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Consultancy, and the Independence of Conformity Assessment Bodies

PURPOSE

The document presents the policy agreed by EA Members for relationship between Conformity Assessment bodies and Consultancy activities.

Authorship

This document has been written by the Horizontal Harmonization Committee.

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CONTENTS

1 SCOPE	4
2 DEFINITIONS.....	4
2.1 CONSULTANCY.....	4
2.2 INDEPENDENCE (TAKEN FROM ISO/IEC 17000)	4
2.3 MANUFACTURER (TAKEN FROM REGULATION (EU) N° 2019/1020 AND REGULATION (EC) N° 765/2008).	4
3 INTRODUCTION	5
4 TABLE OF ACTIVITIES OTHER THAN CONFORMITY ASSESSMENT (APPLIED TO THE CAB AND THE LEGAL ENTITY).....	6

1 SCOPE

This document defines the EA approach to assessing the independence of conformity assessment bodies (CAB) and of these CABs' (third party) conformity assessment activities performed for notification purposes and for certification of products, processes and services, in relation to consultancy activities and other activities outside the accreditation scope. The stated requirements apply whatever accreditation standard is used.

2 DEFINITIONS

2.1 Consultancy

For the purposes of this document, the definition of consultancy in ISO/IEC 17065:2012 has been adopted as the issues covered by the document are mainly concerned with product/process/service certification. Although this definition has been taken from a product certification standard, the same definition is intended to apply to all conformity assessment standards.

Participation in:

- a) the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or
- b) the designing, implementing, operating or maintaining of a certified process or a process to be certified, or
- c) the designing, implementing, providing or maintaining of a certified service or a service to be certified.

2.2 Independence (taken from ISO/IEC 17000)

Freedom of a person or organization from the control or authority of another person or organization.

Note 1: For example a conformity assessment body can be independent from the person who is the object of conformity assessment or from the organization providing the object of conformity assessment.

Note 2: The level of freedom between the conformity assessment body and other person or organization who have an interest in the results can be assessed in particular, with regard to engagement in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items or activities related to conformity assessment.

2.3 Manufacturer (taken from Regulation (EU) N° 2019/1020 and Regulation (EC) N° 765/2008).

Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.

3 INTRODUCTION

The note to the expert group on the INTERNAL MARKET FOR PRODUCTS (IMP) entitled “CERTIF 2015-02 – Notified bodies – consultancy” resulted in the need for clarification on what activities are incompatible with the status of independent and impartial third party CABs (Insofar as CABs perform other functions or activities than just assessment alone) and what is a consultancy activity.

To achieve this objective, this document is intended to provide the EA members position on compatibility between the activities of bodies which undertake activities other than conformity assessment for which they are accredited.

This document has a guidance status. It is intended to be used by all National Accreditation Bodies (NABs) for assessment and accreditation of:

- conformity assessment bodies (CABs) for notification purposes, whatever accreditation standard is used,
- conformity assessment bodies certifying products, processes and services (ISO/IEC 17065), whatever the certification scheme.

For each activity identified, the table below specifies the risk of conflict of interest, to whom this activity could be delivered and if it's consultancy or not. If an activity is not identified as consultancy, the activity still may present an unacceptable risk, the table identifies where activities are not suitable for accredited CABs to undertake whether or not they are defined as consultancy. Even where such activities are deemed acceptable, all other requirements of the conformity assessment standard and/or regulatory requirements must be met.

When an activity is considered as acceptable with conditions, the CAB shall demonstrate the fulfillment of conditions and provide detailed proofs of this to the NAB.

Where the requirements of a particular conformity assessment standard are quoted within the table, the principles also apply to the relevant clauses of other conformity assessment standards, where similar provisions are included.

**4 TABLE OF ACTIVITIES OTHER THAN CONFORMITY ASSESSMENT
(APPLIED TO THE CAB AND THE LEGAL ENTITY)**

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
1	<p><i>Development /innovation of products falling within the scope of accreditation</i></p> <p><i>Example: outsourced research and development for a manufacturer</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	<p>NO</p> <p>It is more than consultancy, it is development of a product for a manufacturer. It is forbidden by 4.2.6 a) of ISO/IEC 17065 and annex A1 of ISO/IEC 17020, and article 3 of Decision 768/2008/EC (<i>A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.</i>).</p> <p>This clause prevents manufacturers from becoming CABs.</p>
		<p>NOT ACCEPTABLE: <i>Risk of self-review</i></p>	<p>NOT ACCEPTABLE <i>Risk of competition with party receiving conformity assessment services</i></p>	

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
2	<i>Internal audit concerning products/processes/ services in the field of accreditation</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	NO Internal audit is an activity different from consultancy (ref. ISO 9000) It is forbidden by article 4 of Decision 768/2008/EC "... They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified."
		NOT ACCEPTABLE: <i>Risk of self-review</i>	ACCEPTABLE WITH CONDITIONS <i>Internal audit objectives should be determined in an agreement</i> <i>No certification for a minimum of two years following the completion of the internal audits</i> <i>After two years, verification by the CAB that the internal audit made is not in conflict with the activities of certification of the party becoming applicant</i>	

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
3	<p><i>Supporting the implementation of provisions to meet the conformity requirements for manufacturers in relation to conformity assessment activities for which they are notified</i></p> <p><i>Example: The CAB supports a manufacturer to implement a factory production control</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	<p>YES</p> <p>It is forbidden by 4.2.6 d) and e) of ISO/IEC 17065, 5.2.5 of ISO/IEC 17021-1, annex A1 of ISO/IEC 17020 and article 4 of Decision 768/2008/EC “They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.”</p>
		<p>NOT ACCEPTABLE:</p> <p><i>Risk of self-review and risk of self-interest with regard to competitors.</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
4	<i>Training for the implementation of provisions to meet certification requirements</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	NO when strict conditions are met
		<p>ACCEPTABLE WITH CONDITIONS <i>Generic training (from a public list of pre-established training) with safeguards on trainings carried out in-house for a single company (generic training with adaptation deletion/addition of a part, no case studies from the party, no workshop demonstration)</i></p> <p><i>Bespoke training on the party's specific activities is not allowed.</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
5	<p>Engineering-Prime contractor</p> <p>Example: An entity responsible for all aspects of the construction of buildings, wanting to be a CAB for construction products and/or processes</p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	<p>NO</p> <p>because CAB is the installer/ implementer or maintainer of the products which they assess.</p> <p>It is forbidden by application of 4.2.6a/b/c ISO/IEC 17065 and annex A1 of ISO/IEC 17020 and article 3 of Decision 768/2008/EC (<i>A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.</i>)</p> <p>This clause prevents installer/implementer or maintainer from becoming CAB</p>
		<p>NOT ACCEPTABLE</p> <p><i>Risk of self-interest and self-review</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
6	<i>Engineering (validation of product design and provision of technical solutions)</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	<p>YES</p> <p>because solutions for design input are provided.</p> <p>It is forbidden by 4.2.6 d) of ISO/IEC 17065, 5.2.5 of ISO/IEC 17021-1, annex A1 of ISO/IEC 17020 and article 4 of Decision 768/2008/EC “They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.”</p>
		<p>NOT ACCEPTABLE</p> <p><i>Risk of self-review and risk of self-interest with regard to competitors.</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
7	<p><i>Technical Assistance from conception through shared information and resources.</i></p> <p><i>Examples: The manufacturer uses measurement equipment of CAB (for example within the laboratory environment). The manufacturer requests the CAB to verify the list of all applicable regulations. The manufacturer requests tests during the design phase.</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	NO when strict conditions are met
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>Scope clearly presented in the contract (supply of solutions cannot be included as a service)</i></p> <p><i>Only top-level information provided, no detailed input to design or manufacture.</i></p> <p><i>Commitment recorded of the technicians to not recommend a solution</i></p> <p><i>Realization per person (of the CAB) independent from assessment activities to reduce problems of misunderstanding between parties and CAB</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
8	<p><i>Technical Assistance from conception through design input</i></p> <p><i>Example: The CAB participates in the choice of materials or other study which helps the manufacturer to demonstrate its compliance with the requirement of certification</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	<p>YES</p> <p>It is forbidden by 4.2.6 d) of ISO/IEC 17065, 5.2.5 of ISO/IEC 17021-1, annex A1 of ISO/IEC 17020 and article 4 of Decision 768/2008/EC</p> <p><i>“They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.”</i></p>
		<p>NOT ACCEPTABLE:</p> <p><i>Risk of self-review and risk of self-interest with regard to competitors</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
9	<i>Technical analysis of product failures</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	NO when strict conditions are met
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>Verification before each contract (context, expected output, application of standard methodologies)</i></p> <p><i>Delivery limited to diagnosis</i></p> <p><i>Scope clearly defined in contract</i></p> <p><i>Commitment recorded of the technicians not recommending solutions</i></p>		

Numb	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
10	<i>Technical optimization of the manufacturing process</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	NO when strict conditions are met
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>Verification by the CAB before each contract (context, expected output, application of standard methodologies)</i></p> <p><i>Delivery limited to diagnosis</i></p> <p><i>Scope clearly defined in the contract</i></p> <p><i>Commitment recorded of the technicians not to recommend solution or to take responsibility in the process control</i></p> <p><i>Note: Special attention should be paid to risk-management in this case because there is a risk of self-review and over-familiarity.</i></p>	<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>Verification by the CAB before each contract (context, expected output, application of standard methodologies)</i></p> <p><i>Delivery limited to diagnosis</i></p> <p><i>Scope clearly defined in the contract</i></p> <p><i>Commitment recorded of the technicians not to recommend solution or to take responsibility in the process control</i></p>	

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
11	<i>R&D Project for the sector High level study into general market/design/production trends within the overall sector.</i>	For party receiving conformity assessment services (including applicants)	For party not receiving conformity assessment services	NO
		<p>ACCEPTABLE IF THE FOLLOWING CONDITIONS ARE MET:</p> <p><i>Results shall be made publicly available.</i></p> <p><i>Note: the vocation of some CABs such as technical centres and R&D projects contribute to establishing or updating the state-of-the-art.</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
12	<i>Development of professional rules (guidance papers) and/or characterization methods and/or norm</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	NO
		<p>ACCEPTABLE IF THE FOLLOWING CONDITIONS ARE MET:</p> <p><i>Results are made public after participation of parties involved.</i></p> <p><i>This activity is the vocation of some CABs such as technical centres.</i></p> <p><i>Rules are applicable for everybody in the same way.</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
13	<p><i>Provision of Guidance for the CE Marking Process.</i></p> <p><i>Example: blank templates for helping the manufacturer record information in a retrievable manner (for the technical file).</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	NO when strict conditions are met
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>Guidance material must be generic and not specific to the item/type being certified.</i></p> <p><i>The guidance should show what should be in the content but not identify the content itself.</i></p> <p><i>It is acceptable for form templates to be provided.</i></p> <p><i>The results shall be publicly available</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
14	<i>Development of a new material for the sector, and register a patent and/or a user licence for it</i>	<i>For party receiving conformity assessment services (including applicants)</i>	<i>For party not receiving conformity assessment services</i>	NO when strict conditions are met
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>Analysis before project launch in order to verify there is no impact on conformity assessment or on assessed parties which might be competitors.</i></p> <p><i>Activity relates to the complete sector (neither for the CAB nor for an individual industrial), collective and transparent communication.</i></p> <p><i>No subsequent certification of a product related to a patent (use of a material or implementation of a process subjected to a patent and/or a user licence for it).</i></p> <p><i>No user licence resulting to collective certification (no financial interest)</i></p> <p>NOT ACCEPTABLE:</p> <p><i>If the CAB has revenue from the certified products.</i></p> <p><i>(Risk of self-review and self-interest)</i></p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
15	<p><i>Development of a test protocol</i></p> <p><i>Example: A party wants the CAB to establish a sampling strategy for the party in order to help it to check the conformity of its products</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	NO when strict conditions are met
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET</p> <p><i>The conformity requirements do not include the verification of procedures of tests that will be performed by the party.</i></p> <p><i>The validation of the method satisfies the requirements of ISO/IEC 17025.</i></p> <p><i>Providing a generic test or inspection protocol, publicly available, can be accepted under the conditions expressed in situation 13.</i></p> <p>NOT ACCEPTABLE if the personalized sampling strategy is a requirement of conformity. (Risk of self-review and over familiarity)</p>		

Number	ACTIVITY OTHER THAN CONFORMITY ASSESSMENT	TO WHOM		IS THE ACTIVITY CONSULTANCY?
16	<p><i>Delivery of services that could be conformity assessment but out of the accreditation scope with regard to notification (e.g. maintenance or calibration of test equipment used by the manufacturer)</i></p>	<p><i>For party receiving conformity assessment services (including applicants)</i></p>	<p><i>For party not receiving conformity assessment services</i></p>	<p>NO when strict conditions are met</p>
		<p>ACCEPTABLE ONLY IF THE FOLLOWING CONDITIONS ARE MET <i>Risk analysis on conformity assessment performance and demonstration of control regarding the risks and situations detected.</i></p>		