

Position paper on

M&T Needs in Candidate New Member States

Compiled by the High Level Expert Group on Measurements and Testing
under the 5th European Framework Programme Research and Development

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M&T Needs in Candidate New Member States

1. Introduction:

In the accession period, candidate countries must assume membership obligations that satisfy the union's economic and political conditions. Not only is incorporation of the *acquis* into national legislation required, but also its effective implementation and application through appropriate administrative and technical infrastructures.

Candidate New Member States face major political, sociological, administrative and infrastructural changes during the transition from a planned economy to a market economy when entering the EU and the internal EU market. Measurement and testing (M&T) needs should be treated within the concept of these new socio-economic relations.

Among the 29 negotiating chapters, there are several, such as the free movement of goods, energy, environment, etc. where M&T related activities and corresponding infrastructures are directly involved. There are other chapters, such as consumer and health protection, transport, agriculture, justice and home affairs etc, where, even indirectly, M&T plays a vital role. If not properly tackled, they could cause serious problems and impediments to international trade and the exchange of goods and services.

It is therefore very important to investigate and analyse M&T needs and problems in candidate countries in order to implement the *acquis* in its various aspects. Of equal importance, M&T in candidate countries should contribute to a higher quality of products and services, which goes beyond merely supporting the free movement of goods and services from the perspective of safety requirements only.

The following paper analyses the general M&T situation in candidate countries and suggests a number of solutions in order to effectively deal with the above stated issues.

Particular attention is paid to the scientific and technical expertise required for mutual and multilateral recognition agreements regarding M&T activities related to the implementation of technical directives and international competitiveness.

2. Historical background

In the EU member states, M&T related to trade issues has been developing in the period of the last fifty years to a large extent as a demand driven activity. Following the unification processes in Europe, it was focused on eliminating barriers to international trade. Legal, scientific and industrial metrology developed closely with one another as well as with safety and quality testing to underpin the industrial and social progress.

Meanwhile, developments were different in Central and Eastern European countries where there were planned economies. It is therefore easily understood why M&T in countries with market economies developed differently from M&T in countries with planned economies. Another important distinction is the fact that in the majority of candidate countries, within the entire field of M&T, mainly legal metrology was developed in order to support various national regulations, while significantly less effort was related to industrial metrology or anything related to quality. Testing was mainly limited to safety testing, and only valid within national borders. Scientific metrology often developed in isolation from real needs.

Nevertheless, the fact is that there is a large potential and willingness in candidate countries to catch up with M&T developments in the EU!

To meet these objectives, some activities should be tailored to the specific needs of the candidate countries and their suggestions should be met for optimal solutions.

3. Overview and current status of M&T in candidate New Member States

M&T infrastructures in candidate countries are in the process of major transformation due to the harmonisation of technical legislation, the adoption and implementation of EU technical directives and quality requirements of the internal EU market. In this respect one could distinguish between technical and administrative infrastructures that are explicitly required by the *acquis* and those which are not, but are necessary for its effective implementation, namely M&T laboratories.

Closely related to the need for certain infrastructures is also the requirement for appropriate institutional organisation and separation of regulatory, standardisation, accreditation and certification functions that are necessary for the proper implementation of the relevant directives. The effectiveness and competence of such institutional organisations are sometimes in practice quite difficult to achieve due to a lack of experts and resources. In practice this is not always really needed and justified, although explicitly requested by EU regulators.

In line with EU practice, candidate countries have to assure that public authorities retain mainly the legislative and enforcement functions and those segments of technical infrastructures that can not follow market rules, e.g. the system of the highest national measurement standards in the national metrology system and scientific metrology.

The harmonisation of technical legislation enables the free movement of goods and services in both directions, from EU member states to candidate countries and vice versa. The problem in reality is, however, that due to significantly different technological and quality levels of products and services of EU members, as opposed to candidate countries, **the harmonisation process alone will not replace or ensure competitiveness.**

It is therefore very important for the future positioning of New Member States in the EU in the accession period, as well as later when becoming full members, to actively develop all M&T activities in candidate countries focused on higher quality of products and services as well as on the production of new products and the development of new technologies. This would go well beyond satisfying only the

basic safety requirements and other regulations related to the implementation of technical directives. **In this respect, not only administrative and technical infrastructures for M&T, related to the harmonisation of legislation, should be developed but also appropriate educational programmes, science, research and development activities in M&T combined with public awareness.**

This is the only way to decrease the technological gap between the highly developed EU member states in the M&T area in its broadest sense, and the existing situation in M&T in candidate states.

In general it is regarded that the formal adoption of new legislation, i.e. adoption of directives and written standards, is to a great extent the difficult part of the process. In several cases the set up of appropriate, scientifically and technically competent, internationally accepted and economically justifiable laboratories, capable of operating in competitive market conditions, proves to be much more demanding.

Therefore, special input into M&T is needed in national industries and services in candidate countries where harmonisation of technical legislation is of prime importance and it is equally important to invest in M&T to ensure a higher level of quality of these products and services.

This distinction might seem superfluous, but in reality it could notably improve GDP due to investment in the M&T capabilities of a particular country.

A well functioning regime for mutual recognition and acceptance of conformity assessment results is of major importance for the EU internal market. At the same time, candidate countries still face a lack of mutual confidence and recognition of test results, reports and certificates among laboratories in candidate countries and EU institutions. Quite often national accreditation bodies, in spite of full membership in the European Accreditation (EA), still haven't signed multilateral agreements, MLA. Concerning the mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes, signing the Mutual Recognition Arrangement (MRA), drawn up by CIPM, is the very first step as well.

Another problem is also that notified bodies are still in many cases in the phase of establishment, setting the rules of operation etc.

The lack of metrological expertise required in modern product testing, acceptable by the European single market, represents another serious limitation of the competitiveness of testing laboratories from candidate countries and consequently limits their national industries and economies.

In order to improve the measurement capabilities of these countries in terms of traceability and uncertainty evaluation, there is a clear need to establish and/or improve co-operation among calibration and testing laboratories in candidate countries and EU laboratories.

It is estimated that the implementation of ISO/IEC 17025 quality standard is relatively straightforward when performing basic calibrations, but more complex in testing laboratories, especially when there is not a direct functional relation between measured parameters and parameters on which the final decision of conformity is based. To a large extent, issues such as a practical identification of the uncertainty

components and their interrelations, their reasonable estimation, reporting, etc. still remain, in many cases, unresolved.

The above mentioned problems are particularly crucial in candidate countries' laboratories, especially in new areas where compliance with regulations and demonstration of quality assurance systems rely more and more on the accredited M&T capabilities (such as food and agricultural industries, health, services, etc.). Consequently, it is considered important that the possible perceived lack of confidence in these capabilities can eliminate certain sectors from equal competition in the enlarged single market.

The summarised major problems in candidate countries related to M&T infrastructures and capabilities vary from one country to another. In general they could be identified as:

- lack of understanding of the importance of M&T, as a horizontal and generic activity for research, development of new products and services and international trade;
- lack of co-operation among technical and administrative infrastructures and regulators, industries and M&T laboratories at national and international levels;
- problems with appropriate positioning and financing of M&T infrastructures, while encountering specific nature of particular activities (i.e. market related M&T activities such as certification of products as opposed to national measurement standards etc.);
- obsolete knowledge/ expertise and shortage of M&T instrumentation.

4. The way forward

Developments and investment in M&T infrastructures in candidate countries should target substantial improvements in the capabilities of M&T laboratories. This will enable them to become an important factor of socio-economic growth and to appropriately and fully respond to the needs of industry and society as a whole.

Intensifying all efforts and investment in M&T, in relation to the general problems of the implementation of technical legislation (adoption, required expertise, establishment of infrastructure and formal international recognition of all activities involved) and improved quality, is justifiable and economically important for candidate countries due to the nature of target markets and of the products produced in candidate countries.

These products, such as mass production of electric household equipment, pharmaceuticals, food etc. in order to be competitive, have to be produced in quantities that typically exceed the needs of a particular candidate country's local market. Therefore, the inherent need for appropriate M&T support, such as mutual recognition of conformity assessment results etc. is of utmost importance. This being then the basis for signing agreements, e.g. PECAs (Protocols to the European Agreements on Conformity Assessment and Acceptance of Industrial Products). PECAs are government-to-government agreements between the EU and certain EU

Candidate countries. They provide the necessary legal framework to operate according to the rules of the internal market. PECA agreements have been so far signed between the EU and Hungary and Czech Republic, and negotiations are underway for Estonia, Latvia, Lithuania, Slovakia and Slovenia. They formally eliminate additional testing and certification requirements for candidate countries that have already adopted and consequently also implemented EU legislation in various sectors.

It has to be realised that the appropriate level of technical expertise in the above mentioned areas is essential for candidate countries to endure competition as well as effect further developments. Quite often a generation of new products and entry into common European market largely depends on locally available M&T facilities. An illustrative example is the production of household appliances and other products covered by, e.g. low voltage and EMC directives, where there is a need and tendency for certain industries to establish their own laboratories to support research and development, for production support as well as for testing products and conformity assessment procedures.

It has been demonstrated that not only in new production facilities, but also in existing ones, investments in M&T could generate considerable added value.

The most evident cases for the above stated claims are the production facilities of measurement equipment, such as electric energy meters, electronic balances, dimensional meters, environmental monitoring equipment, etc in some candidate Member States (e.g. Poland, Slovenia, Hungary, Czech Republic, Estonia).

It was only after the establishment of factory laboratories and their accreditation that the produced equipment was also calibrated, tested or verified. Production then became financially more profitable with additional added value.

This appears to be particularly true for the pre-accession countries, where the technologies at the cutting edge of science and technology are rarely accessible. At the same time, options for future economic development have to be made within limited economic and manpower resources in a relatively short time

Hence, new added value is largely generated by using existing technologies and production facilities, but upgraded in terms of quality due to the appropriate M&T strategies and capabilities. Obviously, this has a direct impact on employment policy.

Suggestions for improvements to national M&T infrastructures:

- Prioritising of M&T needs according to specific circumstances and appropriate financing as a governmental responsibility when appropriate.
- Strengthening of national M&T infrastructures and their inter-relations with administrative infrastructures and regulatory bodies and industries.
- Stimulating research and development in M&T, education, transfer of knowledge, sharing of resources and international co-operation.

5. Specific emphasis on metrology

Metrology, as the science of measurements, is fundamental for efficient M&T infrastructures. The European metrology structure, described as scientific, industrial and legal, requires some additional clarifications.

Scientific metrology, at least at the highest level of national measurement standards, requires institutional and financial stability and sustainability. The National Metrology Institute, NMI, is fundamentally different in the modern market economy as opposed to the planned economy in previous Central and Eastern European countries.

From being nominated or appointed bodies, mostly responsible for legal metrology, very often locked within national borders, NMI must be transformed into a modern, scientifically oriented and internationally recognised institution.

This requires substantial changes in management, legislation, organisation, technical and professional abilities, quality system implementation and adequate financing, directly or indirectly by the government.

Due to this fundamentally new role of a typical NMI in a candidate country, it is not possible to retain the old practice where NMI was to a great extent the provider of additional income to the national government through legally prescribed mandatory verifications, type approvals, inspections, etc. Instead, NMIs in candidate countries should focus on their inherent mission – to provide measurement traceability at the highest national level and should be the basis for M&T in its broadest sense. For this activity, governmental funding is necessary.

NMI being responsible for the above stated activities should therefore be:

- independent, impartial, accountable, financially stable, with competent and stable leadership, meeting national needs and foreseeing emerging needs, co-operating internationally, using available resources at the national level and sharing resources internationally
- legally defined by law as well as the full responsibility of the national government and being able to act horizontally and intersectorially (e.g. sectors responsible for science, research, education, development, health, trade and industry, defence, fight against crime and fraud, etc.)

Legal metrology, in many cases must be radically reshaped, where and when it still reflects unacceptable practices of over-regulation, duplicating of type testing, type approvals, initial verifications, lack of traceability and uncertainty statements, etc.

Industrial metrology, is of prime importance for the proper functioning of national trade, industry and other services.

If needed, such laboratories were efficiently set up in most cases due to clear industrial interest and direct market relations.

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