ORGALIME Position on Accreditation[1]

in the context of the Commission Proposal COM(2007)37 final
of 14 February 2007 for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS 2007/0029 (COD)

30 May 2007

Introduction

Manufacturers bear the full responsibility for ensuring that their products conform to all relevant EU legislation. They alone remain responsible for the conformity of the product to all applicable EU legislation, whatever conformity assessment procedure has been applied and whatever conformity assessment body has been involved. Therefore, manufacturers have an equal interest to public authorities and other stakeholders to be assured of the competence of bodies performing third-party conformity assessment. Equally important is confidence in the competence of national accreditation bodies that assess conformity assessment bodies. Mutual confidence in the certificates and other conformity assessment results wherever they are issued in the internal market can only be strengthened by means of a properly functioning European accreditation system with the aim of ensuring equivalence, transparency, consistency and efficiency of accreditation performed across Europe.

Orgalime supports the purpose of the proposed Regulation COM(2007)37 to establish a European accreditation system with binding rules which will contribute to provide both economic operators and public authorities with the necessary assurance that accredited conformity assessment bodies are competent to carry out their tasks. Therefore we suggest further that these rules should:

- be based on clear and common definitions for "conformity assessment" and "conformity assessment bodies", consistent with the terminology laid down in the relevant international standards;
- apply to all activities that can be subject to accreditation (including calibration in particular), and irrespective of whether accreditation is provided to support conformity assessment required by legislation or not. As such, accreditation should provide to both economic operators and public authorities the assurance that accredited conformity assessment bodies are competent to carry out their tasks, irrespective of whether such tasks are required by legislation or by private contractual agreements;
- Incorporate the need for national accreditation bodies to demonstrate compliance with the relevant standard for their competence and impartiality through successful participation in peer evaluation, as set up under the supervision of all accreditation stakeholders.

[1] This position paper is complementary to **Orgalime position paper of 20/04/2007** on COM(2007)37 final.

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Accreditation with a broad scope for ensuring equal trust in all conformity assessment procedures, including quality assurance

Orgalime believes that the present wording of Chapter I, Article 1.1, of the draft Regulation is too restrictive in referring to *"….accreditation of conformity assessment bodies performing assessment of any substance, preparation or other product…"* only.

For the sake of consistency with the Commission proposal of Decision COM(2007)53, which provides for various "conformity assessment procedures" in its Annex I, Orgalime believes that the scope of accreditation should also cover conformity assessment bodies which are accredited to provide conformity assessment under Modules 'D', 'E' and 'H' which are based on "quality assurance".

Moreover, accreditation is also used for some activities that may not be regarded as conformity assessment, such as calibration or proficiency testing. Therefore, we suggest referring to these activities and broadening the subject matter and scope (article 1.1) of accreditation accordingly.

A single accreditation system for cost-effective and trustworthy accreditation provided in both the regulated and non-regulated areas

European accreditation should be considered as the highest level of control of the whole conformity assessment system and should be set up under the authority of all EU Member States. As such, accreditation should provide to both economic operators and public authorities the assurance that accredited conformity assessment bodies are competent to carry out their tasks, irrespective of whether such tasks are required by legislation or within private contractual agreements.

According to recital 9, **a common accreditation system with binding rules** will contribute to enhancing the principle of mutual recognition of certificates and test reports **in relation to conformity assessment bodies carrying out conformity assessments in both the regulated and non-regulated areas**. Orgalime supports the principle and suggest mentioning in the body of the Regulation that these rules should equally apply when accreditation is provided to support conformity assessment required by legislation or not (see our proposal of definitions 14 and 15).

Should the proposed Regulation not provide for such clarification, it would run the risk of failing in its overall goal to reinforce confidence in the European single market: without a common and binding accreditation system there would be a costly and unnecessary duplication of assessments and procedures in order to control the competence of assessments made against requirements set by customers in the course of a commercial relationship. Moreover, it is essential to note that such customer requirements often already contain, anticipate or even go beyond requirements laid down by legislation. This is why the implementation of EU legislation often relies on procedures applied for the assessment of conformity in the non-regulated area, such as quality management system certification (Modules D, E and H) or environmental management system certification (Regulation No 761/2001 - EMAS).

Referring to the positive experience with the peer evaluation system operated by the European cooperation for Accreditation (EA) and the fact that this system *de facto* already operates today in support to the regulated area, Orgalime supports the proposal that EA's role should be consolidated to formally entrust EA with the operation of the European accreditation network.
