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

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EUROLAB Special Briefing

EUROLAB meeting with the European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH)

Participants on behalf of the European Commission:
Mrs Valentina Superti (Director – Single Market for Goods)
Mr Daniel Bunch (Deputy Head of Unit - Internal Market and its International Dimension)
Mrs Nike Boennen (Policy Officer - Internal Market and its International Dimension)
Mrs Norma Mcgovern (Internal Market for Goods and Market Surveillance - Administrative Coordination Assistant)

Participants on behalf of EUROLAB aisbl:
Mr Jiří Sobola (President)
Mr Alvaro Silva Ribeiro (EUROLAB Board member)
Mr Drewin Nieuwenhuis (Secretary)
Ms Laura Martin (Junior International Affairs Manager)

EUROLAB had a meeting with the European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs on 4th February 2015. The meeting started with a short introduction of EUROLAB, given by Mr Jiří Sobola and Mr Drewin Nieuwenhuis on EUROLAB's main activities, objectives and priority areas of focus for 2015.

The discussions continued with the current issues of concern for EUROLAB and DG GROWTH and the legislative developments in the following key areas:

- ***The General Product Safety Directive (GPSD)*** - The European Commission proposed a new Product Safety and Market Surveillance Package, following the public consultation on the revision of the current directive. With a new package of legislative and non-legislative measures the European Commission wants to improve consumer product safety and to strengthen market surveillance of products in the EU. The package is being discussed in the European Parliament and the Council of the EU. The European Commission has as main objective for the coming period to arrive to a common consensus on critical issues such as Article 7 – Indication of Origin on which a study is currently conducted.
- ***The Blue Guide*** – There were follow up discussions related to the latest revised version of the Blue Guide. For the coming period the European Commission has no intention to

extend the scope of the Blue Guide to some other specific areas which are currently not covered. (e.g. construction products)

- ***The Medical Devices Directives*** - The Medical Devices Directives are currently under revision, awaiting Council 1st reading position / budgetary conciliation convocation. The industry recognises the need to modernise and strengthen the current medical devices legislation in Europe by strengthening the Notified Body system and pushing to an increased EU Member States coordination. The main objective is to develop an overall regulatory framework which looks towards the future - and which guarantees rapid market access for innovative medical devices to the benefit of patients, whilst at the same time offering the highest possible levels of safety by means of intensified control activities.
- ***Accreditation and Standardisation*** – According to the Regulation (EC) No 765/2008 which embodies the European accreditation policy in relation to conformity assessment, there is only one Accreditation body per member state, requirement that is welcomed by the EUROPEAN laboratory community. The main concerns are the different views on the other side of the Atlantic, where free competition is strongly supported. In Europe Accreditation Bodies can accredit only to harmonised European standards, requirement which does not apply outside the EU. Thus, EUROLAB put forward these issues to the European Commission, asking for their support in the future development of ISO standards and in the revision of ISO 17025 in particular.
- ***Validity of notifications in Nando*** - EUROLAB understands that for entities directly involved in notification, it is important to know when certain accreditations that are linked to notifications expire. EUROLAB suggested to the European Commission to reconsider the publication of the date of expiry in the public domain of Nando as this can give a misleading impression to clients seeking to select a Notified Body (NB) and might lead to market distortion. Considering the above reasons, the expiry date can be made available in the members' area only.

As an overall conclusion, there is a general political consensus for the need to improve the market surveillance system and better implement and enforce the legislation already in place and make CE marking stronger, which EUROLAB has supported. The European Commission welcomes a closer cooperation with EUROLAB considering future exchange of views and opinions collected by EUROLAB from the laboratory community.