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PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

COMMISSION STAFF WORKING DOCUMENT
Accompanying

the report from the Commission to the European Parliament, the Council and the European economic and social Committee

on the implementation of 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

Guidance papers on accreditation

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Guidance papers on accreditation

1. INTRODUCTION

This Commission staff working document gives an overview of the so-called 'CERTIF' documents which were discussed with the Senior Officials for Standardisation and Conformity Assessment Policy Group ('SOGS') and which, following the discussions, represent a consensus between the Commission and Member States representatives on how to approach certain matters concerning the implementation of Chapter II on accreditation of Regulation (EC) No 765/2008. The objective of these 'CERTIF documents' is to provide informal guidance on question raised by national authorities and accreditation bodies throughout the Union[1].

This staff working document therefore contains all the documents on which a consensus was reached between 2008 (the year of the adoption of the Regulation) and autumn 2012.

2. IMPACT OF THE EU ACCREDITATION FRAMEWORK AT INTERNATIONAL LEVEL (CERTIF 2008-03)

The new Regulation (EC) No 765/2008[2] embodies the European accreditation policy in relation to conformity assessment. It introduces for the first time a common legal base for accreditation by providing for a horizontal framework for accreditation which lays down at European level the principles for its operation and organisation. This framework covers accreditation linked to conformity assessment independently whether the conformity assessment is performed in the mandatory or voluntary sphere. Moreover it applies beyond the New Approach legislation covering conformity assessment activities carried out in industrial sectors not covered by the New Approach as well as in other areas such as environment, health and agriculture.

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1 Further CERTIF documents are currently being discussed between the Commission and Member States. A full list of CERTIF documents, not only concerning accreditation can be found on: http://ec.europa.eu/enterprise/policies/single-market-goods/documents/certif_doc_en.htm.

2 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

This document attempts to explain the impact of the new accreditation framework at international level. This includes outlining the main features and specific principles of the European accreditation policy, the effects on the international cooperation between accreditation bodies and its significance for the Community's external trade policy in the field of conformity assessment.

2.1. Background

Accreditation as an impartial means of assessing and conveying formal demonstration of the technical competence, impartiality and professional integrity of conformity assessment bodies is an effective quality infrastructure tool used worldwide.

At international level, cooperation between accreditation bodies takes place within two organizations: namely within the International Accreditation Forum (IAF) between accreditation bodies accrediting certification and inspection bodies and within the International Laboratory Accreditation Cooperation (ILAC) between accreditation bodies accrediting laboratories and inspection bodies. Both entities provide for multilateral mutual recognition arrangements between its accreditation body members. IAF manages a Multilateral Recognition Arrangement (MLA), while ILAC operates a Mutual Recognition Arrangement (MRA). Although the names of the arrangements changes, both organizations have the aim through these arrangements to establish confidence concerning the equivalence of the operation of the signatories to the agreement and that the results of accredited conformity assessment bodies issued under accreditation of the signatories are equally reliable. These multilateral mutual recognition arrangements/agreements of competence at technical level between accreditation bodies have the ultimate aim to allow products and services accompanied by accredited conformity attestations to enter foreign markets without a re-testing or re-certification in the import country. The objective of such recognition arrangement/agreements between accreditation bodies is therefore to contribute to reinforce the acceptance of conformity assessment certificates.

At the regional level, cooperation organizations between accreditation bodies have been established in[3]:

- Europe: European co-operation for accreditation (EA)
- America: Inter America Accreditation Cooperation (IAAC)
- Asia – Pacific: Asia Pacific Laboratory Accreditation Cooperation (APLAC) and Pacific Accreditation Cooperation (PAC)
- Africa: Southern African Development Community Accreditation (SADCA)

Except for SADCA which is currently developing its regional mutual recognition arrangement, the above listed cooperation organisations have agreements/arrangements in place within their region on which the ILAC/IAF arrangements build upon. By granting special recognition IAF accepts the mutual recognition arrangements established within EA and PAC: accreditation bodies being

[3] Only the main accreditation cooperation organisations at regional level are listed.

member of IAF and signatories to the EA Multilateral agreement (EA MLA) or the PAC Multilateral Recognition Arrangement (PAC MLA) are automatically accepted into the IAF MLA[4]. ILAC accepts the mutual recognition arrangements and underlying evaluation procedures of EA, APLAC, and IAAC. Accreditation bodies which are not affiliated to any recognised regional cooperation entity may apply directly to ILAC and/or IAF for evaluation and recognition.[5]

2.2. The New Legal Environment

Regulation (EC) No 765/2008 provides for a comprehensive horizontal legal framework for the operation and organisation of accreditation in the European Economic Area (EEA)[6] applicable as from 1 January 2010. It imposes obligations and requirements on European national accreditation bodies, Member States and the European Commission and sets out the respective responsibilities as well as the co-ordinating role of the European co-operation for Accreditation (EA). Under Regulation (EC) No 765/2008 EA is recognised as the official European infrastructure for cooperation in the field of accreditation responsible for the management of the European peer evaluation which ascertain the competence of the European accreditation bodies[7].

The stabilization of accreditation as authoritative and therefore last level of control of conformity assessment activities from a technical competence point of view is at the core of the European accreditation policy. In this respect Regulation (EC) No. 765/2008 formalizes a set of requirements in particular for accreditation bodies. These requirements are in line with the globally accepted requirements laid down in the relevant ISO/IEC international standards, although some of them can be perceived as being more rigorous, going beyond the requirements set out in the applicable standards. In particular

- Accreditation is carried out by one single national accreditation body appointed by its Member State (Art 4.1)
- Accreditation is performed as a public authority activity (Art 4.5)
- National accreditation bodies operates free from commercial motivations (Art 8.1) and on a not-for- profit basis (Art 4.7)
- National accreditation bodies do not compete with conformity assessment bodies and among each other (Art 6.1 and Art 6.2)

Cross frontier accreditation is carried out only under certain limited circumstances (Art 7): European conformity assessment bodies are required to request accreditation

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4 While the special recognition by IAF granted to EA and PAC covers the IAF Product MLA, the IAF Quality Management System MLA and the IAF Environmental Management Systems MLA, special recognition granted to IAAC is limited to the IAF Quality Management Systems MLA. http://www.iaf.nu/

5 For more detailed information on the IAF MLA and the ILAC MRA and their signatories: http://www.iaf.nu/ and http://www.ilac.org/ilacarrangement.html

6 The Agreement creating the European Economic Area which came into force 1 January 1994 extends the Single Market to the EEA EFTA States (Norway, Iceland, Liechtenstein) therefore covering, among others, all the *acquis* relevant to the free circulation of products.

7 The peer evaluation managed by EA forms the basis for the EA multilateral agreement (EA MLA), underpinning the ILAC MRA and IAF MRA.

by the national accreditation body of the Member State in which they are established. The possibility of a conformity assessment body to request accreditation in another Member States is limited to the cases where in its Member State there is no national accreditation body, where the national accreditation body does not offer the requested accreditation service or where the national accreditation body has not received a positive result in the peer evaluation in relation to the conformity assessment activity for which accreditation is requested

By laying down these specific "supplemental" requirements, Regulation (EC) No 765/2008 protects accreditation in Europe against the risk to become an additional layer of commercial certification which would jeopardize its reliability, neutrality and credibility. Accreditation would in this case not only entail added and unjustified cost without added value but would also be unable to provide the necessary confidence to the market creating the need for an extra layer for supervision.

2.3. The Impact on the Relation between EA and ILAC and IAF

According to Regulation (EC) No 765/2008 European national accreditation bodies fulfilling the requirements of the Regulation are member of EA (Article 4.10). Different from European national accreditation bodies, accreditation bodies not members of EA may not necessarily meet all the above outlined EU requirements as these do not apply outside the EEA and are not addressed to third country accreditation bodies. Although Regulation (EC) No 765/2008 does not provide for rules regarding the relationship between EA and international co operations between accreditation bodies, the question arises on the impact for the co-operation between European and third countries accreditors at international level taking place within ILAC and IAF and within their respective global Mutual Recognition Arrangement and Multilateral Agreement to which EA belongs as a Region. If EA would recognise the equivalence among accreditation bodies and the equal reliability of accredited conformity assessment bodies' only by accreditation bodies meeting the same requirements, EA would undermine the international multilateral mutual recognition arrangement/agreements and isolate itself. As this is in no way the intention of Regulation (EC) No 765/2008, EA recognizes that attestations of conformity issued in accordance with the requirements of ISO/IEC 17011 under accreditation bodies signatories to the ILAC MRA and IAF MLA but not signatories to the EA MLA or BLAs[8] and not complying with all the requirements of the EU regulation are considered to be equally reliable from a technical point of view to those issued within the EA MLA and BLAs.[9]

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[8] Nationally recognized accreditation bodies not established in one of the EU Member States or EFTA or a candidate country to the EU, which according to the current Articles of Association of EA may not become EA "full members", may enter into a contract of cooperation with EA. An accreditation body that has signed a contract of cooperation with EA may apply to be a signatory of a Bilateral Agreement (BLA). The BLA conveys the same benefits in relation to mutual recognition as the MLA: recognition of the equivalence of the operation of the Bilateral Signatory accreditation body to those of EA MLA signatories and equal reliability of conformity assessment attestations issued by organizations accredited by the Bilateral Signatory accreditation body. For more detailed information: http://www.european-accreditation.org/content/mla/what.htm

[9] Such a statement has been formally endorsed by the EA General Assembly the 19 November 2008.

2.4. The impact on trade relations in the field of conformity assessment between the EU and Third Countries

The international mutual recognition between accreditation bodies allow certificates and reports accompanying exported goods and services to be more readily accepted on the international and the European market, but the ultimate acceptance in the EU of conformity assessment attestations issued under accreditation by non-European bodies not necessarily complying with the new European requirements does not depend on the cooperation and mutual recognition of accreditation bodies. The ultimate acceptance of conformity assessment attestations is decided by the public authorities and, from an economic point of view, by industry users and consumers. The voluntary multilateral mutual recognition agreements between accreditation bodies taking place at technical level support, further develop and enhance intergovernmental trade agreements.

The requirements set out above affect the acceptance of non-European certificates and test results accredited by non-European Accreditation bodies not complying with the new EU requirements but signatories to the ILAC/IAF MRA/MLA in the following way:

2.4.1. Conformity assessment delivered in the voluntary sphere

It will be up to the non-European conformity assessment body operating on the European market to decide if and where to get accredited. In order to boost the acceptance of its conformity assessment attestations by the European market (industry as purchasers of conformity assessment attestations and ultimately consumers) the non-European conformity assessment body opting for accreditation may choose whether to resort to the service of a third country accreditation body not necessarily conforming to the new European requirements but signatory to the ILAC/IAF MRA/MLA or rather to that of a European accreditation body. Unchanged compared to the present situation, non-European Conformity assessment attestations issued under accreditation by non-European Accreditation bodies not fulfilling the new European requirements, can continue to be used on the European Market.

2.4.2. Conformity assessment delivered in the mandatory sphere

Where conformity assessment is legally regulated, national authorities of European Member States may refuse to accept attestations of conformity issued under accreditation by non-European accreditation bodies not complying with the new European requirements but signatories to the ILAC/IAF MRA/MLA. However this refusal cannot be based on the sole argument of the non-fulfilment by the third country accreditation body as such. The conformance to the EU requirements by the third country accreditation body is not a condition for recognition, but non-conformance could reinforce doubt as to the quality and value of the accreditation and therefore as to the quality and confidence in the accredited certificates or reports.

However, where government-to-government Mutual recognition agreements (MRAs) between the Community and a third country in relation to conformity assessment are

in place[10], national authorities of European Member States will accept the test reports and certificates issued by bodies that the foreign party has designated under the MRA for assessing conformity in the categories of products or sectors covered by the MRA. The products accompanied by such conformity attestations can be exported and placed on the other party's market without undergoing additional conformity assessment procedures. Each importing party agrees, by the terms of the MRA, to recognize the conformity assessment attestations issued by agreed conformity assessment bodies of the exporting party, independently of whether accreditation has been used to back up the designation process of the conformity assessment bodies under the MRA or not, and independently of, in case accreditation is used by the non-European Party, the fulfillment by the third Party accreditation body of the EU requirements.

Accreditation contributes to a quality driven and reliable conformity assessment infrastructure. It provides for confidence which is of great importance for Regulators, purchasers of conformity assessment services and consumers and facilitates cross-border trade of goods and services. By providing mutual confidence in the competence of CABs and attestation issued by them, accreditation technically underpins trade by promoting mutual recognition and the global acceptance of conformity assessment results within the Internal Market and in relation to third countries. The "additional" requirements for accreditation bodies set out in Regulation 765/2008 designed to consolidate the added value of accreditation do not create a technical barrier impeding trade. The level of acceptance of conformity attestations issued under accreditation of accreditation bodies not meeting the EU requirements in the European Union will continue to be accepted or refused in the same way as they are today.

3. CROSS BORDER ACCREDITATION ACTIVITIES (CERTIF 2009-06 REV 6)

3.1. Introduction

This document concerns the interpretation of the cross border accreditation provisions of Article 7 of Regulation (EC) 765/2008 ("the Regulation") in relation to multinational conformity assessment bodies. Bearing in mind that the ultimate say on matters of EU law rests with the European Court of Justice, this draft paper contains a proposal for a common understanding and pragmatic solution on the implementation of the cross-border accreditation regime which is the result of the discussions held between all interested parties involved (public authorities, EA and its members, conformity assessment bodies and the Industry).

The application of Article 7 of the Regulation must be done in the light of the Single market principles such as the freedom of establishment and the freedom to provide services and account must be taken of other pieces of legislation such as Directive 123/2006/EC on Services in the Internal Market (the "Services Directive"), whilst guaranteeing the full respect and application of the fundamental principles and objectives of the European accreditation policy. This is valid in particular for the non-competition principle, which is a necessary condition for accreditation to be the last level of control of the adequacy of conformity assessment services.

[10] Currently MRAs between the European Union and the following countries are in place: Australia, Canada, Israel, Japan, New Zeeland, Switzerland, United States

3.2. Background

According to Article 7.1 of the Regulation, conformity assessment bodies (CABs), whether third-party or first-party/in-house bodies, are required when requesting accreditation to do so with the national accreditation body (NAB) of the Member State in which they are established. This general rule allows for exceptions: the possibility of a conformity assessment body to request accreditation with a NAB in another Member State is limited to cases where

- there is no NAB in its own Member State [Article 7.1(a)],
- the NAB does not offer the requested accreditation service [Article 7.1(b)]
- the NAB has not received a positive outcome in the peer evaluation in relation to the conformity assessment activity for which accreditation is requested [Article 7.1(c)].

Article 7.1 of the Regulation is closely linked to and is a logical consequence of the non-competition principle embodied in Article 6 of the same Regulation. It is important to prevent conformity assessment bodies from shopping around for accreditation certificates, thus creating a "market for accreditation" leading to the commercialisation of accreditation which jeopardizes the added value and role of accreditation as a public authority activity and last level of control of the conformity assessment chain.

3.3. Problem Definition

Against this background, the issue to be tackled concerns multinationally active CABs, i.e. CABs having their head office in one Member State and which exercise their activity in another or several Member States. This activity can be carried out in another Member State on a temporary basis (free provision of services)[11] or on a permanent basis by means of one or more local entities such as subsidiaries, branches or agencies (freedom of establishment)[12].

CABs may provide their services to clients in other Member States on the basis of free provision of services without having to be established there. The accredited conformity assessment results given on the basis of free provision of service will be recognised by the public authorities and accepted on the basis of the mutual recognition principle set out in Article 11(2) of the Regulation. Indeed, under this provision, "*National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer*

[11] This can happen in the four following modes: a) the CAB (service provider) moves temporarily to the service recipient's Member State to provide its services and then comes back; b) the service recipient moves temporarily to the Member State of the CAB to receive the service; c) neither the service recipient nor the CAB moves, whereas the service is done from a distance (for ex. over the email and/or by phone); d) both the CAB and the service recipient move to another (third) Member State where the service will be provided

[12] Differently from subsidiaries which have separate legal personality, agencies or branches or offices do not need to be separate legal entities. It follows from Art. 49 TFEU providing for the freedom of establishment and the case law of the ECJ that the same undertaking can be established at the same time in one or more other Member States.

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."

Business operators are free to organise and structure themselves in the way they think is best to serve their clients, for example to get established in various Member States and to operate via local entities.

In this case the question arises for the need for an accreditation for the multinational organisation as a whole or of parts of that organization in the locations where they are established and operate: can the operations of the local entity be covered by the accreditation of the head office issued by the NAB where the head office is established or shall the local entity be accredited by the local NAB?

The cross-border provision laid down in Article 7 is perceived to be very stringent and unnecessarily burdensome for multinational CABs with local entities/sites established in other Member States working under the supervision of the head office and under the same quality system and management, as implying costly duplications of assessments. The risk of suffering a competitive disadvantage compared to third-country organizations is feared. The Regulation does not apply to third-country bodies which are therefore free to request accreditation (even multiple accreditations) with the European NABs of their own choice. In case of a strict legal interpretation of Article 7, due to their structures, multinational CABs may not benefit from the advantage of one accreditation certificate sufficient for the whole territory of the EU, although avoiding multiple accreditation is one of the objectives of the Regulation[13].

Practice shows, however, that for a long time the majority of multinational CABs have been having their local entities accredited by local NABs, resulting in multiple accreditations from various NABs, for reasons linked to commercial arguments more than to necessity. Moreover, it appears that a number of these organizations are fully prepared to continue with this practice, for the same reasons. According to the concerned parties, such multiple accreditations are due to the demand from local regulators and/or from the local market not recognizing the equivalence of the accreditations issued by the different NABs signatories to the European Co-operation for accreditation multilateral agreement (EA MLA).
In light of the mutual recognition principle provided for in Article 11.2 of the Regulation, such statements in relation to public authorities are no longer acceptable, as national authorities are obliged to recognize the equivalence of the services delivered and to accept the accreditation certificates issued by the NABs which have successfully passed the peer evaluation managed by EA and which are as a result, signatories to the EA MLA for the relevant accreditation activity.

The acceptance by the market place indeed remains a challenge and problem to be tackled. End users still perceive some European NABs and related accreditation certificates and logos to be more valuable than others. To overcome these perceptions and resistances the EA MLA should be promoted through activities targeting the CABs and their clients. CABs should contribute to convince the market

[13] Recital 19: "….The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value…."

that the accreditation given by the EA MLA signatories are equivalent by abstaining from promoting one or another NAB which hinders the process of acceptance of the equivalence of services offered by the NABs and fosters the use of multiple accreditations. Instead, the value and quality of accredited certificates, independently of which NAB has accredited them, should be promoted. Within this context a statement on the accreditation certificate attesting the equivalence of the accreditations issued by EA MLA signatories and the introduction of a single European accreditation symbol, an EA symbol, to be used by the signatories to the EA MLA could be further considered. Such measures, in particular the latter, may go beyond the Regulation but could possibly be an effective tool to foster the understanding and visibility of the EA MLA and thereby the acceptance of the equivalence of the EA MLA signatories.

3.4. Solution

3.4.1. General terms

(1) Duplication of unnecessary assessments and burdens on multinational CABs should be avoided. This is required by the principle of non-duplication, which is to be inferred from the case law about Article 56 TFEU and is explicitly set out in Article 10(3) of the Services Directive.

(2) Market needs in relation to accreditation should be met, but without compromising the fundamental principles of the European accreditation policy.

(3) Adequate controls of local entities of multinational CABs must be assured.

(4) Exchange of information and effective cooperation between NABs for assessment, re-assessment and surveillance of local sites of multinational CABs is necessary. Based on mutual recognition of all assessments carried out by EA members, any duplication of assessments of organisational aspects or requirements should be strictly avoided.

(5) If necessary and on reasoned request, relevant information on carrying out accreditation against national legislative requirements of another Member State and/or requirements set out in relevant national sectoral schemes shall be provided by the local NAB to the national authorities of the other Member State. National authorities of the Member Stats in which the local NAB is established should be kept informed thereof.

(6) It should be underlined that the solution proposed has no effect on the civil liability regimes across the European Union.

3.4.2. Multi-site accreditation

The CAB with local sites(regardless of their legal personality), provided that the latter operate under the same global quality system and management and that the head office has the means to substantially influence and control their activities, can be considered as being only one organisation with regard to the conformity assessment activity carried out. Such a CAB is therefore allowed to request accreditation with the NAB of the head office whose scope can also cover the

activities performed by the local site, including those located in another Member State.

The multi-site accreditation is however only permitted under the Regulation if the accredited CAB maintains the final responsibility for the activities performed by local sites covered by the scope of the multi-site accreditation. The accreditation certificate issued by the NAB where the head office is established names one legal entity - the head office - and it is this legal entity which holds the accreditation and which is responsible for the accredited activities of the CAB, including any activity performed by the local site that forms part of the scope of the accreditation. Where these local sites carry out key activities (as listed in EN ISO/IEC 17011[14]), then the accreditation certificate (in its annexes) shall clearly identify the address of these site offices.

The local site is entitled to offer directly to the local market conformity attestations under the multisite accreditation, but only on behalf of the accredited CAB. These accredited certificates and reports are therefore issued under the accreditation, name and address of the head office without the logo of the local site. However this does not impede mentioning on the conformity assessment certificate or report the contact details of the local site issuing the certificate or report in question.

The multi-site accreditation is meant for use only by companies within the same organisation and where the head office maintains the responsibility for the activities performed and certificates/reports issued by the local sites. The responsibility shall be demonstrated on the basis of contractual or equivalent legal relationships between the head office and the local entity and internal regulations that further specify these relationships in terms of management and responsibilities.

The solution of the multi-site accreditation can be applied to all types of local entities (subsidiaries, branches, agencies, offices etc), regardless of their legal personality and is in principle valid for all types of CABs, including laboratories, inspection and certification bodies as long as they carry out clearly identified and relevant activities for the purpose of accreditation.

The multi-site accreditation solution is excluded when the above mentioned conditions are not fulfilled, i.e. the CAB can not be considered as one organisation with regard to conformity assessment and the head office does not maintain the ultimate responsibility for the activities of the local entities. In this case the local sites being separate legal entities should apply for their own accreditation with the local NAB. As a consequence it can be considered that the local entity carries out the conformity assessment service completely independently of the head office.

In case of the multi-site accreditation, initial assessment and reassessments must be carried out in close cooperation between the respective local NAB and the NAB of the head office taking the accreditation decision, while surveillance must be carried out in cooperation with or by the local NAB. The multinational CAB must fully cooperate with the NABs involved. Local entities cannot reject the participation of the local NAB in the assessment, reassessments and surveillance process.

[14] Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the result of conformity assessments

Harmonised rules for co-operation between NABs exist in the form of the EA cross frontier policy. Multi-site accreditation needs to be managed under the EA cross frontier policy in order to guarantee the involvement of the local NAB. EA is therefore requested to review its existing cross frontier policy for cooperation between EA members, so as to fully implement the multi-site accreditation, without complicating or compromising the proper execution of the peer evaluation.

3.4.3. About Subcontracting

The multi-site accreditation does not supersede sub-contracting, which remains a viable solution in case a CAB may wish to sub-contract part of its activities to legal entities located and operating in the same or other Member States, which however do not belong to the same organisation, i.e. are not part of a multinational CAB. In this case, the subcontractor is not covered by the accreditation of the CAB. The accredited CAB may subcontract specific parts of its conformity assessment activities to a different legal entity according to the applicable CAB standard to which it is accredited and only to the extent allowed in this standard. The CAB must be able to demonstrate to the NAB that subcontracted activities are carried out in a competent and reliable manner consistent with relevant requirements of the applicable normative documents for the activities in question. The accredited conformity assessment attestation must be issued exclusively under the name and responsibility of the accredited CAB, i.e. the legal entity holding the accreditation. The contractual relationship with the client remains with the accredited CAB.

4. SYSTEMATIC APPROACH TO ADDRESSING ACCREDITATION ISSUES WITHIN SOGS (CERTIF 2009-07 REV 1)

This draft document represents a revised version of a proposal on how accreditation should be systematically addressed within SOGS and on how to manage the attendance and presence of the representatives of the European Co-operation for accreditation (EA) during SOGS meetings. The draft document, representing the views of the Commission in accordance with the national authorities college of the EA Advisory Board (EAAB-NAC), can be interpreted as a set of informal rules of procedures, supplementing the existing draft terms of reference of SOGS. A diagramme has been added explaining the relations and communication channels between the main actors of the European accreditation policy.

4.1. Rationale

SOGS is an informal a group, i.e. a forum where Commission services and representatives from national administrations of Member States can have an open discussion and reach a common understanding on general policy related to standardization and conformity assessment. Accreditation exists in relation to conformity assessment (forming the last level of control in the conformity assessment chain ensuring conformity with the applicable requirements) and is essential for a competent, trusted, quality-driven and transparent conformity assessment structure, able to play its part in the protection of public interests. As a result, accreditation issues have been tabled for discussion within SOGS whenever the Commission felt that there has been a need to do so.

Regulation 765/2008, which enshrines the new European accreditation policy, reinforces considerably the role of accreditation, thereby giving to accreditation a level of significance and recognition which it never had before. Under technical harmonisation legislation the use of accreditation is intensified as it constitutes the privileged technical instrument in support of notification, i.e. the decision of national authorities by which conformity assessment bodies are authorised to carry out specific conformity assessment in support of technical harmonisation legislation. Accreditation must therefore be operated in such a manner as to provide national authorities with the necessary sound technical base they can rely on in order to back up their notification decisions.

Continuous and comprehensive substantial discussions on the needs in relation to accreditation are required. As a consequence accreditation and related issues should not be put on the SOGS agenda sporadically, but should instead be discussed on a regular basis, and following a set of common rules of procedure. The creation of a special SOGS subgroup dedicated exclusively to accreditation is not envisaged – as has been the case with market surveillance. Instead a part of the plenary meeting should be devoted to accreditation.

It essential that the Community has a common understanding of the interpretation, implementation and future development of the European policy on accreditation. In the framework of this policy EA is placed in the position of an organisation of major European interest, similar to the European Standardisation Organisations (CEN, CENELC and ETSI) in the field of the European standardisation policy. Pursuant to Article 14 of Regulation 765/2008 EA is recognized as the official European Infrastructure for Accreditation. The operation and management by EA of a robust, uniform and transparent peer evaluation system in accordance with the Regulation and the further developments of such a system is at the centre of the European policy on accreditation. In light of Article 11 of Regulation 765/2008 having successfully undergone the EA peer evaluation implies

– presumption of conformity for the evaluated national accreditation bodies to the requirements of the Regulation

– mutual recognition by the national authorities of accreditation certificates and accredited conformity assessment attestations.

EA is expected to fulfill its new role and related tasks by providing Europe with the necessary reliable, effective and trustworthy infrastructure which meets the evolving needs of the market, regulators and society. EA shall be fully accountable for technical expertise, impartiality, cost efficiency and cost effectiveness, capacity of response to arising needs and challenges - also in view of the Community financing which may be granted to EA on the basis of the Framework Partnership Agreement.[15]

Particular attention should therefore be given to the co-operation with EA, by translating into practical terms the commitment to cooperate effectively to implement the European policy on accreditation contained in the General Policy Guidelines for Cooperation between the European co-operation for Accreditation and the European

[15] Currently under negotiation

Commission, the European Free Trade Association and the competent national authorities**,** which have been signed by EA, EFTA, the Commission and the vast majority of SOGS members.

SOGS is deemed to be the appropriate platform where a substantial and comprehensive exchange between the Commission, national authorities and EA takes place in order to assure that EA serve the aims and needs of national authorities and the Commission in particular in relation to the operation of accreditation in support of the implementation and development of Community harmonisation legislation.

In no way does this document intend to compromise, to replace or to put into question the existence and function of the EAAB-NAC, which continues to guarantee the representation of the interests of national authorities of EU and EFTA Member States within the EAAB, thereby providing advice to EA and input to EA policies, strategies and related documents.

5. NOTIFICATION WITHOUT ACCREDITATION - ARTICLE 5.2 OF REGULATION 765/2008 (CERTIF 2010-08 REV1)

5.1. Objective of the paper

The present paper provides guidance with regard to the assessment process not based on accreditation to support the notification of conformity assessment bodies under technical harmonisation legislation. It describes the main elements on which such an assessment process should be based on. It is not the aim of this paper to set up an "Article 5.2" assessment methodology or to provide a detailed description and list of documents to be sent in by the notifying authorities.

5.2. Background

Member States notify - via the designated notifying authorities - to the Commission and to the other Member States those conformity assessment bodies they have decided to authorise to carry out specific tasks pertaining to the conformity assessment procedures laid down in the applicable piece of technical harmonisation legislation.

By taking the political and legal decision which bodies to notify, Member States take the final responsibility for the technical competence and independence of such bodies which they must therefore verify by the means of an adequate assessment process.

According to the New Legislative Framework, the verification of the technical competence and independence during a notification process can be supported form a technical point of view either by an accreditation according to the 17000 series of harmonised standards taking into account the sector specific requirements stemming from the applicable harmonisation legislation and other normative documents if applicable, or, if it is decided not to use accreditation, by an alternative assessment process.

While not obligatory under the New Legislative Framework, and although accreditation and the alternative evaluation procedure are legally equivalent, the preference of the use of accreditation to support notification is clearly expressed in

the New Legislative Framework through the facilitated notification procedure for notification based on accreditation. Accreditation as an independent and impartial assessment carried out by a competent authoritative third party, i.e. the designated national accreditation body, should be considered by the notifying authorities as the privileged instrument for the assessment of the technical competence and impartiality of a candidate notified body. This because

– accreditation being a standard based total, reduces the differences in the criteria applied for notification

– accreditation provides for established complaint and appeal procedures

– accreditation provides for the possibility to object to an assigned assessor

– accreditation provides for established procedures and plans for regular surveillance at close intervals to monitor the continued fulfillment by the accredited CAB of the applicable requirements

– the existence of the EA peer evaluation system ascertaining conformity to the requirements of Regulation 765/2008, EN ISO/IEC 17011 and other applicable requirements and therefore verifying the competence of the national accreditation bodies to assess CABs in view of notification, makes accreditation the most transparent assessment system in place, able to give sufficient guarantees and confidence.

To date, we do not have a comparable and substantially equivalent alternative assessment system based on codified rules and procedures, which entails a similar level of harmonisation and transparency in comparison with accreditation. In particular no other assessment method provides for a systematic, structured and widely accepted process of evaluation of those assessing the competence of conformity assessment bodies, which clearly represents an added value of the accreditation tool. This is why the New Legislative Framework has considerably strengthened the role and use of accreditation in the regulated area.

5.3. Assessment under Article 5.2 of Regulation 765/2008

When a Member State nevertheless decides for whatever reasons to use an alternative assessment method and not to base its notification on accreditation, according to Article 5.2 of Regulation 765/2008 “it 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”.

In order to ensure the necessary level of confidence in the impartiality and technical competence of conformity assessment bodies and in the issued test reports and conformity assessment certificates issued by them, national authorities, when carrying out the assessment without accreditation, should give detailed and comprehensive information describing on how the candidate Notified Body has been assessed as qualified to carry out the tasks for which it is notified and showing that it fulfils the applicable criteria relating to Notified bodies. This information linked to a given notification is made available through the NANDO tool to the Commission and the other Member States.

The alternative evaluation procedure should be based at least on the following elements:

– candidate Notified Bodies should be made aware of general conditions, their rights and obligations and requirements relating to the assessment carried out in view of notification

– existence of a formal application procedure

– Assessment process against applicable requirements. The assessment should consist in

  - a review of documents verifying the completeness and appropriateness from a substantial point of view with regard to conformity to the applicable requirements

  - an on-site assessment to check technical and procedural aspects such as availability and appropriateness of facilities/equipment, technical competence of staff, existence of an appropriate management system and to check other aspects demonstrating that conformity to requirements is properly implemented. The assessment must include witnessing of technical activities

– production of an assessment report

– decision making process

– existence of a systematic surveillance and related sanction mechanism providing for periodic surveillance including on-site visits, in order to verify the continued fulfillment of requirements by the Notified Body

– demonstration of the national authorities own technical competence for assessing conformity assessment bodies for the purpose of notification under technical harmonisation legislation

When choosing to go down the route of the alternative assessment process rather than of formal accreditation, national authorities should indicate the reasons why accreditation is not chosen to back up the notification process. Moreover, national authorities should not outsource the assessment of conformity assessment bodies that seek to become Notified Bodies to the national accreditation body, without asking for accreditation. Such "light accreditation" using the service and competence of national accreditation bodies without the recourse to accreditation is a practice which undermines the accreditation and should therefore not be used. It should be noted that in some cases national accreditation bodies are obliged to carry out the assessment of candidate Notified Bodies as this is required by existing national laws or bylaws.

6. WITNESSING FOR NEW SCOPES OF ACCREDITATION (CERTIF NO 2012-03)

6.1. Witnessing for new scopes

This paper aims to provide a common understanding on the interpretation of Regulation (EC) 765/2008 ("the Regulation") in relation to granting accreditation relating to new activities of conformity assessment bodies.

This can either relate to new conformity assessment bodies wishing to enter the market, to existing conformity assessment bodies wishing to extend the scope of their accreditation, or to new regulatory requirements.

According to EN-ISO 17011, accreditation cannot be granted without a witnessing having taken place. The results of the on-site assessment have to be taken into account in the decision-making.

However, especially when it comes to new regulatory requirements and accreditation for the purposes of notification, this may lead to a "catch-22" situation:

A conformity assessment body will not be accredited because it has never performed a certain activity – and may encounter difficulties finding clients as it is not accredited or may not be able to be notified for this reason. Such a situation would effectively lead to a closure of the conformity assessment market for new actors or activities.

6.2. Solution

In order to maintain the accessibility as well as quality of accreditation and not to create contradictory administrative requirements, a pragmatic approach to this problem is suggested. A number of EA members already follow this approach. It seems advisable to reach a consensus to adopt it as a general approach across Europe and to enable EA peer evaluation to take the solution into account.

In the case of a new activity, a conditional attestation should be granted to the conformity assessment body, if all other conditions for accreditation are fulfilled by the conformity assessment body, and a simulation does not present itself as a viable option. However, this should only be granted without witnessing under the condition that, before any accredited certificate is issued, a witnessing takes place. Furthermore, the conformity assessment body should have procedures in place that ensure a continued competence in areas where there is little activity.

Once the witnessing has taken place an accreditation certificate may be issued. In practice, this means that the conformity assessment body has to ensure that a witnessing takes place, the first time before it finalises its assessment for this specific activity.

Another solution in the regulated area, where the accreditation certificate represents the preferred means for demonstrating the technical competence of a body, could be a temporary notification of the new entrant conformity assessment body on the basis of the documents reviewed. Unless the accreditation is confirmed by a witnessing within a given timeframe, the notification is automatically withdrawn by the notifying authority. This approach has the double benefit of being a pragmatic

solution that is in line with the relevant international standards while ensuring that accreditation is not weakened, and maintains its role as last level of control in the conformity assessment system.

7. PUBLISHED AUDITED ANNUAL ACCOUNTS OF ACCREDITATION BODIES (CERTIF 2012-05)

7.1. Objective of the paper

This paper aims to provide a common understanding on the interpretation of Regulation (EC) 765/2008 ("the Regulation") in relation to its Article 8(11) that requires national accreditation bodies to publish audited annual accounts prepared in accordance with generally accepted accounting principles.

The goal of the present paper is to clarify the intentions of this provision, namely safeguarding the principle on non-commerciality and demonstrating that the accreditation body has sufficient resources to perform its tasks adequately. Both aspects are fundamental to the correct functioning of accreditation as the last level of control in the conformity assessment system. Thus when implementing this provision these objectives should be borne in mind rather than a pure focus on whether the accounts are presented in detail in compliance with accounting standards.

A strict focus on financial accounting may lead to difficulties in those Member States where the accreditation body is part of a larger governmental structure, as such a strict reading would require a reform of the accounts of the authority in question without contributing proportionately to more clarity in terms of demonstrating that the aims of the provision are met.

Bearing in mind that the ultimate say on matters of EU law rests with the European Court of Justice, this draft paper contains a proposal for a common understanding and pragmatic solution for this question.

7.2. Background

The Recital 14 of the Regulation states:

"For the purposes of this Regulation, not-for-profit operation by a national accreditation body should be understood as an activity that is not intended to add any gain to the resources of the body's owners or members. While national accreditation bodies do not have the objective of maximising or distributing profits, they may provide services in return for payment, or receive income. Any excess revenue that results from such services may be used for investment to develop their activities further, as long as it is in line with their main activities. It should accordingly be emphasised that the primary objective of national accreditation bodies should be to support or engage actively in activities that are not intended to produce any gain."

In the same vein, Article 4(7) of the Regulation states:

"*The national accreditation body shall operate on a not-for-profit basis."*

Article 4(9) of the Regulation stipulates:

"Each Member State shall ensure that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks, including the fulfilment of special tasks, such as activities for European and international accreditation cooperation and activities that are required to support public policyand which are not self-financing."

Article 8(11) then contains the provision under discussion, stipulating that the national accreditation body

"shall publish audited annual accounts prepared in accordance with generally accepted accounting principles."

National accreditation bodies operate in accordance with the international standard EN ISO/IEC 17011 which states:

"4.5.2 The accreditation body shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities. The accreditation body shall have a description of its source(s) of income."

7.3. Problem definition

The requirement for publishing audited annual accounts does not pose a problem for accreditation bodies that have an independent private law status of some form. It may, however, be more problematic for accreditation bodies that are, for example, part of a ministry as no separate accounts for the accreditation body may exist, the budgetary and financial management often being globalised in a overall public authority financial statement.

Thus, if the requirement to publish accounts is approached from a purely financial perspective, a number of national accreditation bodies will encounter difficulties in demonstrating their compliance during peer evaluations. Considering that it is otherwise considered to be acceptable that accreditation bodies are part of ministries as long as no conflict of interest exists, this requirement thus needs to be applied in a way that is meaningful for the purposes of the Regulation. Hence Article 8(11) needs to be applied in a way that allows national accreditation bodies to demonstrate that they are complying with the goals and provisions of the Regulation without Member States having to substantially reform the financial management of a ministry, which is otherwise controlled by public institution.

7.4. Solution

The intentions of Article 8(11) go over and beyond demonstrating sound financial management, for the purposes of peer evaluation national accreditation bodies should therefore clearly demonstrate that the guiding principles of non-commerciality and sufficient resources for competence of the accreditation body are respected. Bearing in mind the overall objective of the Regulation of establishing accreditation as last level of control in the conformity assessment system, in those cases where the accreditation body is part of a larger structure, Art. 8(11) should thus be understood to be a tool to demonstrate compliance with these principles, rather than being used to create unnecessary bureaucratic burdens for Member States. Thus the accreditation

bodies situated in ministerial departments must be in a position to present at least their overall budgetary and financial figures covering overall budgetary resources and their global and operational expenses; together with any financial policies that apply to them in order to be able to demonstrate that they have sufficient resources to perform their tasks adequately whilst safeguarding the principle of non-commerciality