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**NOTE TO THE EXPERT GROUP ON THE INTERNAL MARKET FOR PRODUCTS (IMP)**

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<p><b>This paper aims to clarify the relation between notification of conformity assessment bodies for the purposes of EU harmonisation legislation and the peer evaluation of national accreditation bodies providing the technical assessment of such conformity assessment bodies. This paper addresses the case where a national accreditation body may not have been peer evaluated for all scopes of accreditation or where it may lose its peer evaluation status at one point in time. Given that according to Regulation (EC) No 765/2008 the recognition of accreditation certificates by national authorities is based on a successfully passed peer evaluation, only those notifications of conformity assessment bodies accredited by a peer evaluated accreditation body should be considered as accredited for the purposes of notification.</b></p>			
<b>Keywords:</b>	<b>Notification, Accreditation, peer evaluation</b>		
<b>References:</b>	<b>Regulation (EC) No 765/2008 setting out requirements for accreditation and market surveillance relating to the marketing of products</b>		



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## **Notification and the peer evaluation status of a national accreditation body**

### **1. OBJECTIVE**

This paper aims to clarify the relationship between the peer evaluation status of a national accreditation body and the notification of conformity assessment bodies for the purposes of EU harmonisation legislation.

The peer evaluation of national accreditation bodies plays a central and essential role in the European accreditation system as set up by Regulation (EC) No 765/2008 setting out requirements for accreditation and market surveillance relating to the marketing of products (the Regulation). A successfully passed peer evaluation is the corner stone of the recognition of accreditation certificates by national authorities, and thus of the facilitated accreditation procedure set out in the Regulation and in Decision No 768/2008/EC on a common framework for the marketing of products.

Peer evaluation is, however, a process that may by its very nature also produce negative results for a national accreditation body. In addition, not all national accreditation bodies have been peer evaluated for all scopes of accreditation. Accordingly, this paper proposes a consensus on how to proceed should such cases arise.

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**

Accreditation as provided for by the Regulation should be the preferred means of demonstrating the technical competence of conformity assessment bodies selected for the implementation of EU harmonisation legislation. A system of accreditation that functions according to binding rules helps to enhance the mutual confidence between Member States as regards the competence of conformity assessment bodies<sup>1</sup>.

Member States may decide not to use accreditation and Article 5(2) foresees that in such cases the Member State *'shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question.'*

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<sup>1</sup> See recitals 12 and 13 of the Regulation.

National accreditation bodies have to regularly undergo peer evaluation to make sure that they meet the requirements of the Regulation. Peer evaluation is therefore *'a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements of this Regulation, and where applicable, additional sectoral technical specifications'*<sup>2</sup>. The peer evaluation process is described in Article 10 of the Regulation.

The importance of peer evaluation is highlighted by Article 11(2) which, when setting out the presumption of conformity of national accreditation bodies, indicates that: *'National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in paragraph 1 of this Article, the accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them.'*

Furthermore, Article 7 obliges conformity assessment bodies to seek accreditation in the Member State of their establishment or the accreditation body to which their Member State has had recourse, unless where the national accreditation bodies has not successfully undergone peer evaluation under Article 10 in respect of the conformity assessment activities for which accreditation is sought.

Member States are to monitor their national accreditation bodies on a continuing basis, in doing so they are to take the *'utmost account'* of the results of the peer evaluation process. According to Article 9, Member States are obliged to take corrective action or ensure that corrective action is taken should a national accreditation body not meet the requirements of the Regulation or fail to fulfill its obligations. It shall inform the Commission of such action.

Finally, concerning the continuous competence of conformity assessment bodies, for aligned legislation, Article R.25 of the Decision states: *'1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article [R17] or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.'*

### **3. PROBLEM**

The preference given to accreditation when notifying conformity assessment bodies for the purposes of EU harmonisation legislation rests entirely on the presumption that the peer evaluation process guarantees the competence and quality of the work of national accreditation bodies. The peer evaluation process gives the guarantee that conformity assessment bodies are adequately assessed. The presumption of conformity of the technical competence of a conformity assessment body expressed in Article 11 of the Regulation, does not apply where an accreditation certificate is not underpinned by peer evaluation – as there is no guarantee to its quality.

In the case of an unaccredited notification, the technical competence of the conformity assessment body needs to be demonstrated by the supporting documents provided by the

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<sup>2</sup> Article 2 (16) of the Regulation.

notifying authority (see [CERTIF 2010-08 REV1 - Notification without accreditation \(Article 5.2 of Regulation 765/2008\)](#)).

However, not all accreditation bodies have been peer evaluated for all scopes of accreditation, and there may – in future – be a situation where a national accreditation body fails to pass its peer evaluation.

The latter situation especially may pose doubts as to how to proceed with the recognition of certificates issued by conformity assessment bodies accredited by this national accreditation body – and notified for the purposes of EU harmonisation legislation.

#### **4. SOLUTION**

A number of scenarios are possible with respect to the above problem:

##### **4.1. The national accreditation body has not been peer evaluated for the specific accreditation activity in question**

Should a national accreditation body not have undergone peer evaluation for a specific accreditation activity but still evaluate the competence of a conformity assessment body for this activity, the notification of this conformity assessment body should not be considered as accredited for the purposes of EU harmonisation legislation. According to Article 11(2) of the Regulation, national authorities are only obliged to recognise certificates of those accreditation bodies that have successfully undergone peer evaluation.

Such certificates may merely serve as one element in the supporting documentation for a notification according to Article 5(2) of the Regulation. This notion is strengthened by Article 7 of the Regulation, which expressly identifies this as a situation where a conformity assessment body may seek accreditation outside its Member State of establishment.

##### **4.2. The national accreditation body has not successfully undergone peer evaluation at a re-evaluation.**

Should a national accreditation body previously have been successfully peer evaluated for a given activity but be suspended at a subsequent peer evaluation, the situation for new notifications of conformity assessment bodies assessed by this national accreditation body should be relatively straightforward - as in 4.1.1, they should be considered as unaccredited.

As a principle, accreditation certificates issued up until the point of the suspension of the peer-evaluation of the national accreditation body, should continue to be recognised by national authorities.

If the grounds for suspension do not directly cast doubts on the notified bodies' competence, their notification should in principle be maintained. The responsible notifying authorities would have to guarantee that the surveillance of these bodies is adequately ensured. It should inform the Commission and other Member States, how this surveillance is performed.

Should the grounds for suspension of the national accreditation body result in serious doubts about the competence of the notified bodies, the responsible notifying authority

would have to inform the Commission and other Member States how it intends to ensure the competence of the bodies notified, and of any corrective measures taken, including the de-notification.

The Member State in question should keep the Commission and other Member States informed about any developments in this respect.

For new applications for notification, updates to notifications or re-notifications, Article 7 of the Regulation identifies this as a situation where a conformity assessment body may seek accreditation outside its Member State of establishment.