ORGALIME

Position Paper

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Assessment and surveillance of Notified Bodies using subsidiaries and sub-contractors in third countries

Executive summary

Orgalime believes that it is essential that third-party certificates and other attestations issued by Notified Bodies wherever they are located in the EU or outside of the EU should provide an equal degree of reliability. This is essential both for the confidence of consumers, whether private or professionals, and to ensure a level playing field for manufacturers and EU based notified bodies.

Therefore, Orgalime **calls on the national accreditation bodies within EA** to make sure that subsidiaries and subcontractors of accredited Notified Bodies are subject to proper and consistent supervision, including in particular if these are located in third countries.

Existing international guidance on cross-frontier accreditation should be applied rigorously and consistently.

Orgalime calls on the European Commission to clarify in a revision of the Blue Guide on the implementation of New Approach directives that Article R20(1) of Decision 768/2008/EC of 9 July 2008 is not sufficient in itself to ensure such consistent supervision. In particular, the information to be provided to the notifying authority should be further specified and aligned with the requirements of section 14.2.b and c and 14.3 of the IAF/ILAC guidance on ISO/IEC 17020.

Orgalime calls on Member States to notify non-accredited conformity assessment bodies under the above conditions only.

1. Introduction

Decision 768/2008/EC of 9 July 2008 on a common framework for the marketing of products provides for a framework for the assessment and surveillance of Notified Bodies. In particular, article R17 defines requirements for Notified Bodies. Moreover, article R20 allows Notified Bodies to subcontract specific tasks or to have recourse to a subsidiary. In such cases, Notified Bodies must ensure that these subcontractors or subsidiaries meet the requirements set out in article R17 and must inform the notifying authority accordingly. In addition, Notified Bodies are required to take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established (article R20 paragraph 2). This possibility poses several difficulties when it comes to implementation and gives rise to concerns related to the surveillance of Notified Bodies.

Orgalime, the European Engineering Industries Association, speaks for 32 trade federations representing some 130,000 companies, mostly SMEs, in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.6 million people in the EU and in 2009 accounted for some €1,427 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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2. Problems encountered

- **Non-compliant products**

During recent months, several non-compliant Chinese products were found on the market and it turned out that all the tasks related to the assessment of conformity of these products had been performed by subsidiaries of European Notified Bodies located in China, on their behalf. Such examples occurred in the fields of pressure equipment and construction products.

In one case, the Member State in question imposed accreditation on the subsidiary, without a legal basis. In the same context, some European Notified Bodies admitted that they had difficulties in monitoring the activities of their subsidiaries located in third countries, especially in China.

In another case, certificates concerning gas appliances that were carried out by subsidiaries of European Notified Bodies located in Far East countries were found with several inconsistencies. For instance, one of them was entitled “EC type-examination certificates” although it did not include any test report, which is mandatory for gas products; it specified specific functional performances that were not relating to the essential safety requirements of the Pressure Equipment Directive (PED); there was no indication of the associated “set range” and “inlet pressure range” as requested by relevant harmonised standards.

Although Notified Bodies take the full responsibility for the tasks performed by subsidiaries, this system cannot be fully trusted.

- **Discrepancies between accreditation rules and notification requirements**

The rules set out in the Decision 768/2008/EC are not fully in line with those used by accreditation, in particular when the reference standard used for accreditation is ISO/IEC 17020 *General criteria for the operation of various types of bodies performing inspection*. This standard restricts the possibility to have recourse to subcontractors beyond what is allowed under the Decision. On the other hand, the definition of “subsidiary” has not yet been introduced in the reference documents used by accreditation. These difficulties are currently encountered when elaborating accreditation reference documentation in the field of EC-type examination based on inspection standards.

3. Issues to be addressed

The issues to be addressed are:

- improve the surveillance of subsidiaries of Notified Bodies, particularly of those established in third countries
- align rules for accreditation with the requirements of the Decision
- promote further the use of accreditation

Accreditation used as the basis for notification

When accreditation is the path chosen by a Member State for the purpose of notification, the accreditation body uses different documents to accredit a Conformity Assessment Body, among which:

- The relevant ISO/IEC standard (e.g. ISO/IEC 17020)
- EA 2-17: Guidance on the horizontal requirements for the accreditation of Conformity Assessment Bodies for notification purposes
- The relevant Directive-specific requirements for Notified Bodies.

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In particular, ISO/IEC 17020 defines requirements relating to inspection bodies. According to the current version of this standard, subcontracting of inspection is considered as an exception: "*The inspection body shall itself normally perform the inspections which it contracts to undertake*" (clause 14.1). According to section 14.1.a of the IAF/ILAC guidance on the application of ISO/IEC 17020 (IAF/ILAC-A4:2004), subcontracting of inspections is limited to the following cases:

- It is necessary because there has been an unforeseen or abnormal overload, key inspection staff members are incapacitated or key facilities or items of equipment are temporarily unfit for use.
- A small part of the contract from the client involves inspection not covered by the inspection body's accreditation or beyond the capability or resources of the inspection body. This does not prevent the inspection body to subcontract testing tasks to a laboratory.

In these cases, the competence of the subcontractor may be demonstrated either by the subcontractor having accreditation to ISO/IEC 17020 or ISO/IEC 17025 for the relevant inspections/tests and providing endorsed reports or certificates, or by the inspection body itself assessing the competence of the subcontractor for compliance with the requirements of ISO/IEC 17020 or ISO/IEC 17025, as applicable.

In the same context, IAF and ILAC guidance on cross-frontier accreditation specifies that accreditation bodies are required to visit and assess all foreign locations of their accredited Conformity Assessment Bodies, including subsidiaries and subcontractors, where key activities (cf. EN ISO/IEC 17011) are performed (so-called "critical locations"). This means that when accreditation is used, third-country critical sites should be regularly visited and checked, with such checks being duly documented.

There are also differences in the treatment of subcontracting and subsidiary companies: the current version of ISO/IEC 17020 deals only with subcontracting. EA 2-17, in particular clause 7.2.5, makes no distinction between a subcontractor and a subsidiary and does not investigate the potential impact of any differences. Instead, it states that "In this guidance, the term subcontracting includes also having recourse to a subsidiary".

On the other hand, Decision 768/2008/EC does make a formal distinction between subcontractors and subsidiaries, although article R20 deals with both in the same way. While the Decision requires the NB to ensure the competence of subcontractors and subsidiaries, it does not specify how this competence needs to be assessed and demonstrated and, in particular, it does not require these subcontractors and subsidiaries to be accredited themselves.

Hence the need for alignment in the following fields:

- Conditions for subcontracting or having recourse to a subsidiary
- Assessment and differences in the treatment of subcontractors and subsidiaries

Notification not based on accreditation

In such cases, the requirements set out in Article R20 are quite vague when it comes to the surveillance of subcontractors and subsidiaries, located in or outside Europe. The most important element that should serve as the basis for such surveillance appears to be the *information* which the Notified Body is obliged to provide to its notifying authority when the body decides to subcontract specific tasks or to have recourse to a subsidiary.

4. Solutions envisaged

If accreditation is the chosen path for notification, it must cover the subsidiary companies of Notified Bodies to which they have recourse. The accreditation bodies must take this into account,

either by properly applying the existing international guidance on cross-frontier accreditation or by specifying it in the accreditation documents.

If notification is not based on accreditation, then the notifying authorities should be made aware that Article R20 is not sufficient to ensure the proper and consistent supervision of subsidiaries and subcontractors, in particular if they are located in third countries. In such context, article R20(1) should be clarified in a revision of the "Blue Guide to the Implementation of Directives Based on New Approach and Global Approach"[1].In particular the contents of the information to be provided to the notifying authority, should be further specified by aligning it to the requirements of section 14.2.b and c and 14.3 of the IAF/ILAC guidance on ISO/IEC 17020 [i].

In addition, Member States should be made aware that some Notified Bodies being considered for accreditation (mother and subsidiary companies) might prefer that their subsidiary companies come under the umbrella of a sister company whose Member State notifies through R17/R20. This would undermine the stricter rules for accreditation and the overall objective of a similar level of competence of all Notified Bodies throughout the EU as well as fair and transparent competition among them.

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[i] Section 14.2.b and c and 14.3 of the IAF/ILAC guidance on ISO/IEC 17020 stipulate:

14.2b Competence of a sub-contractor may be demonstrated either:

- by the sub-contractor having accreditation to ISO/IEC 17020 or ISO/IEC 17025 for the relevant inspections/tests and providing endorsed reports or certificates. Or
- by the inspection body itself assessing the competence of the sub-contractor to the requirements of ISO/IEC 17020 or ISO/IEC 17025, as applicable.

14.2c. Where the assessment of the sub-contractor is carried out by the inspection body, it should be able to demonstrate that the assessment team is technically competent and knowledgeable in the application of ISO/IEC 17020 or ISO/IEC 17025.

14.3a. If the competence of the subcontractor is based partly or in full on its accreditation, the scope of its accreditation shall cover the activities to be subcontracted and the inspection body shall have records available to show that it has checked the status of the subcontractor. If the subcontracted bodies are not accredited according to the relevant standard for the specific activities to be subcontracted, the inspection body shall provide appropriate evidence of the subcontracted body's competence, such as records of evaluation performed by qualified personnel according to appropriate procedures.

[1] http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/