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

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Abstract:

The objective of the present paper is to lead to a common understanding on how to proceed with bodies based or active in the EU that claim to provide accreditation of conformity assessment bodies but have not been appointed as the national accreditation body within the meaning of Regulation (EC) No 765/2008.

Keywords:	**Accreditation, single national accreditation body**
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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‘Non-national accreditation bodies’ that claim to provide 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 scope of Chapter II on accreditation of the Regulation.

It concerns accreditation activities performed by bodies based or active in Europe that are not national accreditation bodies according to the Regulation. These bodies assess the technical competence of conformity assessment bodies, claiming that they provide “accreditation” – be it in parallel or in direct competition with national accreditation bodies. In many cases, these bodies claim to fall outside the scope of the Regulation by using variants of the harmonised international conformity assessment body standards.

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 3 of the Regulation states that Chapter II on accreditation applies *to accreditation, used on a compulsory and voluntary basis, relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing the accreditation.'*

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 2(11) stipulates that a national accreditation body means *'the sole body in a Member State that performs accreditation with authority derived from the State.'*

Furthermore, Recitals 10 and 11 of the Regulation highlight that it is '*necessary to develop a comprehensive framework for accreditation'* and the *'establishment of a uniform national accreditation body'* instead of the previous different approaches and systems throughout the Union.

According to Article 4(1) and Recital 15, Member States may only appoint one single national accreditation body, and accreditation is to serve as the *'last level of control in the conformity assessment chain'* exercising public authority (Recitals 15 and 19).

3. Problem definition

While Member States have all appointed national accreditation bodies, a number of "non-national accreditation bodies" are still active within the European Union. They are active within or from within the EU without being a national accreditation body according to the Regulation.

The fact that they claim to "accredit" conformity assessment bodies leads to considerable confusion amongst public authorities, stakeholders and the public as to the nature of accreditation. A number of public authorities across the EU have recognised the services of these bodies following their claim that they provide "accreditation" – thus an "authoritative" statement on the technical competence of conformity assessment bodies. The notion that the accreditation of conformity assessment bodies may be something other than that provided by the national accreditation body according to the provisions of the Regulation undermines the principle of accreditation as a public authority activity that leads to the mutual recognition of certificates.

These 'non-national accreditation bodies' might thus lead to the paradoxical situation where national accreditation bodies are bound by the principles of non-competition and non-commerciality while these bodies would be free to compete.

4. Solution

The Regulation defines the notion of accreditation of conformity assessment bodies and specifies that there can only be one single national accreditation body in each Member State. Therefore, the activities of 'non-national bodies' - 'accreditation bodies' that are not the officially appointed national accreditation bodies – cannot be considered as accreditation in the sense of the Regulation but should rather be considered as commercial conformity assessment activities. It will thus be necessary for them to change the denomination of their activities by replacing the term 'accreditation' by another term. According to the Regulation, accreditation of conformity assessment bodies may only be provided by national accreditation bodies according to harmonised standards.

When using accreditation for notification purposes or for the recognition of conformity assessment bodies, Member States' authorities and the European Commission should pay particular attention that the accreditation bodies providing the certificates comply with the Regulation or - for conformity assessment bodies based in non-EU countries – that the accreditation body is a member of ILAC/IAF complying with EN ISO/IEC 17011 that has undergone peer evaluation in its respective region.[1]

Furthermore as Member States are responsible for the implementation of the Regulation on their territory and in accordance with the principle of sincere cooperation as laid down in Article 4(3) TEU, the Member States and Commission should assist each other to

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[1] Should subcontracting outside the EU and EEA or Turkey take place, the subcontracted bodies should have been accredited by an ILAC/IAF Member.

continuously ensure that only the officially appointed national accreditation bodies carry out accreditation of conformity assessment bodies in the Union.