Position Paper

Brussels, 08 October 2012

Accreditation to verify proportionality of conformity assessment

1. INTRODUCTION

The EU New Legislative Framework (NLF)[1] specifies in more detail relevant provisions, already contained in Decision 93/465/EEC, that require conformity assessment to be performed in a proportionate manner, and national accreditation bodies to verify this. Triggered by two successive draft papers submitted by NORMAPME, initial discussions on the subject within the European co-operation for Accreditation Advisory Board (EAAB) concluded that "*the issue of proportionality of conformity assessment should be developed further within the entire EAAB Industry College, and that an agreed-upon proposal on practical issues (not only principles) should be presented for further discussion within the Board and with EA.*"[2]

On the basis of this decision, Orgalime and NORMAPME cooperated to publish the following joint position paper. Further information on the background discussions, the relevant literature as well as the contributors of this position paper can be found in the ANNEX of this document.

2. RELEVANT LEGISLATIVE PROVISIONS AND THEIR SCOPES OF APPLICATION

The scope of application of the NLF provisions that address the issue of proportionality as required of conformity assessment bodies and national accreditation bodies is the following:

- **Article R17 (6c) of Decision 768/2008/EC**[3] applies to EU harmonisation legislation and therefore to **regulatory** conformity assessment foreseen in the EU legislation for the marketing of **products**;
- **Article 8 (10) of Regulation (EC) 765/2008**[4] applies to accreditation, performed by national accreditation bodies, in support of **both regulatory and voluntary conformity assessment** carried out in relation to a **product, process, system, person or body**.

[1] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

[2] 26th EAAB meeting of 5 May 2011

[3] Article R17 (6c) of Decision 768/2008/EC reads as follows: [Requirements for notified bodies] (…) At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary (…) *"(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.*"

[4] Article 8 (10) of Regulation (EC) 765/2008 reads as follows: [Requirements for national accreditation bodies] A national accreditation body shall fulfill the following requirements (…) *"(10) it shall verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;*"

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3. OUR VIEWS ON THE APPLICATION OF THE PROPORTIONALITY PRINCIPLE IN CONFORMITY ASSESSMENT

We fully support the principle that conformity assessment must be carried out in a proportionate manner, taking into account the size and the nature of the organisation concerned and other relevant criteria, and that this principle should be properly implemented.

The issue of proportionality of conformity assessment is not an issue that is specific or limited to SMEs – but applies to organisations of any size and type. This is also why the relevant NLF provisions do not refer to SMEs in particular but to undertakings in general[5].

Proportionality of conformity assessment does not imply simplified conformity assessment procedures or ***light*** certification/testing. Proportionality does not affect the technical requirements or the assessment method specified for products, but rather seeks to relate the administrative conditions and the overall scale of a conformity assessment procedure to the size and individual situation of an undertaking.

Conformity assessment bodies (CAB) need to apply the principle of proportionality as contained in Article 17 (6) of Decision 768/2008/EC and Article 8 (10) of Regulation (EC) 765/2008 when carrying out the conformity assessment procedures set by relevant legislation (regulatory conformity assessment schemes, e.g. the conformity assessment modules providing for the use of notified bodies as contained in Annex 2 to Decision 768/2008/EC) or voluntary conformity assessment schemes based on defined technical specifications. However, there is no room for the development of new or other conformity assessment procedures or schemes:

- as for regulatory conformity assessment, the procedures are set by the legislator. Therefore, it is neither the task of conformity assessment bodies, nor of any trade association, to develop new or other procedures, nor is it the task of national accreditation bodies to verify this;
- as for voluntary conformity assessment, having conformity assessment bodies or trade associations develop other schemes than those required by customers in the market place would only generate significant additional costs and burden for undertakings – in particular SMEs – as the results of those other schemes are unlikely to receive the same level of acceptance.

Users and consumers are always exposed to the risks presented by the individual product which they use, regardless of whether the product stems from large or small series production or is a single product unit. This is also the reason why conformity assessment under EU product harmonisation legislation is intended to demonstrate the compliance of each individual product with the relevant legislative requirements that apply to it. There is no justification for generally associating large series production with higher risks. Each NLF module, and in particular the management system modules based on quality assurance (modules D, E and H and their variants D1, E1, H1 in Annex 2 to Decision 768/2008/EC), offers considerable flexibility for product conformity assessment under EU harmonisation legislation to take proper account of the size and other relevant (organisational etc.) aspects of the manufacturing undertaking concerned.

Proportionality in the application of conformity assessment may also include the need to take into account the size of production, for example where the scheme in question provides for sample testing based on the number of products manufactured, and whether it is a tailor-made (one-off) product or series production. However, the test methods to be performed to demonstrate conformity are usually specified in the relevant standards and the specific conformity assessment method to be applied (e.g. various forms of testing, design examination, inspection, certification) depends on the rules of the scheme in question and on the nature of the product rather than on the size of the production.

[5] This principle was highlighted by the EA Advisory Board at its meetings on 15 April 2010 and 05 May 2011

Proportionality of conformity assessment is a requirement that needs to be applied to the organisation of the relevant processes, but not to the assessment as such. Therefore, we believe that the typical stages of a conformity assessment procedure or scheme will have to be examined to determine the possible elements suitable for proportionate application. Not all of the stages or elements to be considered are relevant for each type of conformity assessment procedure or scheme[6].

4. OUR VIEWS ON HOW TO APPLY PROPORTIONALITY IN THE RELEVANT STAGES OF A CONFORMITY ASSESSMENT PROCEDURE

a. The Application Phase

We consider that conformity assessment bodies (CABs) should:

- be required to ensure that assessors/inspectors/auditors performing the conformity assessment have relevant knowledge of the specific economic/technological sector and the degree of complexity of the product technology in question. As for auditors involved in management system certification, they should also have relevant knowledge of the structure of the economic sector and be aware of the characteristics related to the size of the undertakings operating in the business sector concerned;
- when developing the audit programme for management system certification, be required to apply the man-day tables as defined by IAF commensurate to the sector, size and scope of activities of the undertaking and take adequately into account considerations such as the level of risk in question, overtime compliance and existing qualifications of the entrepreneur.

b. The Assessment Phase

In our view, CABs should:

- in order to avoid duplicate assessments, check whether relevant assessment activities have been carried out earlier (including earlier in the supply chain, where applicable) and, if so, whether the results of such assessments (e.g. test reports issued by an accredited in-house laboratory, quality management certificates issued by another accredited CAB) already cover one or several aspects of the scheme under assessment and whether these results can be used ("accepted") for their own determination or attestation activities;
- the place of the assessment (whether on the premises of the manufacturer or in an in-house laboratory of the CAB or at a third party testing facility) may be seen as an element suitable for proportionality in the wider sense. Accordingly, CABs should acknowledge relevant requests by the client undertaking wherever feasible and appropriate, andfor example carry out testing at the manufacturer's accredited testing facility instead of at the CAB's own facility. However, if the assessment procedure is a third-party procedure, the possibility of using the applicant's premises for testing or the acceptance of test reports of accredited laboratories (owned by the manufacturer or not) is given by the relevant scheme rules. Performing tests on the applicant's premises together with the external CAB is always possible. The choice of place is therefore mainly a question of the individual technical capabilities rather than an issue for proportionality in practice.

[6] See ISO/IEC Guide 68/Future ISO/IEC 17067 "Conformity assessment - Fundamentals of product certification and product certification schemes"; ISO/IEC 17065 "Conformity assessment - Requirements for bodies certifying products, processes and services"; ISO/IEC EN 17021:2006 "Conformity assessment - Requirements for bodies providing audit and certification of management systems"; Modules for conformity assessment contained in Annex 2 to Decision 768/2008/EG

c. The Surveillance / Maintenance Phase (where relevant)

We believe that CABs should, for management system certification or product certification (if surveillance is required by the relevant scheme and insofar as the relevant scheme does not itself contain specific rules), determine the level and frequency of surveillance / reassessments / factory inspections / production verifications taking into account the specifics of the client undertaking, such as the volume of his business activities, the specific risks of the products supplied, the results of previous assessments / audits etc. carried out by third parties (level of compliance achieved over time), etc.

According to Article 8 (10) of Regulation 765/2008, national accreditation bodies are required to verify that CABs respect and apply these elements related to proportionality.

5. CONCLUSIONS

Although a number of the above elements related to proportionality of conformity assessment are already addressed in the relevant standards for CABs (notably in ISO/IEC EN 17021:2006) and in application documents, industry would support, in principle, the development of (additional/supplementary) guidance addressing these elements, notably as far as management system certification is concerned.

We consider that all relevant existing guidance should be taken into account in this process and the relevant IAF application documents should be examined to ensure that the principle of proportionality is sufficiently addressed.

Accredited conformity assessment bodies should not only operate conformity assessment in a proportionate manner, as required by Article 8 (10) of Regulation (EC) 765/2008, but they should also be made to report on the application of the aforementioned principle.

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Orgalime, the European Engineering Industries Association, speaks for 37 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 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. The vast majority of the members companies represented in Orgalime are SMEs.

Normapme is the European Office of Crafts, Trades and Small and Medium-sized Enterprises for Standardisation. Its members represent **over 12 million enterprises** in all European countries, including all European Union and European Free Trade Association (EFTA) member states.

ANNEX

1. BACKGROUND

The EU New Legislative Framework (NLF)[7] specifies in more detail relevant provisions, already contained in Decision 93/465/EEC, that require conformity assessment to be performed in a proportionate manner, and national accreditation bodies to verify this. Triggered by two successive draft papers submitted by NORMAPME, initial discussions on the subject within the European co-operation for Accreditation Advisory Board (EAAB) in particular concluded that "*the issue of proportionality of conformity assessment should be developed further within the entire EAAB Industry College, and that an agreed-upon proposal on practical issues (not only principles) should be presented for further discussion within the Board and with EA.*"[8] On the basis of an agreed-upon "NLF fiche" on the subject of proportionality of conformity assessment, ORGALIME prepared extensive comments on the NORMAPME papers.

At the meeting of the ORGALIME New Approach & Market Surveillance (NAMS) Task Force on 4 November 2011, the issue of accreditation to verify proportionality of conformity assessment was further discussed between the EAAB industry college members representing ORGALIME, BUSINESSEUROPE and NORMAPME and the other members of the ORGALIME NAMS Task Force. It was decided to set up an ad-hoc Working Group with the task of identifying the common elements in both positions and preparing a proposal for a consensus document on the subject. Members of the ad-hoc WG are Messrs. H. de Pauw, A. Evans, B. Gerber, J. Hartge, M. Stadler (Convenor) and K. Stochholm.

2. PURPOSE OF THIS PAPER

This proposal for a joint contribution by the EAAB Industry College constitutes the work result of the ad-hoc WG and is submitted for adoption to the organisations represented in the EAAB industry college, and notably to NORMAPME and ORGALIME/BUSINESSEUROPE. This proposal reflects the degree of consensus reached within the ad-hoc WG, following extensive and detailed debate among the experts on the basis of a discussion document that drew together a number of principles and elements taken from both NORMAPME's and ORGALIME's papers. Final discussions of the various comments made took place at the meeting of the EAAB industry college on 25 April 2012 and led to a common understanding of what industry's expectations of proportionality of conformity assessment are, what it means, where it is relevant and where not. This document is intended to be supported by the entire EAAB industry college and should serve as a substantial contribution to relevant guidance on the issue of accreditation to verify proportionality of conformity assessment, to be developed further together with EA and accreditation experts.

3. DOCUMENTS, REFERENCES, BIBLIOGRAPHY

- IAF Mandatory Documents for the application of ISO/IEC EN 17021:2006:
  - IAF MD 1:2007 *"Certification of Multiple Sites Based on Sampling"*
  - IAF MD 4:2008 *"Use of Computer Assisted Auditing Techniques for Accredited Certification of Management Systems"*
  - IAF MD 5:2009 *"Duration of QMS and EMS Audits"*

[7] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

[8] 26th EAAB meeting of 5 May 2011

- NORMAPME
  - *"Guidelines for National Accreditation Bodies in evaluating the capacity of Conformity Assessment Bodies to assess SMEs"* (undated, sent to EAAB on 10-03-10)
  - "*Accreditation of Proportionate Procedures"* (Normapme position paper, undated, sent to EAAB on 11-04-15)
- ORGALIME
  - *"Proportionality of conformity assessment"* (Orgalime NLF interpretative fiche, last update 11-03-18)
  - *"Proportionate Procedures in Conformity Assessment to EU harmonised legislation"* (Orgalime comments on the Normapme position paper, issued 11-06-15)
- CEN/CLC TC 1
  - *Draft comparisons between the NLF, including the Modules, with the standards ISO/IEC EN 17020, 17021 and 17065*

4. RELEVANT LEGISLATIVE PROVISIONS AND THEIR SCOPES OF APPLICATION

It is necessary first to be clear about the scope of application of the NLF provisions that address the issue of proportionality as required of conformity assessment bodies and national accreditation bodies:

- **Article R17 (6c) of Decision 768/2008/EC**[9] applies to European Union harmonisation legislation and therefore to **regulatory** conformity assessment foreseen in the European Union legislation for the marketing of **products**;
- **Article 8 (10) of Regulation (EC) 765/2008**[10] applies to accreditation, performed by national accreditation bodies, in support of **both regulatory and voluntary conformity assessment** carried out in relation to a **product, process, system, person or body**.

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