

EUROLAB COMMENTS**ON THE DESIGNATION PROCEDURE OF CONFORMITY ASSESSMENT BODIES
(CABS) UNDER MUTUAL RECOGNITION AGREEMENTS (MRAS)****(DOCUMENT CERTIF. 94/8)****SUMMARY**

The EU Commission has received a mandate from the member states to negotiate mutual recognition agreements (MRAs) with third countries aimed at facilitating trade through the acceptance of test reports, certificates and other conformity assessment procedures related to legislation in these third countries and in the EU. Discussions are well advanced with Australia, New-Zealand, the USA, Canada and Switzerland. They are being initiated with Hong-Kong, Japan, Singapore, Korea and Israel.

One of the key elements of the negotiation is the mutual recognition of third party operators to assess compliance with the requirements of respective legislations. EUROLAB has, in the membership of its national associations and committees, a large number of laboratories notified for the implementation of EU "new approach" directives, either for testing or for certification services. Many of them provide also services of technical assistance to exporters in countries outside of the EU, and notably in the third countries having entered into negotiations for MRAs with the EU or having expressed the wish to do so.

The EU Commission has issued a guidance document (CERTIF.94/8) on the designation procedure of conformity assessment bodies (CABs) under MRAs. EUROLAB has analysed this document, together with other existing documents relating to the characteristics and obligations of "notified bodies" for EU "new approach directives".

The note of comments relates to these documents. This analysis leads to the following questions from the European laboratory community to the member states and DGI:

- *will third country CABs be subject to the same rights and obligations as the notified bodies operating within the EU? If so, how will this be ascertained?,*
- *what is the relationship between designation and accreditation?*
- *will third country CABs be allowed to operate EU conformity services world-wide?*
- *what counterparts are obtained by the EU as a result of the MRAs in terms of recognition of conformity assessment services provided by the operators located in the EU of an efficiency in the third countries equivalent to that provided by the CE marking?*

Considering the need to clarify a number of issues related to the conditions of notification and surveillance of CABs in the context of MRAs, and the potential impact of such MRAs on the conditions and fairness of competition both for manufacturers and conformity assessment operators, EUROLAB considers that clear answers should be given by the EU Commission and by the member states to these questions before concluding a first MRA, which, undoubtedly will set the jurisprudence for subsequent agreements. In particular, EUROLAB wishes that the European laboratory community be associated to the determination of these answers and is ready to provide the interface to do so.

1. Background on the negotiations of MRAs between the EU and third countries

The EU Commission has received a mandate from the member states to negotiate mutual recognition agreements (MRAs) with third countries aimed at facilitating trade through the acceptance of test reports, certificates and other conformity assessment procedures related to legislation in these third countries and in the EU. Discussions are well advanced with Australia, New-Zealand, the USA, Canada and Switzerland. They are being initiated with Hong-Kong, Japan, Singapore, Korea and Israel. In September 1995, draft agreements have been circulated in the EU by DGI for the first time outside of the Commission services and of the member states administrations, thus enabling economic partners in the EU to voice their opinions as to the aims, procedures, content, implementation and possible effects of such agreements. A formal meeting took place on September 28 in Brussels between representatives of DGI, DGIII, EAC, EAL, EOTC and EUROLAB. A second meeting is planned for next December 20, 1995.

2. EUROLAB interest in these negotiations

EUROLAB has, in the membership of its national associations and committees, a large number of laboratories notified for the implementation of EU "new approach" directives, either for testing or for certification services. Many of them provide also services of technical assistance to exporters in countries outside of the EU, and notably in the third countries having entered into negotiations for MRAs with the EU or having expressed the wish to do so. Consequently, earlier in 1995, EUROLAB had expressed concern to DGI as to the modalities for developing the MRAs and its desire to be consulted. An enquiry was launched in the EUROLAB membership to determine third country legislations for which recognition should be sought as a counterpart to accepting third countries' conformity assessment services in connection with the CE marking. The results of this enquiry have been transmitted to DGI and DGIII.

3. Questions and comments from EUROLAB on CERTIF.94/8

It is with this background that EUROLAB has been invited to comment on document CERTIF 94/8 on the designation of CABs. These comments, some in the form of unanswered questions, are the following:

- what will be the exact procedure for the designation of CABs to operate in connection with EU directives? Will the EU Commission have a delegation from the member states to accept automatically any CAB designated by the third country signatory to an MRA, provided it gives assurance that the generic designation mechanism contained in the agreement has been followed? Or will there be an examination by the Commission services prior to the designation of a third country CAB for an EU directive, with the possibility to refuse such designation? If so, who in the Commission will conduct, and on what basis, that examination? Or will the member states be consulted prior to designation with a right to oppose a designation? If designation is automatic, provided that the third country authority has granted it, how will the agreements with Australia and New-Zealand apply since the corresponding authorities are the accreditation bodies themselves, operating on a commercial basis and accrediting both third party and manufacturers' laboratories? These bodies present an additional difficulty, since both NATA and TELARC (the respective accreditation bodies) operate in the same organization both accreditation and QA system certification, putting them in the situation of applying themselves for CAB statute!

- will the CABs be subject to meeting the obligations of the "charter of notified bodies" mentioned in § 6 below? Is there a draft of this charter? In any case, accreditation should not exclude the obligation to take part in intercomparisons and in co-ordination activities which will be imposed on EU notified bodies.
- will designated CABs be allowed to perform services in connection with the CE marking only for companies manufacturing products in their country or will they be allowed to operate world-wide? How about subcontracting?
- to date, for most directives, there is no clear correspondence between the modules applicable to affix the CE marking and the EN 45000 and EN ISO 9000 series of standards; in some cases, there are even differences between the modules as described in the July 22, 1993 decision and those applicable to some of the new approach directives. Doc. CERTIF 94/8 makes a distinction between designation for assessing compliance to standards and designation to assess compliance to essential requirements (cf. §B.7.a). How will the third country authority know how to apply this clause, since the situation is far from being clear within the EU? What type of accreditation will be required as a preferred prerequisite to demonstrate the competence of a CAB to provide services in the context of a directive?
- to date, no cooperation, let alone harmonization, has occurred between the European accreditation bodies (within EAL and EAC) concerning their procedures and referentials for assessing organizations for scopes and activities connected to EU directives: they should be encouraged to do so, as, clearly, there are major differences of approach to this subject,
- MRAs should lead to equivalent effects for manufacturers as to gaining effective market access; in this respect, the currently proposed limitation of the MRA with USA to the recognition of test results seems unacceptable, both for European laboratories, which would be at a disadvantage with US designated CABs in terms of the completeness of the service offered to exporters, and to European manufacturers who would not gain equivalent facilities of access to the US market as that given to US manufacturers through the possibility to affix the CE marking on the basis of in-house or external test result.

The following considerations may help in answering some of these questions and concerns.

4. Negotiating to achieve balanced mutual benefits

MRAs should lead to benefits for the economies of all signatories. The EU has a lot to offer by facilitating access to its unified market through the CE marking. Without MRAs, in the field of new approach directives, substantial simplifications have already been implemented, with many products for which manufacturers' declarations are the basis for the CE marking, and thus to gain access to the market; for those for which the intervention of a third party is necessary, a great choice of notified bodies, some of them having subsidiaries overseas, is available. For many product categories, the situation is far less transparent and straightforward in many of the countries currently negotiating with the EU, especially in the USA and Canada, with their federal structure, and in Japan. It is therefore important that the negotiations be conducted in an offensive manner by the EU, and not on the defensive because we are sometimes accused of building "a fortress Europe", which is absolutely not the case.

MRAs should not have a negative influence on the fairness of competition with third country counterparts for European industry and European conformity assessment operators. This would be the case if the affixing of the CE marking and the designation of third party conformity assessment operators would be under less constraints and surveillance for third countries' companies and operators.

The negotiation of MRAs should also take into consideration the fact that, for most "new approach" directives, the modalities of implementation are far from being clarified and stabilized.

5. EU relevant documents

EUROLAB has examined document CERTIF.94/8, issued by DGI on April 3, 1995 and distributed at the above mentioned September meeting. This document addresses the designation procedure of Conformity Assessment Bodies (CABs) under MRAs. This document has inspired corresponding annexes to the draft agreements with Australia and new-Zealand, and possibly for the current discussions with the USA and Canada. It appears that CABs will play the role allocated to notified bodies in the EU and thus the conditions of their designation should be related to the conditions of designation of notified bodies.

Consequently, CERTIF.94/8 can not be examined independently of other reference documents relating to the designation, rights and obligation of notified bodies. EUROLAB has identified the following:

- CERTIF 91/7 (1992-06-11) on notified bodies, which is now part of the Guide on the new approach issued by the Commission,
- Council decision 93/465/EEC of July 22, 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives and the new approach,
- CERTIF 94/6 rev 4b(1995-06-1) on the framework for coordination and cooperation between notified bodies, member states and the EU Commission under the Community harmonization directives based on the new approach and the global approach,
- CERTIF 95/2 rev 1 51995-09-12) on the European quality assurance standards EN ISO 9000 and EN 45000 in the Community's new approach legislations.

6. Recall on EUROLAB's position on the co-ordination of notified bodies

In a position paper issued and circulated in June 1995, EUROLAB had commented on the CERTIF 94/6 rev 4b document. An extract of the conclusions of this paper reads as follows:

"(The CERTIF 94/6) document announces that the EU Commission will propose in the near future to the national authorities a "common charter containing the fundamental rights and obligations of notified bodies" and suggests ways to organize the cooperation between notified bodies, national authorities and the EU Commission in order "to ensure a correct and uniform implementation of the technical requirements of the Directives". In particular, it introduces the concept of formally

constituted "groups of notified bodies" for each directive, together with the possibility of having "intersectoral groups" in the case of simultaneous application of two or more directives to one product or for the treatment of horizontal issues. It proposes the organization and responsibilities of these groups, and solutions for providing and financing their secretariats, distinguishing between administrative and technical secretariat.

In relation with these proposals and when testing is involved, EUROLAB expresses the following wishes, that:

- *the proposed charter describes the requirements for notified bodies in such a way that those which may be assessed by accreditation bodies be clearly identified and that these requirements induce equivalent economic consequences on the notified bodies,*
- *the groups of notified bodies to be formed for each directive may have an input on the interpretation and implementation of EN 45001 in the corresponding fields of testing,*
- *intercomparison and proficiency testing be organized on a European scale as a means to monitor the homogeneous implementation of Directives,*
- *the revision of the EN 45000 series of standards be achieved as soon as possible, on the basis of the functions' approach, of full coherence of QA aspects with the requirements of the ISO-EN 9000 and also between functions, so as to optimize assessments for bodies operating several functions (testing and certification in particular),*
- *a clearer correspondence between the modules and the EN 45000 standards be achieved."*

Two other passages of this position paper are relevant to the subject of the designation of third country CABs as notified bodies. They are related to:

- **the connection between testing and legislation:**

"Testing is often performed as part of the process for determining the compliance of products to requirements set by legislation before they are put on the market. It may be carried out by the manufacturer himself, or by his authorized representative, or by an external laboratory designated by the administration responsible for implementing the legislation, or even sometimes by the administration itself. Testing may be applied to a specimen or sample representative of the production for which demonstration of conformity is sought ("type examination"), or on all individual products before they are marketed ("unit verification") or it may be performed on samples or specimen on a periodic basis and coupled with the assessment of the quality control of the production ("product certification").

Key issues to determine the adequacy of the tests involved for an effective implementation of the legislation prescribing them are:

- *the **identification of the tests to be applied**, usually ,but not always, described in regulatory documents and/or in national, European or international standards,*
- *the **determination and selection of the specimen or sample** to be tested,*
- *the **technical competence and independence of the staff** performing the tests,*

- *the adequacy of the equipment and laboratory facilities and procedures,*
- *the ability of the laboratory to interpret the test results (and tolerances) and conclude on the compliance of the tested item(s) to the requirements of the legislation and the repeatability of such ability for the laboratory and also between laboratories when several are designated, which implies the establishment and maintenance of a jurisprudence of interpretation,*
- *the principle, extent and conditions of acceptance of test data generated or produced by the manufacturer or performed by the third party laboratory at the manufacturer's premises and using his testing facilities .*

These issues determine the content, and therefore the cost, of testing services associated to legislation. Homogeneity and transparency of interpretation is thus crucial when several laboratories are designated to operate for the implementation of a given legislation, in order that fairness of competition between them and between their customers is ensured, as well as to ascertain that market control will not be faced with (too much) controversy about the results of tests."

- and, since accreditation is mentioned in the draft agreements as the preferred mechanism for the designation of CABs, to the subject of the **relationship between accreditation and notification:**

"As a means of demonstrating technical competence and ensuring the quality of the corresponding services, third party accreditation is obviously encouraged by the EU Commission as a prerequisite to notification of operators by national authorities. It is hoped that the cooperation between national accreditation bodies, the harmonization of their assessment and surveillance practices and procedures and the mutual recognition agreements which are developed in the context of EAL and EAC will ensure that this prerequisite is fulfilled in a homogeneous manner. It should be noted that accreditation has a significant internal and external cost for laboratories and that it is essential that accreditation, if it is to be de facto required for providing testing services in the regulated sphere, be optimized, both technically and economically.

On the basis of the experience of laboratories, of EUROLAB studies (cf. the study and intercomparison for the implementation of the "toys directive"), of the exchanges taking place in the groups of notified bodies which have already been formed for some directives and the symposium on notified bodies organized by the EU Commission in October 1994, the main difficulties encountered so far in relation with the use of accreditation as a prerequisite for accreditation are the following:

- *the extent to which accreditation requirements cover the issues listed in §1 above, although it is clear that accreditation, being usually performed by private or non governmental entities, will never be able to cover all of them, as they address not only technical aspects but also requirements having legal or financial implications ,*
- *the correspondence between the scope of accreditation and the scope for which a laboratory is notified,*

- *the fact that laboratories are usually accredited to perform tests described in standards, whereas for a number of Directives, third party laboratories are notified to determine compliance with their essential requirements when the product assessed does not comply with a harmonized standard, or when there are no harmonized standards at all,*
- *the lack of intercomparisons and proficiency testing organized on a European basis for tests performed in the context of Directives,*
- *the ambiguity between testing and inspection,*

The question of the true equivalence of accreditation procedures implemented by the accreditation bodies having entered the EAL multilateral agreement and the exact implication and impact of this agreement (and its corollaries with third countries) remains open, as this agreement is fairly recent."

7. Conclusion

Considering the need to clarify a number of issues related to the conditions of notification and surveillance of CABs in the context of MRAs, and the potential impact of such MRAs on the conditions and fairness of competition both for manufacturers and conformity assessment operators, EUROLAB considers that clear answers should be given by the EU Commission and by the member states to the questions in § 3 above before concluding a first MRA, which, undoubtedly will set the jurisprudence for subsequent agreements. In particular, EUROLAB wishes that the European laboratory community be associated to the determination of these answers and is ready to provide the interface to do so.

In summary, the major issues are:

- **will third country CABs be subject to the same rights and obligations as the notified bodies operating within the EU? If so, how will this be ascertained?**
- **what is the relationship between designation and accreditation?**
- **will third country CABs be allowed to operate EU conformity services world- wide?**
- **what counterparts are obtained by the EU as a result of the MRAs in terms of recognition of conformity assessment services provided by the operators located in the EU of an efficiency in the third countries equivalent to that provided by the CE marking?**

Considering that the operators of the third countries are being closely associated by their governments to the current negotiations, EUROLAB would not understand that European operators could not be treated on an equal basis by the EU Commission.