National strategy of the harmonization of Croatian technical legislation with the *acquis communautaire* refers to one of the fundamental freedoms on which the EU internal market is based, namely the free movement of goods. This strategy should cover the legislative framework, institutional adjustments and the influence of legislation harmonization on economic factors.

2 Current state of affairs in the Croatian legislation

2.1 Technical regulations

Although the Republic of Croatia has adopted new legislation in the field of product safety, standardization, accreditation and certification after it became independent, the existing system of technical regulations, standardization, accreditation and certification, as well as of the structure of institutions that enforce this legislation, has for the major part been taken over from the former system of technical legislation and only a part of it has been harmonized with European and global requirements. It is thus not adjusted to the needs of a modern market oriented economic system.

In 1996 the Croatian Parliament passed the *Law on Standardization*. This Law regulates the enactment of technical regulations from the field of product safety and consumer protection, conformity assessment and accreditation system. Under the Law, standards are defined as voluntary documents. The Law also laid down the date when the existing standards taken over from the legislation of the former state ceased to be mandatory.

The adoption of procedures regulating the safety of technical products, manufacturer's liability for products, placing of the products on the market and the supervision of the implementation of these regulations are regulated by the *Standardization Act* and other laws in relevant areas. Under the *Standardization Act*, fundamental requirements for products are enacted by the General Director of the State Office, unless otherwise provided by other laws. In other words, ministers and general directors of governmental bodies enact regulations from the scope of their respective ministries or bodies (e.g. the minister responsible for construction and environmental protection enacts requirements for products in the area of construction, the health minister enacts requirements for medical products, the minister of maritime affairs, transport and communications enacts requirements in the field of transport and communications etc.).

In the Republic of Croatia, the field of product safety is regulated by several dozen ordinances on the mandatory certification of certain kinds of appliances and equipment (mainly household appliances and similar electrical appliances, some kinds of machinery equipment, lifts and lift components, some kinds of medical devices, some kinds of construction products etc.), taken over from the legislation of the former state. These ordinances stipulate the testing and certification of certain products against the then valid standards. These standards, although most of them were technically equivalent to the relevant international and European standards at the

time of their adoption, are now "obsolete" because almost all of their international counterparts have been revised in the meantime.

The safety aspects of complex installations are covered by the so-called normative requirements laying down the technical conditions for the design, construction and erection of complex installations. These regulations have been taken over from the former state on the basis of the *Standardization Act*.

A list of individual regulations in force in the Republic of Croatia in the field of construction, machinery, mining, medical technology etc. is attached hereto as Attachment I.

2.2 Regulations in the field of agricultural products and foods, pharmaceuticals and chemicals

Agricultural and veterinary products, chemical products, pharmaceuticals, cosmetics, medical products etc. are regulated by special laws and/or regulations.

2.3 Standardization

The legal basis for regulating the standardization system in the Republic of Croatia is the *Standardization Act* (Official Gazette, 55/96).

Under this Act, Croatian standards are prepared and issued by the State Office for Standardization and Metrology as a governmental body. The State Office is the national standards body, i.e. the standards body recognized at the national level that has as a principal function the preparation, approval or adoption of national standards. The State Office represents the Republic of Croatia in international and regional standards organizations.

The standards currently in force in the Republic of Croatia are partly new standards taken over from the standardization systems of European and international organizations. These standards have been taken over to the Croatian standardization system mainly in the original form without translation.

Beside these standards, some of the standards taken over from the standardization system of the former state are still in force. At the time of their adoption these standards were in part harmonized with international standards. However, these international standards have mostly been revised or replaced by other standards in the meantime. As a result, these Croatian standards do not reflect the state of the art (or the current international and European standards) in the relevant field. They are being gradually replaced by new European and international standards and withdrawn from the Croatian standardization system.

One of the priority tasks of the harmonization of the standardization system is the withdrawal of the entire collection of standards taken over from the standardization system of the former state and their replacement with new Croatian standards. These standards should be withdrawn by 31 December 2003. By that time, priorities for the

adoption of new Croatian standards to replace the withdrawn ones should be set in agreement with other governmental bodies and interested parties.

In this respect the fact should be taken into account that, in parallel with the taking over of certain new approach directives, the pace of taking over the European standards adopted on the basis of this approach should be accelerated. These standards serve as detailed technical specifications of the requirements defined in a directive, referring to safety and other technical characteristics of products. Products conforming to the requirements defined in these standards are assumed to conform to the requirements of the directive itself and can be placed on the market of the European Union. Due to their exceptional significance for the application of the future technical legislation, most of these standards should be taken over by translation into the Croatian language.

Standards are prepared in technical committees whose members are experts from interested institutions (industry, science, state administration, professional associations, consumer associations etc.). Croatian standards are adopted in accordance with international and European rules by consensus and their application is voluntary. Croatian standards are issued as separate publications.

So far 150 technical committees and 250 subcommittees and working groups have been established, in which 2,500 experts from all industries, scientific institutions and universities, professional associations, governmental bodies and public institutions, consumer protection associations etc. are active. Such a work ensures that the standardization system is open for the participation of all interested parties in the development of standards.

Counseling bodies and programme committees for vocabulary, construction etc. have been established, too. They provide guidance to technical committees in their relevant fields in the process of setting priorities and decision-making.

The State Office for Standardization and Metrology is a member of international standardization organizations (ISO, IEC) and an associate member of European standardization organizations (CEN, CENELEC, ETSI). In order to ensure that interests of the Croatian economy are represented in the work of the said international and European organizations and that standards and documents developed in these organizations are accessible, funds should be provided in the budget of the Republic of Croatia to continuously finance the membership in these organizations. Joint activities of government administration with the chambers of commerce and trades and crafts should secure incentive funds for the participation of Croatian representatives in the work of technical bodies (technical committees, subcommittees and working groups) of these organizations in the fields where the Croatian economy finds an interest.

2.4 Testing and certification

The assessment of product conformity with regulations and standards (testing, certification, market surveillance) is regulated by the *Standardization Act*. So far testing and certification have been done by laboratories in industry, institutes,

faculties and independent companies registered for the work in this field and accredited by the ministries and governmental bodies on the basis of a law regulating their respective scopes. Authorizations are based on relevant regulations, and the criteria on technical competence and capabilities are in many cases not harmonized with European requirements.

Mandatory testing and certification are mostly done in accordance with regulations (ordinances on mandatory certification) taken over on the basis of the *Standardization Act*. These regulations refer to certain standards that are mostly obsolete. These regulations, as well as other regulations on products, should be harmonized with the technical legislation of the European Union.

The State Office for Standardization and Metrology acts as the national accreditation body. It accredits testing laboratories and certification bodies. After their competence for these activities has been positively assessed, these laboratories and certification bodies are issued a formal recognition granting them the appropriate accreditation under the rules of the certification system. The State Office maintains a register of accredited laboratories and certification bodies, surveys their work and publishes a directory of these laboratories and certification bodies from time to time.

The State Office also prescribes the criteria for the accreditation of laboratories and conformity assessment bodies.

Accreditation is granted on the basis of the assessment and inspection of a laboratory. Accreditation is generally done in accordance with European or the equivalent Croatian standards HRN EN 45001 (now the standard HRN EN ISO/IEC 17025) and a large number of other regulations and guidelines. The State Office regularly surveys the work of accredited laboratories.

The State Office is an associate member of the European Co-operation for Accreditation (EA) and a full member of the International Cooperation for Laboratory Accreditation (ILAC).

In the current Croatian legislation there is no modularity in certification procedures. All certifications in accordance with the current legislation are carried out by a third party. These certification procedures currently in force have been inherited from the former system. This system, being expensive and inappropriate for the modern market economy, should therefore be radically changed and up-dated, with elements of approach integrated in any future adjustments.

2.5 Homologation of motor vehicles

The certification of the conformity of vehicles and their parts in the Republic of Croatia, i.e. homologation, is based on the *Standardization Act* and regulations which form an integral part of international agreements Croatia is bound with. The Croatian homologation system has been harmonized with the international UN-ECE system.

The State Office for Standardization and Metrology has so far enacted 89 by-laws (ordinances and regulations) on the homologation of vehicles.

2.6 Metrology

Like in the field of standardization, conformity assessment and accreditation, laws and regulations in the field of metrology were taken over from the former state after the Republic of Croatia became independent. These metrological regulations, which referred to various types of measuring instruments, were to some extent based on the international OIML recommendations. Within this legislation, a series of metrological regulations have been inherited as well, which covered various types of measuring instruments not falling under legal metrology. These regulations were mostly modifications of various international standards which referred to measuring instruments.

In the field of metrology, the appropriate technical infrastructure is of crucial importance for the functioning of a metrological system and the establishment of traceability of measurements and calibrations. This infrastructure includes measurement standards (material measures for the realization of units of measurement of physical quantities), calibration laboratories etc. This infrastructure was not satisfactory in the Republic of Croatia, since the former Federal Institute for Measures and Precious Metals was responsible for the realization and maintenance of national measurement standards in the former state. By taking over the former metrological legislation, the State Office for Standardization and Metrology has taken over this responsibility.

The aim of changing the legal framework was to define responsibility for the establishment of the metrological infrastructure in the Republic of Croatia, for the realization and maintenance of measurement standards and for ensuring the traceability of measurements.

In 1993 the Croatian Parliament passed the *Law on Metrology* and the *Law on Units of Measurement*. These laws lay down the framework for the regulation of metrology in the Republic of Croatia.

Like in the case of standardization, adjustments made by the Law on Metrology can be considered only as the first stage of the overall harmonization that needs to be carried out within the general transformation of the economic and social system to the market oriented economy in order to bring the entire system of metrology in line with such systems in developed industrial European countries.

Due to the economic and social benefits of an efficient national metrological system and particularly due to its significance for the competitiveness of national industry, it is important to regulate its role on the national level in the correct way. The increase in the industrial and commercial cooperation enhances the importance of metrology. Interests and demands of many users of metrology are not limited to the territory of their own country and the benefits of harmonizing national metrological systems at the international level are manifold. One of the fundamental factors that make it possible to link human activities over geographical and professional borders is the confidence in the validity of results of measurements. It increases with the use of common units of measurement and common measurement procedures, as well as with

the recognition, accreditation and mutual testing of measurement standards and laboratories in different countries. Accurate measurements are not only a basis for accounting in commercial transactions, but also of crucial importance in medical diagnostics, protection of human health and environmental protection, testing and certification of all types of products. Measurements are a basis for the management of industrial processes and one of the foundations of industrial quality management.

The field of legal metrology is regulated by the *Law on Units of Measurement* (Official Gazette, No. 58/93), the *Law on Metrology* (Official Gazette, No. 11/94) and by-laws adopted for their implementation. The system of legal metrology in the Republic of Croatia corresponds to the system currently in force in the European Union and is based on the so-called old approach directives.

The prepackage control system has been harmonized with the appropriate directives of the European Union.

Under the *Law on Metrology*, the State Office for Standardization and Metrology is the central metrology institute, i.e. the institute which keeps and maintains national measurement standards. The State Office performs all activities resulting from legal requirements and referring to measurements, units of measurement, measuring instruments and methods of measurement with the principal aim of protecting citizens from the consequences of erroneous measurements in official and commercial activities, in the field of health protection, environmental protection, safety at work etc.

In accordance with this function, in the mentioned areas the director of the State Office enacts metrological regulations laying down the requirements for measuring instruments and their use, as well as the regulations for measurement and testing methods and prepackages. Metrological regulations regulate the placing on the market and use of the following measuring instruments: water meters, gas meters, electrical energy meters and instrument transformers, heat meters, measuring systems for liquids other than water, automatic weighing instruments, taximeters, gauge blocks, dimensional measurement systems, evidential breath analyzers, exhaust gas analyzers etc. Metrological regulations also regulate the control of the net content of prepackages.

According to the current *Law on Metrology*, in certain fields only appropriately certified and verified measuring instruments can be put on the market and used. To ensure conformity of measuring instruments in use with legal requirements subsequent inspections and periodical re-verifications are prescribed.

The State Office for Standardization and Metrology represents the Republic of Croatia in international organizations and in the relations with other national and regional metrology institutes and BIPM (Bureau International des poids et Mesures). The State Office for Standardization and Metrology is a full member of the International Organization for Legal Metrology (OIML) and an associate member of EUROMET, the European co-operation on measurement standards.

2.7 Control of precious metal articles

The control of precious metal articles is regulated by the *Law on the Control of Precious Metal Articles* (Official Gazette, No. 76/93) and by-laws adopted for its implementation. The European Union does not have regulations in this field.

2.8 Market surveillance

Market surveillance, i.e. the enforcement of relevant laws and regulations related to the safety of products and their marketing, is carried out by appropriate inspection bodies. According to the Croatian legislation the State Inspectorate is authorized for market surveillance in the field of economy and safety at work. The Ministry of Construction and Environmental Protection enforces the laws and regulations in the area of construction and environment. The Ministry of Health is responsible for the enforcement of laws regulating health protection, sanitary measures etc.

3 *Short- and long-term priorities in harmonization*

3.1 Harmonization of legislation

This Strategy defines priorities for the development of draft laws and the adoption of laws that are a prerequisite for the adoption of implementation measures in the fields of particular importance for the Republic of Croatia.

Activities of legislation harmonization will be carried out on various levels. In the first phase of harmonization, priority should be given to the development of draft framework laws for the area covered by new approach legislation in order to create, with the adoption of that law (or these laws), a legal framework for other implementation measures.

Under the Implementation Plan for the Stabilization and Accession Agreement, the framework legislation on the technical requirements for products should be drafted by mid 2003.

This law will cover safety and other aspects of the so-called technical products and introduce principles of new and global approach into the Croatian legislation. This law will also transpose into the Croatian legislation the Directive 2001/95/EEC on general product safety and in part the Directive 85/374/EEC on liability for manufactured product. It will also regulate the field of standardization and its institutional framework, as well as the field of accreditation. The law will define the institutional infrastructure of these activities.

After the new framework legislation has been adopted, primarily all European new approach directives laying down the fundamental requirements for large groups of products (machinery, low voltage equipment, construction products, pressure vessels, medical products, toys etc.) will have to be transposed into the national legislation. Therefore it is necessary at the initial stage to charge ministries and other governmental bodies with the transposition of directives in accordance with their

respective scopes. Under the Implementation Plan for the Stabilization and Accession Agreement, the deadline for the implementation of this measure is June 2005.

The law on the technical requirements for products will not cover agricultural products and foods, chemical and pharmaceutical products, cosmetic products, motor vehicles, products of glass, textile and timber industry and footwear, which are in the European Union currently covered by the legislation of the so-called old approach. In accordance with deadlines under the Stabilization and Accession Agreement (June 2005), for these areas appropriate framework laws will be drafted. This strategy charges ministries and other governmental bodies with this task, in accordance with their respective scopes.

The above mentioned deadlines for the drafting of laws and the performance of measures aimed at transposing certain new and old approach directives into the Croatian legislation do not include deadlines for the full implementation of such harmonized regulations. When European directives are transposed into the Croatian legislation, a sufficiently long transitional period (at least one year) should be defined, taking into account judgements of businessmen associations. In this transitional period the existing regulations could be applied in parallel with the above mentioned directives, in order to enable the Croatian industry to adapt to new requirements.

3.1.1 Harmonization of legislation with New and Global Approach directives

On the basis of a specific conclusion of the Croatian Government, the following ministries and governmental bodies will be responsible, in accordance with their respective scopes, for the drafting of laws and the implementation of measures for the transposition of new approach directives into the Croatian legislation:

Ministry of Economy/State Office for Standardization and Metrology

- 1) For the drafting of the law on product safety and the transposition of the Directive 2001/95/EEC on general product safety and the Directive 85/374/EEC on liability of producer for manufactured product into the Croatian legislation
- 2) Directive 73/23/EEC on low voltage equipment
- 3) Directive 94/9/EEC on equipment and protective systems in potentially explosive atmospheres
- 4) Directive on the procedure for the provision of information in the field of technical standards and regulations (98/34/EC, amendment 98/48/EEC)

The law under 1) and the measure under 4) must be completed by mid 2003 (obligation under the Implementation Plan of the Stabilization and Accession Agreement). Measures under 2) and 3) should be completed by December 2004.

The State Office for Standardization and Metrology will transpose the Directive 90/384/EC on non-automatic weighing instruments into the Croatian legislation, but on the basis of a framework legislation in the field of metrology. This measure should be completed by December 2004.

Ministry of Economy

- 1) Directive 87/404/EEC on simple pressure vessels
- 2) Directive 88/378/EEC on safety of toys
- 3) Directive 90/396/EEC on gas appliances
- 4) Directive 92/42/EEC on new hot-water boilers fired with liquid and gaseous fluids (efficiency requirements)
- 5) Directive 95/16/EEC on lifts
- 6) Directive 96/57/EC on efficiency of refrigerators and freezers
- 7) Directive 97/23/EEC on pressure equipment
- 8) Directive 98/37/EEC on machinery

Measures under 1) to 8) should be completed by December 2004.

Ministry of Environmental Protection and Zoning

- 1) Directive 89/106/EEC on construction products
- 2) Directive 94/62/EEC on packaging and packaging waste

Measures under 1) and 2) should be completed by December 2004.

Ministry of Labor and Social Welfare

Directive 89/686/EEC on personal protective equipment

This measure should be completed by December 2004.

Ministry of Maritime Affairs, Transport and Communications

- 1) Directive 89/336/EEC on electromagnetic compatibility
- 2) Directive 94/25/EEC on recreational craft
- 3) Directive 96/98/EEC on marine equipment
- 4) Directive 96/48/EEC on interoperability of the high speed transeuropean railway system
- 5) Directive 1999/5/EEC on radio and telecommunications terminal equipment

Measures under 1), 2), 3), 4), and 5) should be completed by December 2004.

Ministry of Internal Affairs

Directive 93/15/EEC on explosives for civil uses

This measure should be completed by December 2004.

Ministry of Health

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- 1) Directive 90/385/EEC on active implantable medical devices
- 2) Directive 93/42/EEC on medical devices
- 3) Directive 98/79/EEC on in-vitro diagnostic medical devices

Measures under 1), 2) and 3) should be completed by December 2004.

All the above mentioned deadlines for the transposition of new approach directives are based on the requirements for the establishment of technical legislation system in accordance with EU regulations. To be precise, the adoption of a framework legislation is a pre-requisite for the harmonization of particular areas covered by new approach directives.

3.1.2 Harmonization of technical legislation with Old Approach directives

As already mentioned, the "old approach" will remain in force in the field of motor vehicles, pharmaceutical, foodstuff, aircraft and some other industries.

The following ministries and governmental bodies will be responsible, in accordance with their respective scopes, for the drafting of laws and the implementation of measures for the transposition of old approach directives into the Croatian legislation:

State Office for Standardization and Metrology

- 1) For the field of homologation of motor vehicles and tractors for agricultural industry and forestry
- 2) Metrology and control of the net content of prepackages (as already described in the Strategy)

Measures under 1) and 2) should be completed by December 2004.

Ministry of Health

- 1) For the field of pharmaceutical and cosmetic products

Measures under 1) should be completed by December 2004.

Ministry of Economy

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1) The field of chemical products, for the areas specified in the Pink Paper¹ under the following points:

2.2.1 Limitations

2.2.2 Classification, packing and marking

2.2.3 Detergents

2) For the fields specified in the Pink Paper under the following points:

8.2.9 Glass

8.2.10 Textiles

8.2.11 Footwear

8.2.12 Timber

Measures under 1) and 2) should be completed by December 2004.

Ministry of Agriculture and Forestry

1) The field of agricultural products and foodstuffs

2) For the fields specified in the Pink Paper under 2.2.4 Fertilizers

Measures under 1) and 2) should be completed by December 2004.

Once the by-laws for the implementation of the framework legislation on product safety, transposing European directives, have been adopted, harmonization in the field of technical legislation will be completed.

In the field of legal metrology the State Office for Standardization and Metrology should draft the appropriate law on units of measurement transposing the European Directive 80/181/EEC relating to units of measurement. One should note that the existing *Law on Units of Measurement* is based on the OIML document D 2, which is in turn based on the International System of Units, so that the harmonization of legislation in this field will not pose any major difficulties.

Likewise the State Office must draft the appropriate law on measuring instruments transposing the Directive 71/316/EEC or the new European Directive on Measuring Instruments into the Croatian legislation, if this new directive is adopted in the European Union. Within the existing Directive 71/316/EEC on Measuring Instruments 23 individual directives have been adopted which will also have to be transposed into the Croatian legal metrology system.

Although two laws are currently in force in the Republic of Croatia in the field of metrology, i.e. the Law on Units of Measurement and the Law on Metrology, this

¹ The Pink Paper of the *Directorate General Enterprise* of the European Commission is a structured list of *acquis communautaire* from the scope of this Directorate. It is an exceptionally useful manual for technical harmonization in the areas it covers. It is available on the Internet at <http://europa.eu.int/comm/dgs/enterprise/acquis.htm> .

field can be regulated by a single law, as it has been done in the majority of European countries. In this way both basic metrological directives (Directive 80/181/EEC) and Directive 71/316/EEC) would be transposed into the Croatian legislation.

The deadline for the drafting of this framework legislation is also June 2003. All other metrological directives referring to particular measuring instruments (including the new approach directive 90/384/EEC on non-automatic weighing instruments) would be transposed into the Croatian legislation by June 2005. The drafting of laws and the implementation of measures aimed at the transposition of metrological directives into the Croatian legislation will be the responsibility of the State Office for Standardization and Metrology in accordance with its scope.

An important element of harmonization is also market surveillance. Product surveillance at the production and pre-sale stages will be replaced by the increased liability of manufacturers for their own products and by market surveillance carried out by various competent bodies (ministries and governmental bodies).

Regulations of the European Union relating to safety and other requirements for products do not lay down in detail how the bodies competent for surveying products in the market should be organized. This has been left to member countries. The only demand of the European Union on its member countries is that market surveillance shall be effective and sufficient. Under the current organization, a part of this surveillance will be done by the State Inspectorate, but also by the Veterinary Inspection, Sanitary Inspection or another inspection body in the field of agriculture, building inspection or another inspection body established within a governmental body competent for the enforcement of a law. Beside legal conditions for market surveillance, the Republic of Croatia will have to ensure technical and other conditions necessary to determine whether a product conforms to fundamental requirements (qualifying appropriate laboratories, establishing notified bodies etc.).

To conclude, the harmonization of the Croatian legislation with the old and new approach directives of the European Union will be carried out by the competent ministries and governmental organizations, under the co-ordination of a working group of the Croatian Government, composed of ministers or deputy ministers. The Ministry for European Integrations would give technical and professional assistance in the overall harmonization process in accordance with its scope.

3.2 Harmonization of institutional infrastructure for the enforcement of legislation

Institutional separation of regulatory, standardization, accreditation and conformity assessment functions is an essential prerequisite for a correct application of relevant directives.

The framework legislation must therefore separate the regulatory, standardization, accreditation and conformity assessment functions. Government authorities (ministries and governmental bodies) should keep only the legislative function and the law enforcement function (market surveillance) and ensure that the system of conformity assessment carried out by a third party in accordance with regulatory requirements is technically competent and independent.

Structures needed for an efficient application of technical legislation (primarily the organization of standardization, accreditation and conformity assessment bodies) are not precisely defined by the EU legislation. However, their organization and responsibilities can be deduced by an analysis of individual parts of European legislation and decisions of the European Council. Minimum requirements on ministries and governmental bodies are the following: a satisfactory number of qualified staff to lead the activities on new legislation, a proportionate and efficient market surveillance, funds for testing and qualified staff for the performance of these activities, national standardization infrastructure and a competent body responsible for the policy in this area.

The implementation of new approach directives implies the transformation of a system based on mandatory prescriptive technical requirements and the performance of mandatory certification into a system in which the legally regulated area is limited to essential legal requirements. Beside this, weaker mechanisms of state government control in the phase before a product is placed on the market in the new system demand the establishment of a stricter market surveillance by the competent state authorities (inspection services).

Since each member country has the obligation to report each draft technical regulation on products to the Commission and other members (Directive 98/34/EC), a central information unit should be established within this administrative organization. This would enable the application of the *acquis* as of the day of association. Such a central unit would have two functions: to receive notifications and information forwarded to it by the European Commission and distribute them to the relevant ministries and government bodies and to send notifications and information received from ministries to the European Commission. This refers to the performance of obligations arising from TBT and SPS Agreements of WTO.

3.2.1 Regulatory function (enactment of technical regulations)

In order to implement necessary institutional adjustments, the primary task will be to transform the organization of the State Office for Standardization and Metrology. According to its present scope under the *Law on Standardization*, the State Office is responsible for the functioning of the major part of the existing technical infrastructure (enactment of regulations, standardization, legal metrology, accreditation and conformity assessment).

Pending the adoption of the Law on Technical Requirements for Products, and having in mind further steps of the Republic of Croatia in the process of European integration, in relation to the issue of separating the regulatory, standardization, conformity assessment and accreditation functions, the State Office for Standardization and Metrology as a governmental body should keep regulatory functions for particular areas (general product safety, legal metrology and implementation of specific measures in respect of certain types of products), propose to the Croatian Government measures aimed at implementing the national policy in the field of standardization, metrology, accreditation and conformity assessment, as well as coordinate the implementation of these measures.

3.2.2 Standardization and accreditation

Draft legislation which will define the organization of the standardization and accreditation systems in the Republic of Croatia should envisage the establishment of independent standardization and accreditation bodies.

A national standards body should be an independent body that develops and accepts voluntary standards that, through the technical committees, reflect the consensus of the community as a whole. This should be a unique organization responsible for all standardization areas. In the management of a standardization institute interests other than government interests should be represented as well (industry, consumers, certification bodies, accreditation bodies, professional associations etc.). This body will represent the Republic of Croatia in international (ISO, IEC) and regional organizations (CEN, CENELEC and ETSI).

The framework legislation should define the necessary institutional infrastructure (of standardization and accreditation) that will satisfy the European Union criteria, as well as the necessary adjustment of the existing technical infrastructure, which in the Republic of Croatia functions within the State Office for Standardization and Metrology. This will enable product testing and conformity assessment procedures to be carried out in the Republic of Croatia in accordance with the European regulations and directives taken over.

The new legislation should not only elaborate the establishment of the standardization framework but also the conditions for the assessment of the conformity of technical products with regulatory requirements, as well as accreditation regulations and procedures.

The accreditation system should be regulated by legislation in a similar way.

The new legislation of technical requirements for products, standardization and accreditation should also regulate, beside the legal framework for the harmonization with the EU legislation and the implementation of relevant directives, aspects of institutional adjustment. The latter primarily implies the establishment of institutions responsible for the field of standardization, accreditation, conformity assessment and market surveillance.

Key features of these bodies should be the following:

a) Key features of a standards body:

- Independence
- Decision-making process based on consensus
- Transparent decision-making process
- Representation of all interested parties (government, industry, consumers, certification bodies, accreditation bodies, companies, professional associations etc.)
- Voluntary participation of all interested parties in the preparation and adoption of standards
- Openness of its work results to the public, so that everyone may use them.

b) Key features of an accreditation body:

- National government authorities are responsible for appropriate measures aimed at ensuring independence and efficiency of the national accreditation system and the participation in the European and international cooperation. Accreditation should be established under the aegis of government authorities in order to ensure independent judgment based on clearly accepted standards. The accreditation body should become a member of the European Co-operation for Accreditation (EA) and sign multilateral agreements (MLA) within EA.
- Accreditation should be a non-profit activity. In order to be completely independent, it must not be subject to commercial motives. The pre-requisite is a certain financial support by the government needed for the work of the accreditation body.
- Accreditation should be organized so as to ensure an efficient service satisfying the needs of industry, certification bodies, government authorities, consumers etc. Competition among bodies and unnecessary separation or even duplication of accreditation services should be avoided. Accreditation is mainly carried out by a single body, although various specialized accreditation bodies (e.g. for testing or certification) may coexist.
- A clear difference between accreditation and certification activities must be established and maintained.

3.2.3 Metrology – key features

The future harmonization of metrological legislation with the European Union legislation should solve the following issues: harmonization of legal framework, transposition of the existing metrological directives of the European Union, definition of institutional frameworks for the enforcement of this legislation, as well as the establishment and financing of the material bases (maintenance of national standards) that will ensure traceability and accuracy of measurements carried out on the national level. In other words, the future framework legislation on metrology should regulate all aspects of metrological infrastructure. In this connection one should take into account that, beside formal legal harmonization, the existing metrological infrastructure should be transformed and the competence of measurement and testing laboratories improved.

A well-developed metrological system is of key importance for the efficiency of measurement, testing and products conformity assessment infrastructure. Metrology in all candidate countries, in the Republic of Croatia too, should be organized in the way as accepted in the European Union.

A national metrology institute should be oriented toward its inherent mission, i.e. toward ensuring the traceability of measurements on the highest national level, and be the basis for the organization of measurements and testing in the widest sense. For the establishment, purchase of equipment and work of a national metrology institute, financial support from the state budget should be ensured in order to secure its independence and impartiality.

A national metrology institute represents its country internationally in relation to the national metrology institutes of other countries, in relation to the regional metrological organizations and to the BIMP.

The initial costs of the establishment of a metrology institute and the purchase of appropriate standards for particular physical quantities will, of course, be high. However, the process of establishing a metrology institute may be gradual in order to distribute the costs of establishment over a relatively long period and not to burden the society with large costs at once.

When such a national metrology institute is being established, one should take into account that at this moment the Republic of Croatia does not have to have the appropriate primary standard for each unit of measurement. For a large number of physical quantities, secondary standards can be used as national standards. Their value is defined by periodic comparisons with the primary standard kept for a particular quantity at BIPM or in another national metrology institute.

For less used physical quantities, such an institute does not have to maintain national standards. It can instead refer its customers to foreign national metrology institutes.

On the other side, it is very important for a national economy to have a fully built material metrological infrastructure; the possession of national standards encourages confidence in the traceability of measurements performed on the national level.

To conclude, the future framework legislation on metrology should regulate all aspects of metrological infrastructure. In this connection one should take into account that, beside formal legal harmonization, the existing metrological infrastructure should be transformed and the competence of measurement and testing laboratories improved.

Metrology is divided into three categories in the European Union: *legal, industrial and scientific metrology*.

Legal metrology mainly deals with regulations on measuring instruments for legal use. Harmonization on the European Union level refers to measuring instruments when they are placed on the market, but does not prescribe their use. It is defined by national legislation. For the majority of measuring instruments subject to legal supervision, the European Commission has published the proposal of the new *Measuring instruments Directive (MID)*, which introduces the New Approach into legal metrology as well. Harmonization on EU level has also been carried out for units of measurement and net content of prepackages.

Responsibility for legal metrology lies with government authorities. However, they should not be responsible for industrial and scientific metrology. The purpose of industrial/scientific metrology is to ensure confidence of measurements by calibration and traceability. International cooperation is important in metrology. Traceability with international measurement standards is a key element in the evaluation of the quality of a metrological system. International comparative tests are used to check the quality and competence of international metrological services.

In order to achieve harmonization with *acquis communautaire* in the field of legal metrology, the majority of old approach metrological directives will need to be taken over, a large number of which will be withdrawn once the draft *Measuring instruments Directive* enters into force. With this directive, full harmonization of essential requirements for the majority of measuring instruments subject to legal supervision will be carried out based on new approach principles. A new approach directive from 1990 already exists for non-automatic weighing instruments (Directive 90/384/EEC).

Generally, conformity assessment in the field of legal metrology is carried out by government authorities, although in some countries this activity is performed by private institutes as well. Government bodies responsible for legal metrology should participate in the work of the European Cooperation in Legal Metrology (WELMEC) and the International Organization of Legal Metrology (OIML).

3.2.4 Testing and conformity assessment bodies – key features

Conformity assessment is a procedure in which a third party provides a written assurance that a product, process or service are in conformity with defined requirements. Certification by a third party aims at ensuring confidence between suppliers and consumers and/or national authorities.

Testing includes determination of one or several characteristics of a given product, process or service on the basis of defined procedures.

Certification, testing and inspection activities are carried out by various kinds of bodies. These bodies should be primarily accredited in accordance with the relevant standards of EN ISO/IEC 17000 (EN 45000) series. However, accreditation is not obligatory for notified bodies.

National authorities are responsible for notification. Notified bodies perform conformity assessment tasks from new approach directives when the intervention of a third party is required for the product conformity assessment in accordance with the modules defined in the relevant directive. For some products subject to these directives the manufacturer must require the mediation of a notified body before affixing CE marking on these products and putting them on the market. However, it is not obligatory to notify such bodies in each industrial sector. In countries where an industrial sector is less represented, conformity assessment can be done by notified bodies established in other, EU member countries. Notified bodies can freely offer their conformity assessment services within their relevant scopes to other economic agents established in or outside the territory of the member country.

Evaluation of the body seeking notification must establish whether it is technically competent and able to carry out conformity assessment procedures and whether it can demonstrate the necessary level of independence, impartiality and integrity. The competence of the notified body should therefore be regularly controlled and monitored.

Notified bodies must carry out their activities in an independent and impartial way. Independence and impartiality of staff involved in conformity assessment must be guaranteed, as well as their protection of confidential information they obtain during a conformity assessment procedure. The staff must have adequate knowledge and experience in performing conformity assessment in accordance with the relevant directives.

Notified bodies must also be liable for their professional work, if that liability is not envisaged by national legislation of the notifying member country.

Notified bodies must be appropriately ensured in order to cover their professional activities, if liability is not ensured by national legislation of the designating member country. A notified body must employ the necessary staff with satisfactory and relevant knowledge of and experience in carrying out assessments of conformity with the relevant directive.

3.2.5 Market surveillance bodies – key features

The purpose of market surveillance is to check the conformity of products placed on the market with the relevant laws and regulations. An efficient market surveillance ensures equivalent level of protection for all citizens on the internal European market and a fair market competition for all economic agents.

Market surveillance comprises checks of whether products placed on the market are in conformity with the provisions of the relevant legislation and measures aimed at bringing the non-conforming products in line with the defined conditions.

Market surveillance is particularly important in the areas where there is no approval procedure before placing products on the market.

State authorities are responsible for the application of legislation. This guarantees that market surveillance procedures are impartial. Consequently, national authorities must organize appropriate market surveillance to cover all surveillance fields defined by regulations in the entire territory of the state.

Market surveillance must be independent and carried out in an impartial and non-discriminating manner.

Each national authority may decide on its market surveillance infrastructure (e.g. functional or geographical allocation of responsibilities), provided that the surveillance is efficient and covers the entire territory.

Market surveillance authorities need funds and authorizations (e.g. sampling, imposing of penalties sufficient to discourage from violations) that would enable them to carry out market surveillance efficiently and with sufficient coverage so as to detect non-conforming products.

Market surveillance authorities must have a sufficient number of qualified and technically competent staff for the surveillance of specific products and risk areas.

When carrying out market surveillance, state authorities should take into account the principle of proportionality, i.e. legal measures taken must be in proportion with the degree of risk of non-conformity.

Market surveillance bodies can transfer technical tasks to other bodies, but they bear the responsibility for their decisions.

As a general rule it is not appropriate for a notified body to be responsible for market surveillance. If market surveillance authorities and a notified body are under the competence of the same higher government authority, their responsibilities must be determined in order to avoid conflict of interests.

Since the surveillance of products in the production and pre-market phase will to a great extent be replaced by a stricter liability for products of manufacturers themselves and by the surveillance of various bodies responsible for market surveillance, beside strengthening the role of the existing inspection bodies active in the Republic of Croatia it will probably be necessary to ensure funds for an improvement of their technical equipment.

EU regulations on safety and other requirements for products do not define in detail the organization of bodies which carry out the surveillance of products on the market but leave it to member countries. The only EU requirement on member countries is that the surveillance of products on the market must be efficient and sufficient. According to the present organization of the Croatian government administration, the major part of market surveillance will be carried out by the State Inspectorate, but market surveillance activities will also be performed by other inspections (veterinary, sanitary, building or other inspections organized within the governmental body competent for the enforcement of a particular law).

4 *Methods of technical harmonization*

Technical harmonization is a complex process which must be based on a defined organization and a clearly defined schedule of activities.

In order to ensure that the process of harmonizing technical legislation of the Republic of Croatia with the legislation of the European Union is run as efficiently as possible, a working group for harmonization should be established on the level of the Croatian Government. This working group would be the center for monitoring and coordinating the process of technical harmonization. Pending the establishment of such a working group, the Working Group for the harmonization of legislation in the field of free movement of goods or its subgroup for technical legislation could be entrusted with the co-ordination of technical harmonization.

Members of the above mentioned working group should be the heads of the ministries and governmental bodies participating in the harmonization process. This working group would be responsible for co-ordinating the entire process of harmonizing the Croatian technical legislation with that of the European Union. Its role would be to

collect priority proposals and devise a schedule for their realization, as well as to coordinate and monitor the harmonization process. On the operational level, a certain role should be kept by the Working Group for the harmonization of legislation in the field of free movement of goods or its subgroup for technical legislation.

At the same time, organizational units or working groups should be defined (established) in ministries and other governmental organizations (according to individual directives from *acquis communautaire*) for the harmonization of regulations from their respective scopes. Members of these organizational units/working groups should be experts from these bodies of state administration, in charge of transposing the individual directives into the Croatian legislation.

It should be stressed that each body of state administration which is, under the National Strategy, in charge of the transposition of a certain directive into the Croatian legislation, should include other bodies of state administration as well, depending on their relevant scopes, into the technical harmonization process within the directive it is in charge of, depending on the subject regulated by this directive.

The task of these organizational units and working groups would be to analyze the existing national laws and the appropriate European directives, identify the level of harmony between Croatian regulations and these directives, give their opinion on what needs to be changed or amended in the existing regulations or whether new regulations should be drafted, and analyze the possible ways to enforce new, harmonized regulations.

These experts should co-operate with the European Union experts in the process of analyzing the existing regulations, drafting new regulations and in respect of possible changes to the existing institutions or the establishment of new institutions with a view to ensure a regular and efficient enforcement of technical legislation.

The process of the adoption of laws and regulations should ensure that the interests of all interested parties are represented (industry, consumers, certifications bodies, professional associations etc.) and that they have an access to information in all phases of adjustment.

In view of the fact that an exceptionally large number of regulations are to be harmonized, a unique database on the Croatian technical legislation, available to the public, should be established, having in mind its harmonization with the technical legislation of the European Union.

For harmonization activities technical assistance by experts from the European Union should be organized bilaterally and multilaterally. This implies the assistance provided by foreign experts from the European Union member countries and associated countries with a years-long experience in the field of technical legislation.

Since the process of harmonizing regulations is very important, complex and specific, appropriate preparations are needed. First of all the directives of the European Union to be transposed into the Croatian legislations need to be translated into the Croatian language.

Translation should be organized within the Ministry of European Integrations. First of all the acts directly affecting the legislation of member countries, directives (acts transposed into the national legislation of member countries), decisions (pertaining to specific legal entities and binding for them in their entirety) and other documents essential for the process of harmonizing legislation should be translated. At the initial stage the regulations and directives belonging to the first phase of measures from the *White Paper – Preparation of the associated countries of Central and Eastern Europe for integration into the internal market of the Union* should be translated.

Before translation begins, appropriate methodology for the translation of European Union regulations should be developed in order to ensure a systematic approach and linguistic uniformity of translated texts. This methodology should solve the problem of vocabulary and elaborate the checking, language editing and correcting of the translated texts with a view to aligning the vocabulary before texts are verified.

5 *Influence of harmonized legislation on economic agents*

5.1 Influence of legislation in the field of product safety, standardization, accreditation and conformity assessment

When the influence of new legislation on economic agents is considered, one should primarily bear in mind the long-term effects the new legislation and the new technical infrastructure established on the basis of it will have on the economic development of the Croatian industry and the improvement of its competitiveness on the world market.

The existing technical infrastructure of the Republic of Croatia is based on the existing framework legislation – the *Law on Standardization* and the *Law on Metrology* – and regulates product safety and the liability of producer for manufactured products, as well as the organization of standardization, accreditation, certification and metrology in the Republic of Croatia. Its solutions are not in conformity with the existing technical legislation of the European Union and the envisaged harmonization of legislation cannot be carried out without its application.

Since the existing technical legislation does not reflect the state of the art, it does not enable the Croatian industry's recognition on the global and European markets; products placed on foreign markets must adjust to different technical solutions based on international standards. Such regulations are a big obstacle for foreign investors because they prescribe, for a very limited market, special rules for the manufacture, testing and conformity assessment of various products which are not based on international standards and documents.

The existing technical regulations enacted on the basis of the *Law on Standardization* do not cover all products nor all the aspects of product safety regulated by European directives and new approach directives in particular. These regulations have mostly been taken over from the legislation of the former state. This legislation is entirely inappropriate for a market economy and hampers industrial development because its solutions do not reflect the state of the art. It is therefore in the interest of the Croatian

economy in the first place to replace this legislation as soon as possible with a different system. This system must better protect the justified social interests in respect of health protection, safety, consumer and environmental protection. It must also, based on the technical legislation to be adopted in conformity with international or European standards and documents, respectively, remove unnecessary barriers to trade, which is important not only for foreign manufacturers who sell their products in the Croatian market, but also for the Croatian industry, striving at increasing its share in the global market.

For the export-oriented part of the Croatian economy, big companies in particular, the application of new legislation will not imply any obstacles in business. To be able to do business with EU members countries or sell their products in the European market, they have already subjected their products to conformity assessment procedures and brought them into line with the European requirements. However, although the introduction of the new European legislation will not pose any major problems for the major part of the Croatian industry, the export-oriented industry in particular, a sufficiently long transitional period (at least one year) should be defined for the transposition of European directives into the Croatian legislation, taking into account inputs of industrial associations. In this period the existing regulations might be applied in parallel with the said directives, in order to help the Croatian industry adjust to new requirements.

Although the new legislation will increase the requirements for product safety and manufacturer's liability for manufactured product, as well as for product testing and conformity assessment, manufacturers will be relieved of a part of costs resulting from the application of the existing technical legislation, under which a third party must certify the conformity assessment of all products placed on the Croatian market.

Serious problems may only be experienced by small companies without appropriate equipment for testing under stricter European standards. When regulations are enacted for the transposition of particular European directives into the European legislation, a transitional period must therefore be provided, to enable them to adapt their production and procedures for the demonstration of conformity to the new legislation.

In parallel with the transposition of the European directives, appropriate steps should be taken to qualify and equip appropriate notified bodies in the Republic of Croatia to work in accordance with the strictest requirements of the specified directive. One should expect that these will be the existing bodies accredited for product certification in a given field.

Possibly the biggest problems are to be expected in the adjustment of the existing bodies which carry out testing and conformity assessment procedures. If they want to continue their activities, they must take measures to adjust themselves, in term of qualified staff and technical equipment, to the new conditions of work in accordance with the European legislation.

5.2 Influence of legislation in the field of metrological infrastructure

There is no significant industry of measuring instruments in Croatia. Measurements instruments subject to metrological supervision are mainly imported from EU countries. The change of metrological legislation will therefore not have any significant influence on the Croatian industry. On the other hand, the existing metrological regulations are partly harmonized with the international OIML recommendations, so that Croatian manufacturers will not face any special new requirements for measuring instruments.

The basic weakness of the existing metrological system is that there is no central national metrology institute through which the traceability of measurements and calibrations with international standards (materializations of units of measurement) would be maintained. There is also a shortage of calibration laboratories with high-quality measurement standards, which could perform measurements and calibrations of measuring instruments and working standards of high accuracy on the primary and secondary levels. This problem will be solved when a national metrology institute is established. It will, among other things, help the Croatian economy reduce the costs of calibrations done in foreign metrology institutes.

The absence of such an institute greatly increases the industry's costs for the maintenance of measurement and testing equipment because it must be calibrated by foreign laboratories.

It is therefore of primary importance to ensure a material basis for the traceability of measurements and testing performed in the Republic of Croatia. Confidence of the traceability chain from national standards to working standards on the place of their application is of crucial importance for a national metrological system. All laboratories in every chain, consequently all laboratories in the national network of calibration laboratories, must be able to demonstrate their ability and competence.