



eurolab

**New Regulatory Requirements for
Accreditation and Market Surveillance
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**The European Regulation on Accreditation
and its Impact on Germany**

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The challenge

The European Regulation on accreditation and market surveillance (765/2008/EG) stipulates that each Member State shall appoint a **single** national accreditation body. This body shall be operational by 1 January 2010.

For Germany this demand requires a considerable structural change of its accreditation system.

The beginning

The existing German accreditation system reaches back to the early '90s, when it was agreed

- to establish a sector oriented system of individual accreditation bodies,
- to avoid competition between them,
- to coordinate this system by the German Accreditation Council (DAR) by common horizontal criteria and a joint representation at the European and international levels.

The further development

These objectives were not strictly achieved because the DAR

- has never had a defined statutory basis and could not enforce its decisions among its members,
- does not represent the whole accreditation system,
- could not strictly avoid competition between some private accreditation bodies.

The present situation

- 5 accreditation bodies in the private sector,
- (at least) 11 accreditation / notifying bodies in the legal sector.

The private bodies and some of the public accreditation bodies are members of the DAR.

4 of them are signatories of the EA and the respective ILAC / IAF Multilateral Agreements (MLA).

The Federal Ministry of Economics and Technology (BMWFi) had established an Accreditation Advisory Board and took responsibility for the representation of the accreditation system at the European and international levels.

The way forward

The BMWi has drafted an accreditation law which should provide the legal basis for the establishment and authorisation of a single German accreditation body regarding the European Regulation.

Unfortunately the German Federal Government has not yet agreed on a joint position concerning the legal status of the body: private company, public authority or hybrid structure. The BMWi is in favour of a private body, which is governmentally recognised and controlled.

A potential private accreditation body

The major German industrial association (BDI) together with other trade organisations has offered to establish and maintain the national accreditation body under the coming law. The respective concept was presented in a meeting at the BMWi on 20 August 2008.

The core of the body would be formed by a merger of the 3 major private accreditation bodies. The existing accrediting and notifying authorities are invited to contribute by

- providing permanent personnel and accreditation assessors,
- collaboration within the Technical Committees,
- involvement in the accreditation decisions.

The potential structure

According to the BDI concept the new accreditation body would

- work under the supervision of the BMWi,
- consist of various sector oriented departments,
- use the existing infrastructure of technical committees as far as possible,
- establish an accreditation committee taking the accreditation decisions,
- use the existing Accreditation Advisory Board of the BMWi as its advisory board for stakeholder involvement.

Advantages

During the presentation on 20 August 2008 the broad majority of the stakeholder organisations present supported this concept because the planned merger of the 3 major private accreditation bodies would

- provide the existing expertise in the field of accreditation,
- cover most of the valid accreditations,
- result in an accreditation body which would comply with ISO/IEC 17011,
- be easily acceptable for EA as signatory of the relevant MLAs.

Involvement of the public sector

The involvement of the authorities that grant accreditations / notifications today is essential.

The draft accreditation law defines the notification of competent conformity assessment bodies as a two step procedure:

1. Assessment of the technical competence by the accreditation body,
2. Decision on the notification by the pertinent authority.

The technical criteria for the former step shall either be used, if existing, or be developed by or in co-operation with the notifying body.

Expectations of the CABs

In a letter to the BMWi EUROLAB-D had expressed the expectations of the accredited conformity assessment bodies (CABs) concerning the future development as follows:

- maintenance of the validity of existing accreditations and reasonable transitional arrangements,
- no additional costs or efforts for the CABs,
- use of the existing expertise on accreditation,
- close co-operation with the notifying authorities,
- fair competition and a level playing field for CABs in Europe.

Concerns

So far the problem of the future relation and co-operation between the regulated and the private sector has not been resolved.

If the new national accreditation body, maybe a private company, was not fully accepted by the notifying authorities concerning the final assessment of the technical competence of CABs, the notification process would be more complex and costly.

Conclusions

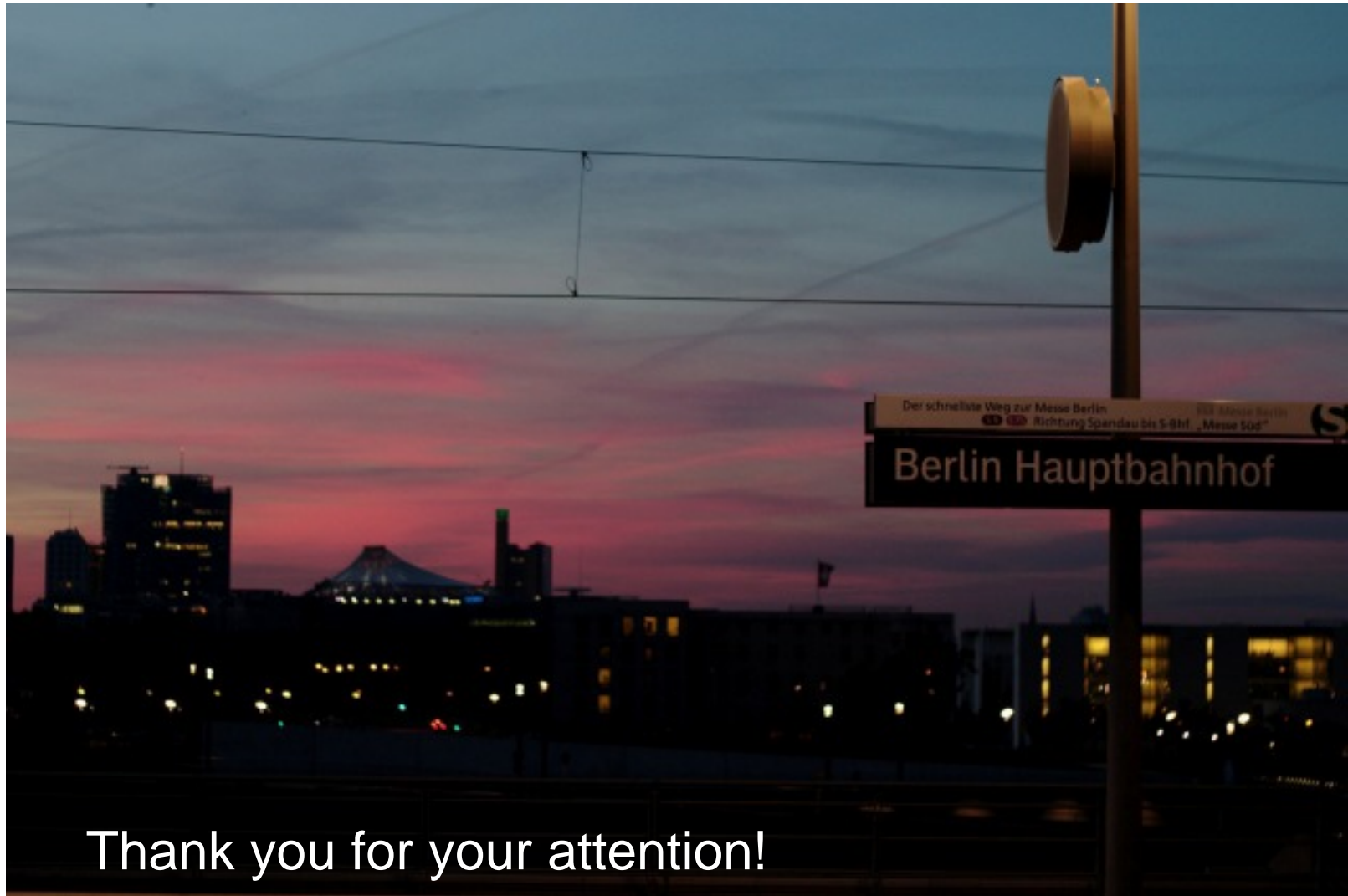
The existing German accreditation system gathered comprehensive accreditation expertise and ensured the competence of the accredited CABs,

but it

- was not very efficient and not transparent for non-German partners,
- was only partly involved in the EA- and ILAC-structures and MLAs,
- does not comply with the European Regulation.

Conclusions

- The Federal Ministry of Economics and Technology (BMWi) has taken responsibility to develop a new accreditation structure.
- An accreditation law is under way providing a legal basis for the establishment of one single national accreditation body (NAB).
- The legal structure of the NAB – private or public – is still open.
- The BMWi and the majority of the stakeholder organisations favour a private company, governmentally recognised and controlled, with the merged ABs as a core.
- Unfortunately an acceptance of this concept by some ministries and notifying authorities is still lacking.



Thank you for your attention!