

New regulatory requirements for accreditation and market surveillance

EUROLAB *aisbl*

The European Federation of National Associations of
Measurement, Testing and Analytical Laboratories

European view of the new regulatory requirements

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Main issues of the Regulation (EC) No 765/2008

- **legal framework will be applicable from 01.01.2010 and apply to EEA**
 - **all 27 Member States and EFTA countries part of EEA**
- **operation and organisation of accreditation at European level**
 - **Requirements for European ABs going beyond ISO/IEC standards**
 - ✓ **1 nationally recognised AB per MS**
 - ✓ **Public authority**
 - ✓ **No competition**
 - ✓ **Not for profit**
 - **Requirements for Member States : corrective measures**

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Status and Role of EA

- **the official European infrastructure for cooperation in accreditation**
- **the regional cooperation body member of ILAC and IAF**
- **operating the Peer evaluation system**

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Consequences for EA and the European laboratory community

- EA and its MLA members considered as signatories to ILAC MRA and IAF MLA
- Attestation of conformity issued under accreditation by ABs signatories of ILAC MRA and IAF MLA
 - not signatories to EA MLA or BLA
 - not complying with requirements of EU Regulation

will be considered by EA to be equally reliable

... BUT acceptance in the EU of conformity assessment attestations certificates issued under accreditation by non European ABs does not depend on the recognition between ABs

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- **Voluntary CA area**

conformity assessment attestations issued under accreditation by non European ABs not complying with the new European requirements but signatories to IAF and ILAC MLA/MRA can continue to be used on the European Market

→ CABs from third countries decides where to get accredited

- **Mandatory CA area**

national authorities of EU Member states may refuse attestations of conformity issued under accreditation by non European ABs not complying with the new European requirements but signatories to IAF and ILAC MLA/MRA,

- **not because of non fulfilment of new European requirements as such**

- **except where MRA in place**

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MRAs are bilateral intergovernmental agreements for CA

6 operational MRAs are in place ; I.e. Australia, Canada, Japan, New Zealand, USA and Switzerland

MRAs will not be modified for the time being BUT for new MRAs or revision of existing MRAs : provisions on accreditation complying with Regulation No. 765 may be inserted

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The EUROLAB view and future activities before the regulation on accreditation (Regulation 765/2008) come into force will focus on :

- The political and technical issues associated with this new regulation**
- The requirements for Notified Bodies to be drafted for implementation**
- The future EA policy for relations with stakeholders**

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Political and technical issues associated with the regulation on accreditation (Regulation 765/2008)

The regulation sets new duties on the European accreditation bodies. These duties can induce stronger requirements and higher costs to European laboratories. To give a very classical example, the European cross-frontier accreditation policy is much more limitative than the ILAC one. There is thus a risk of a two-tier system when a body acting in the regulatory field under the European Multilateral Recognition agreement relies on results by a test laboratory accredited under other rules. For the European laboratories, there is also a risk of unfair competition. These elements should be clarified at EA and at EU level. This issue has also to be elaborated in relation to the effects of globalisation on the laboratory community.

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Requirements for Notified Bodies

Accreditation requirements are currently prepared at EA level. The basic approach is horizontal (covering all sectorial regulatory documents). EUROLAB welcomes the development which will help to improve consistency on the requirements for accreditation. At the end of the day, great care need to be taken of the sectorial differences. Laboratories (conformity assessment bodies) notified under the construction product directive have technical and administrative duties which are basically different from the duties of laboratories notified under the low voltage directive. If all of them are mixed, this will induce undue and unnecessary burden to the accredited notifies laboratories. All necessary steps should also be taken to ensure the technical sectorial competence of the accreditation auditors.

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The future EA policy for relations with stakeholders

The need for clear criteria of stakeholder selection and for detailed information about the role of the existing committees such as EA AB, EA LC, PLG, etc. has been underlined. The political role of EA AB must be reinforced. The expectation of EA to attract and incorporate more representatives of the member states could dilute their impact and influence. But based on existing involvement in EA AB the direct interest of these member state representatives as EA stakeholders was not demonstrated yet.

The document is still under revision. A new version will be issued and addressed to EA AB for comments. The future EA policy for relations with stakeholders is planned to be approved at the Lisbon General Assembly.

Thank you for your attention!



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