Conformity Assessment

Discussion paper
Various factors to be taken in to account in order to clarify the meaning and economic impact of mutual recognition in regulated and non regulated sectors

This paper has been submitted by the Rapporteur on Conformity Assessment. It concerns discussions on mutual recognition agreements (MRAs) and contains proposals for future activities of the Working Party on this subject.

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1. Types of mutual recognition agreements (MRAs)

Many different types of MRAs are possible; the wide range of possibilities does not permit a systematic presentation. However distinctions can be based on:

- the subject described: products, services, management systems... ;
- the agreeing parties, their number (bilateral or multilateral), the geographical positions of the parties and their potential clients ;
- the conformity assessment and/or accreditation activities covered ;
- the obligations resulting from the agreements, e.g. in terms of recognition or acceptance ;
- the legal liabilities of the parties ;
- the trade benefits for the MRA’s signatories.

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The titles chosen for mutual recognition agreements vary. Words such as «agreements» and «arrangements» may have a specific use in a government context; some countries prefer use of the term «mutual recognition arrangements» in the voluntary sector rather than «mutual recognition agreements». Some Accreditation bodies sign «multilateral agreements» called MLAs, others sign MRAs for the same purpose. Certification bodies often refer to «certification agreements».

In order to have a common understanding, three important terms are used with the following meanings in this paper:

- **Recognition**: acknowledgement of the validity of a conformity assessment result provided by another person or organization
- **Acceptance**: use of a conformity assessment result provided by another person or organization
- **Equivalence**: sufficiency of different conformity assessment results as alternatives for the purposes and in the ways specified by particular people or organizations

In Government to Government MRAs or agreements between regulatory authorities acceptance and recognition of conformity assessment procedures have specific binding connotations. The objective of such agreements is to provide effective access throughout the territories of the Parties (i.e. the States or the Authorities concerned). Conformity assessment bodies and accreditation bodies designated to perform the relevant assessment activities provide their services without direct involvement in the recognition or acceptance of their certificates, which is the sole responsibility of the governments/authorities.

In non-regulated sectors, MRAs are signed between bodies undertaking similar conformity assessment activities, not required in order to satisfy governmental regulations. Such activities have two levels:

- the supply of conformity assessment activities, i.e. where such activities have as their objective to satisfy industrial or commercial requirements
- the formal recognition of bodies undertaking conformity assessment based on an assessment by accreditation bodies that they are competent to carry out their specific tasks

It is proposed to consider, in particular, the impact of agreements between governments and those between accreditation bodies.

### 2. Impact of Government to Government MRAs

In the field of government to government MRAs covering the assessment of conformity to specific regulations, the design and content of these MRAs could be evaluated, and/or categorized, using the following elements:

- **a)** What sectoral coverage do they have?
- **b)** What trade volume do they cover, and what trade problems, in any, do they resolve?
- **c)** What degree of access do they permit or require, for example:
- Full recognition of certification; or
- Full recognition of test results; or
- Full recognition of good manufacturing or laboratory practices; or
- Full recognition of marks?

d) Do they only deal with the recognition of certification, test results, marks, etc. or do they also involve recognition of the equivalence of the other party's standards, or a degree of harmonisation of standards?
e) Are the agreements bilateral or plurilateral?
f) Do the agreements cover safety issues only, or others too, e.g. environment?

The impact of these MRAs can be considered in more general terms:

- What sectors covered by an MRA are considered high, medium or low risk or other?
- In what sectors has there been a move to deregulation? Has this meant the elimination of certain regulations? Has it meant more decentralisation e.g. more reliance on manufacturers' declarations? More reliance on market surveillance as opposed to third party assessment?
- Is the impact of the MRA limited by additional conformity assessment procedures required de facto on the national or foreign markets?
- What sectors are considered to have fully competent standards and conformity assessment systems, and/or which require technical cooperation and assistance?

Possible use of a questionnaire on MRAs

For existing MRAs, an agreed questionnaire could be a national tool for a better understanding of the economic impact of the MRAs. It could be also used to compare the perception of an MRA’s impact in the countries of the signatories.

3. Impact of agreements between accreditation bodies

Agreements between accreditation bodies usually means that each party recognises the technical equivalence of accreditation systems operated by the other parties. For example:

…”Through the Multilateral Agreement (MLA) a uniform level of competence of the accredited bodies involved is assured and the need for multiple assessment is diminished or eliminated. This means that a supplier will only need one certificate or report to satisfy the entire European market and all governments”.

This statement does not mean that MLA members accept to grant their own accreditation to bodies accredited under the other systems (i.e. as if they were directly accredited under their own system).
It might be a further (but difficult) step to develop "second generation" agreements between the accreditors of conformity assessment bodies. However, even more complex agreements would not change the fact that accredited conformity assessment bodies will never provide uniform services.

In the real world the clients of the accredited conformity assessment bodies (and the "users" of their certificates) find that the levels of competence - technical and otherwise - are not uniform between bodies and it makes a difference which accredited body performs the service required and issues the report or certificate.

The buyer or user of a conformity assessment service may, therefore, have some good reasons to prefer one or the other body as issuer of its certificate. Two examples can be given:

- at a global level: the automotive industry has organized its "private" accreditation due to the lack of confidence in some of the signatories of the MLA between accreditation bodies assessing the certification bodies.
- at a European level, the European railways have adopted their own accreditation referential, but they rely on existing European accreditation bodies for assessing the compliance to their requirements and organize a kind of surveillance of accreditation body practices in case of problems.

Possible enquiry

Transition economies have great expectations with regard to the role played by accreditation for the recognition, on foreign markets, of the attestations provided by their national conformity assessment bodies.

As some of the expectations are far beyond the possible impact of accreditation and mutual recognition between accreditation bodies, WP 6 may contribute to the clarification of the understanding of their impact.

An enquiry could be initiated to investigate the impact of these agreements, the expectations not satisfied, and the perception of needs for their evolution. Such a study might be organized by the bodies coordinating accreditation bodies at regional level or international level (ILAC and IAF).

WP 6 could also take the initiative of such a study in its regional context, in particular due to the lack of a sufficient representation of the accreditation bodies of transition economies in ILAC and IAF.

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