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The European Federation of National Associations of Measurement, Testing and Analytical Laboratories

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EUROLAB Briefing

European Commission presents first draft of the revised Blue Guide

On 1st March the European Commission, DG Enterprise and Industry, presented the first draft of the revised Blue Guide during a stakeholder meeting, to which CEOC International and EUROLAB were invited.

Background:

The aim of the Blue Guide is to ensure as much common understanding as possible of the New Legislative Framework so as to facilitate the effective implementation by all concerned. Additionally, new and revised EU legislation has to be taken into account, which is why some new and completely revised chapters have been included in the draft document.

The meeting on 1st March was a follow up from the 1st stakeholder meeting, which took place in September 2012. During this meeting the European Commission presented the overall structure of the Blue Guide and announced that the first draft text of the revised Blue Guide would be distributed among the stakeholders six weeks in advance of the next meeting in order to give enough time to go through the document and to prepare comments.

Due to some delays of other legislations (i.e. the new legislation on Market Surveillance) the draft of the Blue Guide was published only six days in advance of the 2nd stakeholder meeting. CEOC International and EUROLAB had however already set up several working groups and online meetings/ telephone conferences so that they were prepared and able to revise the relevant chapter 5 on Conformity Assessment despite the time constraints. A summary of the working groups' comments had been handed over to Mr Hans Ingels, head of the responsible Unit C/1 – Internal Market and its International Dimension (see below the letter to the European Commission).

2nd Stakeholder Meeting: The Revised Blue Guide

On 1st March the European Commission, DG Enterprise and Industry, presented the first draft of the revised Blue Guide during a stakeholder meeting, to which CEOC International (represented by Daniel Pflumm and Franziska Kassler) and EUROLAB (represented by Jiři Sobola and Philippe Dewolfs) were invited. During the meeting the two associations presented their joint comments, which were well received.

Hans Ingels, who chaired the meeting, explained that this document was a very first draft and that the purpose of this meeting was to collect the relevant stakeholders' input. He pointed out that he and his colleagues have been trying to take EU legislation into account that has not yet been adopted (e.g. the Alignment Package and the revision of the Medical Devices Directive) but that due to the nature of the process some sections of the current version of the Blue Guide will have to be aligned with this legislation at a later stage. The plan is to structure and write the Blue Guide in a way that will enable the Commission to update only certain chapters if and when necessary while avoiding the revision of the whole document every time a new legislation has been adopted.

The Commission representatives admitted that six days was not a sufficient time for preparing detailed comments, which was why the meeting focused on the following topics: structure of the Blue Guide; What is missing?; What needs to be deleted?; What are the major concerns?.

The overall feedback of the stakeholders present was that in certain sections some clarifications were necessary, i.e. some concepts needed clear definitions (e.g. what does 'intended use' mean? What is a 'risk'?). Additionally it was pointed out that the wording and the definitions used in the Blue Guide should always be in line with those in Regulation 765/2008 and Decision 768/2008, a point which was also reflected in the joint CEOC-EUROLAB position.

A major point of concern was that the scope of the Blue Guide has not yet been defined. Depending on whether or not the Blue Guide will cover for example the Construction Products Legislation or environmental legislation, the comments that the Commission will receive from the stakeholders might vary greatly from a Blue Guide with the same scope as the previous one. The Commission representatives agreed to inform about the exact scope in a separate email in the coming week. The annexes to the Blue Guide will probably also be send with this email. After the email has been sent out a six week comment period will start, ending on 15th April 2013.

Next Steps

- Week 10 (04-08th March): clarification of the scope of the Blue Guide + Annexes
- 15th April: deadline for comments
- Before/after the summer break: distribution of the next draft version and 3rd stakeholder meeting

For more information please contact: info@eurolab.org

Brussels, 1st March 2013

Revision of the Blue Guide

Dear Mr Ingels,

We would like to thank you for sending us the first draft version of the Blue Guide and for involving us in the revision process.

We very much welcome the objective of the European Commission to align the Blue Guide with the New Legislative Framework.

The most relevant chapters for the CEOC International and EUROLAB members are chapter 5 on *Conformity Assessment* and chapter 6 on *Technical Information and Marking Obligations*. For this reason we have focused especially on these two chapters when preparing ourselves for today's stakeholder meeting.

Generally we would like to point out that the most important point for us is to keep the Blue Guide in line with Regulation 765/2008 and Decision 768/2008, especially with regards to wording and definitions in order to avoid misunderstandings and misinterpretations. We would like to mention some examples where this should be improved:

- The definition of conformity assessment (chapter 5.1.1)
- The definition of accreditation (chapter 5.3.2)
- The definition of CE marking (chapter 6.3.1)
- Clear distinction of the criteria that Notified Bodies and in-house accredited Conformity Assessment Bodies have to fulfil with regards to impartiality (chapter 5.1.3 and 5.2.2)
- Coherent use of the expression 'Conformity Assessment Body' instead of 'Conformity Assessment Activity' (chapter 5.3.2)
- Clear distinction between 'conformity assessment' and 'certification' (e.g. in chapter 5.3.7 and chapter 6.2)
- Coherent use of the wording 'sectoral schemes' instead of 'sector schemes'

Additionally we would like to ask the European Commission to clarify the following points:

- The accreditation and the assessment of Conformity Assessment Bodies with activities outside the EU are covered by the IAF and ILAC cross-frontier policy.
- CE marking (chapter 6.3.7) does not apply to voluntary marks.
- Clarification on the used wording of e.g. putting/ placing/ making available on the market including the question of first time/ last time.
- Is the CPR covered by the Blue Guide? (see footnote 86)

Finally we would like to make some suggestions for improving the application of the Blue Guide:

- Chapter 5.2.2: *Notified bodies have a general obligation to inform the other notified bodies and the national surveillance authority about all certificates suspended or withdrawn and, on*

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request, about certificates issued or refused. We suggest that information should only have to be provided on reasons of non-conformity. Additionally it would be useful to implement a European online platform where the NBs can publish this information.

- Chapter 5.4.4: Suspension – withdrawal – appeal: There should be the possibility of the Notified Body to appeal to the European Commission as the highest instance in cases of withdrawal of its notification.
- This kind of document should not allow for ranking and comparisons of in-house and external bodies (e.g. chapter 5.1.3).

We will take the liberty of sending you our more detailed remarks via email after the meeting.

We would also like to use this opportunity to offer the support of our associations and our members throughout the revision process and we welcome the opportunity to discuss with you in detail our views.

Kind regards

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