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Single Market for goods
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NOTE TO THE EXPERT GROUP ON THE INTERNAL MARKET FOR PRODUCTS

Title:	**CERTIF 2012-02 REV4 – Activities of Accreditation bodies that are not accreditation**		
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Abstract:

The objective of the present paper is to lead to a common understanding on the activities that a national accreditation body may perform. The idea is to ensure that the principles of non-commerciality and non-competition are safeguarded and that accreditation bodies only assess the technical competence of conformity assessment bodies through the full accreditation procedure envisaged by Regulation (EC) No 765/2008.

Keywords:	**accreditation**
References:	**Regulation (EC) No 765/2008 setting out requirements for accreditation and market surveillance relating to the marketing of products**

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Brussels,
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Activities of accreditation bodies that are not accreditation

1 Objective of the paper

This paper aims to provide a common understanding on the interpretation of Regulation (EC) No 765/2008 ("the Regulation") in relation to the activities that accreditation bodies may perform following the adoption and entry into force of the Regulation.

The aim of this paper is to ensure that any assessment performed by a national accreditation body fully meets the requirements of the Regulation and relevant international standards – thus the processes and rules for accreditation. This is to safeguard the confidence in the competence of conformity assessment bodies that have sought accreditation by the national accreditation body. As a consequence, all technical assessment activities are to be subject to the full accreditation cycle according to the harmonised standards and to be peer evaluated.

This paper also aims to clarify, that accreditation bodies should continue to be able to provide activities that add a general value to accreditation but are not assessment services, such as assistance to non-EU countries e.g.

Bearing in mind that the ultimate say on matters of EU law rests with the Court of Justice of the European Union, this draft paper contains a proposal for a common understanding and pragmatic solution for this question.

2. Background

Article 2(10) of the Regulation defines accreditation as *'an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.'*

Article 4 of the Regulation lays down the general principles that apply to accreditation bodies. These general principles include amongst others:

– that Member States appoint a single national accreditation body (Article4(1)).

– that it operates accreditation as a public authority activity regardless of its organisational form (Article 4(5)).

– that its activities have to be clearly distinguished from those of other national authorities (Article 4(6)).

– that it operates on a not for profit basis (Article 4(7)).

– that it is entirely independent of any conformity assessment activities, including consultancy (Article 4(8)).

– that Member States are responsible for ensuring that it has the competence and means to fulfill its tasks adequately, including European and international cooperation activities which support public policy and which are not self-financing (Article 4(9)).

– that it is a peer evaluated member of EA (Articles 4(10) and 4(11)).

The purpose of these provisions is to ensure the quality of accreditation as the last level of control in the conformity assessment system.

Furthermore Article 6 of the Regulation enshrines the principle of non-competition according to which accreditation bodies

– may not compete with conformity assessment bodies (Article 6(1)).

– may not compete with other national accreditation bodies (Article 6(2)).

The aim of the principle of non-competition is to prevent conformity assessment bodies from shopping around for accreditation certificates, thus creating a "market for accreditation" leading to the commercialisation of accreditation which jeopardises the added value and role of accreditation as a public authority activity and last level of control of the conformity assessment chain.

3. Problem definition

Currently, some national accreditation bodies perform assessment activities according to a number of rules and standards that do not or only partially meet the definition of accreditation by the Regulation, by e.g. not being fully compliant with EN ISO/IEC 17011 for accreditation bodies or with the harmonised conformity assessment body standards. In some cases, accreditation certificates are issued for these activities.

Furthermore, some public authorities request their national accreditation body to perform assessments for the purposes of notification according to EU harmonisation legislation or national legislation but without performing accreditation as such. Such practices render meaningless the Regulation's preference for accredited notifications and the confidence that they should instil *ad absurdum*.

As these types of assessment do not meet the requirements of accreditation as defined by the European legislator, they may overlap with consultancy or conformity assessment services. The Regulation clearly prohibits national accreditation bodies from performing such services according to Article 4(8). They equally blur the line with other public authority tasks which should remain clearly distinguished under Article 4(6). Thus, not only do such activities pose a threat in terms of the independence and non-commerciality of the accreditation body; there is no control either of the quality of such services as performed by the national accreditation body. This is because any such activities remain

outside the remit and control of the peer evaluation process. They therefore undermine the very nature and added value of accreditation as a standard-based, transparent and peer-evaluated process.

In consequence, accreditation's reputation may be harmed as it may no longer be clear which of the accreditation bodies' activities are accreditation, and which are some other form of assessment, as these certificates are likely to be related back to the national accreditation body – and the role conferred upon it by the Regulation.

Furthermore, these activities may also provide a potential outlet for commercial activities that are otherwise prohibited according to the Regulation.

4. Solution

Given the prominent role in the conformity assessment system that the Regulation has bestowed upon national accreditation bodies, accreditation bodies should strictly follow the rules of the Regulation when assessing the competence of conformity assessment bodies. The legislator has decided to clearly limit the activities that an accreditation body may perform, keeping a tight control over their remit via the direct reference to harmonised standards. Accreditation bodies no longer have the competence to broaden their activities without having regard to those parameters set by the legislator. It is not incumbent on the national accreditation body to determine whether an assessment activity outside the scope of harmonised standards represents a conflict of interest or not. The purpose of Article 4(6) on the separation of other public functions and Article 4(8) on the separation from conformity assessment activities is to preclude any potential conflict of interest that may arise from having these activities in the same organisational structure. It is up to national authorities to ensure that these provisions are respected and that their accreditation bodies exercise exclusively activities that are entirely in line with the Regulation. Acceptable services would be those that add a general value to accreditation (such as access to national and international expertise or specialised training services) and for assistance to non-EU countries.

This also means that national authorities may therefore not require and should actively prevent their accreditation bodies from performing assessment services outside the full accreditation process or use conformity assessment standards that are not harmonised.[i]

[i] GLP can be regarded as a sector scheme of EN ISO/IEC 17025 in this context. EMAS has to be regarded as a political exception to this process.