

October - December 2014



## Foreword

Dear EUROLAB Members,

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Please find below the fourth EUROLAB Newsbriefing for this year informing you about some developments relevant to the Laboratory sector in the fourth quarter of 2014. The end of the year has been, as usual, rich in events and new developments. Some years ago EUROLAB recognised that active participation in ILAC and IAF is of key importance as documents developed there are then used by EA and European accreditation bodies. The new ILAC strategy is offering some options for increased involvement of stakeholders in the future but even now EUROLAB contributions are recognised directly in key ILAC committees, mainly the Accreditation Issues Committee (AIC), Arrangements Committee (ARC) and Inspection Committee (IC).

Here at this stage I have to express my sincere thanks to all National EUROLABs which responded to the TCQA questionnaire concerning the revision of ISO EN 17025 and to TCQA itself. TCQA did a tremendous job in writing a EUROLAB White Paper on revision of ISO EN 17025. This document was accepted as a key input to the ILAC AIC/LC WG for revision of ISO 17025 and for preparation of an ILAC White Paper which is now under the responsibility of CNAS (Chinese National Accreditation Service). It was also highly appreciated by EA and distributed to EA members. EUROLAB will also be well represented in ISO CASCO WG 44 but still, as a liaison member, is only allowed to comment and discuss but not to vote. Therefore the EUROLAB White Paper was distributed to National EUROLABs to be used in discussions with their National Accreditation Bodies and National Standardisation institutes which will finally decide by their voting. It is obvious that this cooperation at the national level will be decisive in the final stages of the revision. Therefore I am encouraging You, Dear Members, please, cooperate with ABs wherever you can find consensus while EUROLAB will supply you with discussion materials and supportive evidence. As far as ILAC IC is concerned, EUROLAB continues its work in resolving the use of tests and measurements in inspections. Another very serious problem is hidden behind the question: What an AB can and/or cannot do if an inspection body, during accreditation against the current version of ISO 17020, claims conformity with the ISO 9001 standard? The answer is not easy at all. Therefore ILAC IC asked ISO CASCO for an explanation.

New cooperation was launched by establishing direct communication between ILAC PT, ILC and RM committees and the relevant EUROLAB TFG. This is a good step allowing more involvement and wider cooperation in the future thus setting example which should be followed in other areas. Our cooperation with EA has a long tradition and is well established. Nevertheless special attention should be paid to the agenda of EA HHC where issues related to regulatory areas are discussed and new documents are coming up. There are many open questions in accreditation for the purpose of notification, implementation of R765/2008, priority of regulatory requirements above hEN 17000 series, etc.

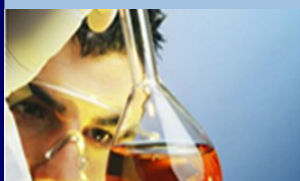
Internally you noted changes in the EUROLAB Statutes aimed at increasing participation, expansion of membership and opening EUROLAB to third countries. You have also been informed that new Board members will be elected or re-elected during next the EUROLAB GA. YES, there are new areas which are to be covered by EUROLAB and you know that every member of the BoA has been allocated certain areas of responsibility already. The new areas to be covered are clinical laboratories, food testing, forensic laboratories, environmental laboratories, medical laboratories (pathology, image processing, sanitary), etc. So it is clear that we need new BoA members with relevant professional backgrounds. It does not mean that we are not going to enhance promotion of testing, analytical and calibration laboratories to politicians as a key source of added value for all conformity assessment areas, implementation of European legislation, security and safety of citizens and improving quality systems, but in the long run we cannot succeed in all these endeavours without sound experience, well established sources of objective information and a highly professional approach.

Last but not least it is my honour and great pleasure to express my sincere thanks to all who were involved in preparation of the EUROLAB – CEOC – IFIA Safety Seminar in Brussels, namely to the president of CEOC Mr. Simo Hassi and to Mr Roger Brockway, IFIA Director General for excellent cooperation. A special vote of thanks goes to the secretariat for perfect preparation and follow up actions like briefings, articles, etc.

Since we are approaching the end of the year I would like to use this opportunity to thank all members for their active contributions to the success of EUROLAB and to wish you a splendid Christmas, enjoyable holidays and Happy New Year.

Yours faithfully

Jiří Soboja  
President EUROLAB



**Focus of the Month****2014 CEOC-EUROLAB-IFIA International Safety Seminar****How safe do you think you are? Why independent testing is important**

On 5<sup>th</sup> November 2014 CEOC International, EUROLAB and IFIA organised the 5<sup>th</sup> International Safety Seminar at the Residence Palace in Brussels. This years' focus was on the importance of independent testing in the field of consumer testing. The event brought together more than 100 participants from the testing, inspection and certification (TIC) sector, EU institutions and consumer and industry associations.

During his opening speech CEOC International President **Simo Hassi** highlighted the importance of working together with different stakeholders to achieve a common goal. One example for this is the excellent cooperation between CEOC International, EUROLAB and IFIA, who have not only organised this event together for many years now but who also regularly work together in committees and publish joint position papers.



The first session, which was chaired by **Roger Brockway (IFIA Director General)**, focused on consumer safety, and included panellists coming from market surveillance authorities, the TIC sector and industry.

**Richard van Buuren (PROSAFE/ NVWA)** outlined the weaknesses of the systems that are currently in place for ensuring consumer product safety. He pointed out that the different actors involved, e.g. market surveillance authorities, testing laboratories, manufacturers, importers and standards setting bodies, need to work closer together in order to address these weaknesses.

The dangers of counterfeit products and which measures can be taken to avoid such products on the market were explained by **Terry Hunter (CSA Group / CIAC)**, who is in charge of anti-counterfeiting and I.P. enforcement in his company and who is also involved in CIAC. CIAC is an international network of certification organizations, co-ordinated by INTERPOL, committed to stopping the worldwide proliferation of products bearing counterfeit certification marks that may endanger public health and safety.

The final speaker of the session, **Annette Dragsdahl (BUSINESSEUROPE/ DI)**, stressed that three things should be kept in mind when talking about product safety: proportionality, enforcement and fairness. While a high level of product safety is undisputable the measures to achieve this high level need to be proportionate and fair. Instead of adding additional requirements the already existing ones should be better enforced. Additionally, mutual recognition of test reports should be strengthened and a global certification system be developed.



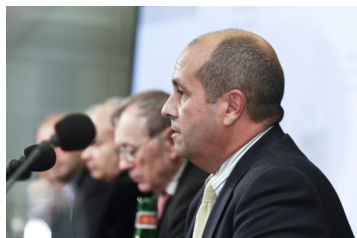


Session two, which was chaired by **Jiří Sobola (EUROLAB President)**, focused on the role of independent testing, especially in light of the currently on-going Transatlantic Trade and Investment Partnership (TTIP) negotiations.

**Jörg Mähler (TÜV Rheinland LGA Products)** explained the differences in the conformity assessment systems in the EU and the US, using the current legal requirements for machinery, toys and medical devices as examples. While it cannot be said that the safety levels on one side of the Atlantic are higher than on the other, it has to be acknowledged that there are considerable differences in the two systems, which will not be easily overcome. Thus mutual recognition of standards and conformity assessment procedures used should be encouraged, while at the same time a high level of safety needs to be ensured.

**František Vaculík and Jiří Boudník (PSJ)** described the experiences they had made as construction company active both in Europe and the US. The main differences of the two markets were related to legal requirements, working conditions, the influence of trade unions, the level of quality and the role that testing, inspection and certification play during the construction process.

The second session was concluded by the presentation of the 2014 IFIA – CEOC market study results by **Marcello Manca (UL)**. The aim of the study, which has been carried out for three consecutive years now, is to gauge the effectiveness of securing



safety of consumer products, comparing self-declaration system and 3rd party testing and certification. In 2012, the first year of the study, typical electrical consumer products were bought that only carried the CE mark. In 2013 the same type of electrical consumer products were bought but this time the products were certified by an independent third party body. In 2014 it was again self-declared CE marked products that were bought in the EU and in addition the same types of products were purchased in the US (certified by an independent third party body). The 2014 results showed that of the CE market products purchased in the EU 78% were non-compliant, with 38 instances of safety critical failures. Only 26% of the products taken from the US market were non-compliant, with no instance of safety critical failures. If the data of all three studies is applied to one example, household appliances, then this means that in 3 out every 4

households in Europe there is an appliance that is not in compliance with EU standards and regulations. One in every 8 household has an appliance with a 'major', potentially dangerous, issue. This is surely a level of safety that is not acceptable.

The seminar was concluded by CEOC President Simo Hassi, who thanked all speakers and participants for their contribution to this successful event.

All presentations can be found on the [CEOC International website](#).



- > Confuses consumers into thinking that products are 'safe' (let alone 'compliant' with all applicable directives and regulations)
- > Misunderstood by most operators
- > Mandatory, ergo not distinguishing
- > Counterfeited and misused over 78% of the time (with very few penalties)
- > More confusion: it is applicable to some consumer products, but to others not (ref. GPSD > CPSR)
- > No pride of ownership, direct responsibility

## National Members' News

### BMTA News



Promoting measurement and testing - speaking with one voice to Government, UKAS and the European Laboratory Community

#### Medical Laboratory Accreditation Workshop, Leeds 5th February 2015

BMTA is holding its 3rd medical laboratory accreditation workshop to help medical laboratories with the transition from CPA to ISO 15189:2012. The day will open with a talk by Helen Verrill (Consultant Clinical Scientist, North Tees & Hartlepool NHSft).

After this we split delegates into groups to attend 3 workshops covering the issues that laboratories need to address to obtain accredited status (Measurement Uncertainty, Verification and Validation, and Traceability). These workshops are preceded by an introductory talk on the subject, and then run by our expert speakers. The programme will also benefit those whose laboratories are already accredited. £100 BMTA members £200 Non-members (exl VAT). Book before Christmas to receive 20% off!

More information and booking forms can be found at <http://bmta.co.uk/news.htm>

### Fenelab News



#### Calibration Event 2014!!

After the successful Fenelab Calibration Event for auditors in September, DARE!! and Kalibra International B.V., organized in November a new, two days Calibration Event. The event was a great success and both days were fully booked. The presentations and discussions have led to an enormous exchange of information. Companies of all the major markets visited the event to learn about the latest developments in the calibration world and to sharpen their knowledge in regard to measurement uncertainty and traceability.

During the different lectures, it was made clear what the value is of an accredited service supplier for calibration, inspection and testing. As these companies deliver guaranteed certainty and quality.

The importance of this subject is growing because of the growing importance of documented traceability of measurement, but also in regard to growing quality demands of complete and complex core processes. This in combination with process control, will become even more important in the future. The use of accredited suppliers is the first step to support any manufacturer in safeguarding the quality of the process and thereby (eventually) lowering costs.

The many questions asked during the event, is a good indication that many companies acknowledge that this subject is high on their agenda and that the impact of the quality of calibrations is regarded as a vital part of their business. Not only are companies working to sustain their calibration process, but are looking to optimize this process to achieve maximum efficiency and quality whereby minimizing costs.



The event was a success and based on the comments received from the visitors, the event is likely to become an yearly event! (for more information about the event see [www.kalibratie-event.nl](http://www.kalibratie-event.nl))

### RELACRE News



"RELACRE (Eurolab Portugal) is currently organising the 3rd National Conference on NDT, joining the NDT Sectorial Forum (FSEND-RELACRE) in partnership with the Portuguese Air Force. It also has the support of CANEND – National Aerospace Non Destructive Testing Board and OGMA (Portuguese Aeronautic Material Laboratory).

It will have more than 30 papers presented, 10 partners for technical exhibition and 5 sponsors. Some of the international entities that already confirmed are ICNDT, EFNDT, ABENDI (Brazil), AEND (Spain), Siemens, TUV Rheinland, Karl Deutsch."



Further information can be found on RELACRE [website](#) and the programme of the conference can be downloaded by following the [link](#).

**EUROLAB-Spain****XI SYMPOSIUM FELAB - THURSDAY, NOVEMBER 27, 2014.**

“Situation and Prospects of National and International Markets. Monitoring and Technical Legal Issues in the scope of laboratories”

Dear Eurolab Members,

On Thursday, November 27, 2014, the XI Symposium was held under the title: “Situation and Prospects of National and International Markets. Monitoring and Technical Legal Issues in the scope of laboratories”. The Symposium focus on several topics such as: the latest laboratory legislative news and trends at the national, European and international level; the development of standardization and accreditation; the market environment and the internationalization; the markets outlook. Further details about the speakers and the topics discussed can be found in the program below.

**XI SYMPOSIUM FELAB PROGRAM (AELI / EUROLAB-SPAIN), THURSDAY, NOVEMBER 27, 2014.**

**9:00 - 9:30 RECEPTION.**

**9:30 - 9:45 OPENING AND INAUGURATION**

- D. Julio Hernández Pérez, President of FELAB.
- Dr. D. Benjamín Calvo Pérez, Director of the Foundation Gómez-Pardo.

**INAUGURATION:**

- Ilmo. Mr. Dr. D. José Luis Parra y Alfaro, President of the Board of the Foundation Gómez-Pardo and Director of the E.T.S.I. of Mines and Energy. UPM.

**9:45 - 10:30 TABLE 1 - PROTOCOL INSPECTION OF WASTEWATER DISCHARGE FOR THE MANAGEMENT ASSOCIATES OF HYDRAULIC.**

- Coordinator: Mr. D. Jorge Oliver-Rodés President of AELI.
- Speaker: Dra. Ms. Alejandra Puig Infante - Head of the Control and Monitoring of Water Quality. S. G. Integrated Public Water Management. Directorate General of Water. Ministry of Agriculture, Food and Environment.
- Introduced the debate: Mr. D. Fernando González López – Environment Technical Director ATISAE and Mr. D. Pedro Martínez González Commercial Director IPROMA.

**10:30 - 11:00 TABLE 2 - REVISION OF CGA-ENAC-LEC, GENERAL CRITERIA FOR ACCREDITATION OF TESTING LABORATORIES AND CALIBRATION.**

- Coordinator: Sra. Ms. M<sup>a</sup> Teresa Sanfeliu Ribot – Vice-President Internal Quality, Safety, Health and Innovation APPLUS
- Speaker: Mr. D. Oscar Recuero Fernández. Head of Environment ENAC – National Accreditation.
- Introduced the debate: Dr. D. Luis Coll Almela – Technical Director of Laboratories ECOSUR.

**11:00 - 11:30 Coffee Break**

**11:30 - 12:45 TABLE 3 - MARKETING AND INTERNATIONAL.**

- Coordinator: Ilmo. Mr. Dr. D. Fernando Ferrer Margalef, Director, Centre for Metrology Spanish – CEM - Ministry of Industry.

**Speakers:**

- Mr. D. Blas Francisco Vicente López – Assistant Director General of Inspection, Certification and Technical Assistance for Foreign Trade. Ministry of Commerce. Ministry of Economy and Finance.
- Sra. Ms. Mercedes Pizarro Santos – Director of Industrial Technology Division and Professional Services. ICEX Spain - Export and Investment. Ministry of Commerce. Ministry of Economy and Finance.
- Mr. D. Juan Millán Mateu – Managing Partner of GEDETH Network. (International Markets).
- Introduced the debate: Mr. D. José Luis Sánchez Álvarez-Campana – EUROLAB-Spain Vice President and member of Board Administrators of EUROLAB.aisbl.

**12:45 - 12:50 Break**



**Sectoral participants:**

- Sra. Ms. Ana María Escario García-Trevijano – Director General of BIOLAB, S.L (Health Sector).
- Dr. D. Juan Manuel Aguiar Merino Director General of Control Microbiológico, S.L. (Agrifood Sector).
- Mr. D. Francisco A. García Andreu. Quality Manager and Production Coordinator Mediterranean bow and the Canary Island LABAQUA (Environmental Sector).
- Mr. D. José Manuel López Mejías, Managing Director – Center for Laboratories and Industrial Services Madrid - CLM. (Sector Metrology and Calibration).
- Mr. D. Federico Muñoz Sánchez – Technical Sales Manager CEIS, S.L. (Sector: Industrial Goods and Building).

**14:15 - 14:30 CLOSURE and CONCLUSIONS.**

- D. Julio Hernández Pérez, President of FELAB.
- D. Javier Moles Gómez, Vice President of FELAB.
- Dr. D. Miguel Sánchez Fernández, Manager of FELAB (AELI/EUROLAB-Spain).

**CLOSING:**

- Ilmo. Mr. D. José Manuel Prieto Barrio, Deputy Director General of Quality and Safety - Ministry of Industry.

**EUROLAB-Germany**

**eurolab-Deutschland**

**Chemische Analytik; Mess- und Prüftechnik e.V.**

Eurachem organises workshops on Proficiency Testing in Analytical Chemistry, Microbiology and Laboratory Medicine in co-operation with CITAC (Cooperation on International Traceability in Analytical Chemistry) and EQALM (European Organisation for External Quality Assurance Providers in Laboratory Medicine) in 3 year intervals. The eighth event of this series of workshops took place in Berlin on 6 – 9 October 2014. This time the local organiser was EUROLAB-Deutschland, the German member of the European Federations EUROLAB aisbl and Eurachem.

The workshop commenced with a training course on *ISO 15528 and beyond* on 6 October 2014. Two groups with in total 100 participants were trained in a morning and an afternoon session. The subject of this training was the revised Draft International Standard ISO 15528-2 *Statistical methods for use in proficiency testing by interlaboratory comparisons*.

This draft standard and the accreditation of PT providers against ISO/IEC 17043 *Conformity assessment -- General requirements for proficiency testing* were also main topics of the following days together with

- PT on sampling,
- evaluation of qualitative PT,
- PT activities in developing countries.

These topics were addressed in keynote lectures and intensively discussed in working group sessions. The programme was complemented by the presentation of 77 scientific posters. Many of the lectures and posters as well as the summaries of the working group sessions are available from the workshop website (<http://www.eurachem2014.de>).



With some 250 participants from 64 countries the series of Eurachem workshops has obviously developed to one of the most important events on proficiency testing globally and will hopefully continue being successful in 2017.

EUROLAB-D wants to thank the sponsor organisations and in particular BAM Federal Institute for Materials Research and Testing and DRRR, a German PT provider, who provided staff for the support services during the workshop. Special thanks are due to Dr. Michael Koch, University of Stuttgart, and Roswitha Nüsser, BAM, who bore the main burden of the organisation of this very successful event.

### Main Turklab activities



#### **KALDER 23rd Quality Congress", 17-19 November 2014, Istanbul, Turkey**

TURKLAB, UDDER and CEOC participated and the Ministry of Economy chaired the session titled: "Safe Life, Safe Products and Services: Conformity Assessment"

Emerging new technologies, new products, consumer protection, increasing social awareness brings a new era to Testing, Inspection and Certification sector. TIC Sector is becoming more and more important in every field of our social life. Attendants of Quality congress showed high interest for this session. Dr. Mehmet Karabay, General Director for Product Safety and Inspection in the Ministry of Economy chaired the meeting and presented the importance of TIC sector for the Turkish economy. Mr. Simo Hassi, President of CEOC, presented data for the importance of TIC sector in the European trade activities and the future of the sector. President of UDDER, Ms. Ayfer Adıgüzel, made a presentation, titled "Importance of Conformity assessment in Product safety". National structure of TIC sector, importance of certification, results of Market surveillance activities, market share of TIC sector in Turkey and future perspectives. President of TURKLAB, Dr. Ömer Güzel, made a contribution to the national structure of Market Surveillance activities, statistical and research results from EU Market Surveillance projects.

#### **2nd National Laboratory Accreditation and Safety Symposium. 30-31 October 2014.**

Turklab is one of the supporting organizations of this symposium. The President of TURKLAB, Dr. Ömer Güzel Chaired the meeting titled: "Private Laboratory Practices".

Mr. Derya Turgay, member of TURKLAB, had a presentation on "Inspection Periods of Calibration and Important Criteria's for Calibration Certificates"

The total Number of participating delegates was 505, 20 oral presentations and 17 poster presentations .



Ankara Chamber of Industry, UDDER and TURKLAB organized a full day **PROD-UCT SAFETY SEMINAR**, 23 September 2014, in Ankara.

**General Secretary of Chamber of Industry , Assoc. Prof. Dr. Yavuz Cabbar made the opening speech. Mr. Jiri Sobola, EUROLAB, Dr. Mehmet Karabay, General Director of Product safety and inspection, Ministry of Economy, Mr. Muhsin Dere, Industrial Products Safety and Inspection General Director, Ministry of Science and Technology, Ms. Ayfer Adıgüzel, President of UDDER, Dr. Ömer Güzel, President of**



TURKLAB were key note speakers. "Product Safety and Legal regulations", "Market Surveillance and unsafe products", "products safety for producers and consumers" were three main topic for presentations. Turkish National Accreditation Body , TURKAK, Turkish Consumer Protection Associations TÜDEF, Turkish Construction Materials Producers Association, IMSAD, had presentations.



#### **Workshop on Construction Products, 19-20 September 2014, Istanbul.**

Mr. Jiri Sobola, President of EUROLAB, invited by TURKLAB, expert in the field.

The workshop was organized by TURKAK, NAB, and with the support of EUROLAB-TURKLAB and UDDER. The workshop was organized to discuss the PCR-EU Regulation No 305/2011 and adaptation to Turkish Construction Products Legal Documents. All parties in this area were invited to the workshop. First day assessors from NAB did participate. The second day Notified



Bodies shared the problems with NAB and National Authorities. This was the first work shop organized by an accreditation body and TIC sector in specific area.

## Accreditation

- The revised draft of **EA-5/02: EA guidance on the application of ISO/IEC 17020 in periodic inspection of the roadworthiness of motor vehicles and their trailers** has been submitted by the ad hoc Task Force Group to IC Members' for a 60-day commenting period.
- The following document **"Draft EAEX(14)18 rev1: Recognition of Accreditations issued outside the framework established by Regulation (EC) 765/2008"** has been circulated among members.
- IAF has circulated the draft document **IAF IDX: IAF Remote Assessments** for a 30 days comments period. This document is the result of the collaboration and consensus of the IAF Technical Committee Task Force on Remote Assessments.
- The **draft resolutions for the ILAC General Assembly** which took place on 17 October 2014 in Vancouver have been circulated among members
- The **Resolutions from the IAF 28th General Assembly** have been circulated among members.
- The **draft Policy Document - IAF PL5: Structure of the International Accreditation Forum, Inc.** was circulated to all IAF Members for a 30-day vote and it is now closed. Members voted in favour of the revision.
- With the publication of **IAF MD16:2014 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies** the MLA Committee is now accepting through the MLA MC, applications from the Regional Groups and unaffiliated Accreditation Bodies for the expansion of scopes to include Certification of Food Safety Management Systems at the level of **ISO/TS 22003:2013: Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems and ISO 22000:2005 Food Safety Management.**
- The draft document **IAF IDX: Information on the Transition of Management System Accreditation to ISO/IEC 17021-1:2015 from ISO/IEC 17021:2011** has been circulated for a 30 day comment period.
- IAF has submitted the Draft **IAF MD8:201X IAF Mandatory Document - Application of ISO/IEC 17011 for Medical Device Quality Management Systems (ISO 13485) (Issue 2)** for 30-day ballot period. The draft document specifies the criteria for the Accreditation Bodies (ABs) assessing and accrediting Conformity Assessment Bodies, which provide audit and certification against ISO 13485, in addition to the requirements contained with ISO/IEC 17011.
- IAF has submitted the Draft **IAF MD9:201X IAF Mandatory Document for the Application of ISO/IEC 17021 in the Field of Medical Device Quality Management Systems (ISO 13485) (Issue 2)** for 30-day ballot period. The draft document specifies normative criteria for CABs auditing and certifying organization's Quality Management System to ISO 13485, in addition to the requirements contained within ISO/IEC 17021.
- EA has resubmitted for a final round of comments a **draft of the revised EA - 4/15: Accreditation for Non-Destructive Testing.**
- The set of comments received by IAF on **IAF PL5:2014 - Structure of the International Accreditation Forum, Inc.** has been published on **IAF website ([iaf.nu](http://iaf.nu)).**
- IAF Technical Committee (TC) has submitted a revised IAF Mandatory Document titled: **IAF Mandatory Document - Determination of Audit Time of Quality and Environmental Management Systems (Issue 3)** for 30-day ballot to all IAF Voting Members.
- IAF is resubmitting the new IAF Informative Document titled: **IAF ID X:201X Transition Planning Guidance for ISO 9001:2015** to all IAF Voting Members for a second 30-day voting period.
- The result of the ballot on **New IAF MDX:201X: Witnessing Activities for the Accreditation of MS Certification Bodies** have been circulated among members. Members voted in favour of the revision.
- After a recent ILAC Arrangement Council ballot, the continuation of recognition for the Asia Pacific Laboratory Accreditation Cooperation (APLAC) as a Recognised Regional Cooperation Body of ILAC has been confirmed. The recognition of the APLAC MRA should be continued for the accreditation of calibration and testing laboratories using ISO/IEC 17025, medical testing laboratories using ISO 15189 and inspection bodies using ISO/IEC 17020.
- A new draft document titled **EA-2/XX M "EA Document on the Confirmation of the Continuation of Accreditation based on the Results of Surveillance Activities"** has been circulated among members for comments.
- **The ballot on the approval of revised EA-1/22 EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Members** has been closed. The document is approved and will be published soon.

## Standardisation

- The list of resolutions of the 19th ISO/TC 135 Plenary meeting of 11th October 2014 has been circulated among members.
- The following appointments concerning the ISO/CASCO Working Group in charge of the revision of ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories (ISO/CASCO WG44) have been communicated: **Convenor: Mr. Warren Merkel nominated by ILAC; Co-convenor: Mr. Steve Sidney nominated by SABS; Second co-convenor: Mr. Heribert Schorn subject to confirmation by IEC.** The first WG44 meeting will take place from 10-12 February 2015, in Geneva, Switzerland.
- The following committee internal ballots (CIB) have opened for a period of 6 weeks: - **application of Quest Forum for A liaison with CASCO;** - **application of WADA for D liaison with CASCO WG44 revising ISO/IEC 17025**
- The complete **Report (minutes) and presentations of the 30th CASCO Plenary Meeting** which was held in Geneva, Switzerland, 24-25 September 2014 have been circulated among members.
- The **ISO/TC 234 - Fisheries and aquaculture report to the ISO/TC 34/SC 17 - Management systems for food safety plenary meeting** which took place on 19th September 2014 has been circulated among members
- The following ballot has opened: **Programme for the Endorsement of Forest Certification (PEFC), Application for D liaison status with CASCO/ WG42 carrying out the revision of ISO/IEC 17011:2004.**
- The ballot on **ISO/TC 34/SC 17 N 336 regarding the possibility of SC 17 members providing comments on ISO/IEC DIS 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements** has closed.
- The detailed results of the voting on **ISO/TC 34/ SC 17 N 336 regarding the possibility of SC 17 members providing comments on ISO/IEC DIS 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements** have been circulated among members.
- The new quality document of CASCO "the common elements in ISO CASCO Standards" that replaces the 5 CASCO PAS (17001 to 17005) has been circulated among members.
- The results of the **Committee Internal Ballot (CIB) on the applications for A liaison with CASCO and D liaisons with CASCO WG42** have been circulated among members. CASCO members accepted the application of NCSL International for A liaison status with CASCO and the application of ISEAL for D liaison with CASCO WG42 revising ISO/IEC 17011.
- Following the end of the term of office of Mr David Bell as Chairman of the CEN Certification Board (CCB Chair) on 31st December 2014, Mr Pambos Kammass has been nominated to succeed David Bell as CCB Chair.
- The **Report of the 22nd CPC Meeting (Chairman's Policy and Coordination Group)** held on 23rd September in Geneva, Switzerland has been circulated among members.
- The results of the closed ballots on **Committee internal ballots (CIBs) on Quest Forum application for A Liaison with CASCO WADA and the application for D liaison with CASCO WG44** have been circulated among members.

## Business News

### Other news

- In the third quarter of 2014, Core Laboratories N.V. (NYSE: "CLB US" and Euronext Amsterdam: "CLB NA") posted the most profitable quarter in Company history. The record results were driven primarily by new, or recently introduced, technology and related services by Core's Reservoir Description and Production Enhancement operations, in addition to Reservoir Management operations' most profitable third quarter ever. <http://tinyurl.com/lbwzobh>
- CORE LAB has announced a cash dividend of \$0.50 per share of common stock payable in the fourth quarter of 2014. <http://tinyurl.com/lwa3o84>
- Advanced Biological Laboratories (ABL), S.A., the University of Hong Kong and the Hong Kong Polytechnic University have launched their collaborative tuberculosis (TB) project to develop a deep-sequencing assay and its tailored bio-informatics pipeline. This aims to enable early and improved diagnosis of TB when there is an increasingly drug resistant strains of TB emerging world-wide with multi-drug resistance. <http://tinyurl.com/mmyk69m>
- ABL has announced a new collaboration with the New Zealand Liver Transplant Unit and LabPlus at Auckland City Hospital. This will evaluate the susceptibility to develop Hepatocellular Carcinoma (HCC) during 30 years follow-up, based on key baseline genomic variations of HBV in a large cohort of Maori.
- ALS Industrial has secured the Inside Battery Limits, Structural Mechanical and Piping, Non Destructive Examination (NDE) services contract with Bechtel on the Chevron-operated Wheatstone Project in Western Australia. <http://tinyurl.com/m96sz6d>

- **Health and Safety Executive (HSE) reports published in the Guardian newspaper (Ian Sample, Science Editor, 5th December 2014) revealed that UK-based high-security laboratories that handle the most dangerous viruses and bacteria have reported more than 100 accidents or near-misses to safety regulators in the past five years.** The reports show that over 70 incidents at government, university and hospital laboratories were serious enough to merit HSE investigation. <http://tinyurl.com/kx5whp3>
- **Bureau Veritas has initiated a workshop between Chinese and French authorities to share experience about the deregulation of the Testing, Inspection and Certification (TIC) markets**
- **Bureau Veritas Consumer Products Services India Pvt Ltd. has announced that The Bureau of Indian Standards (BIS), the National Standards Body of India has recognized it as an approved laboratory to test toys and juvenile products as per Indian Standards – IS 9873.**
- **CSA Group has opened a new hazardous locations laboratory in Plano, Texas, United States.** It will offer testing and certification services to the requirements of national and international standards mainly for hazardous locations products. This involves testing of equipment that is used in a location where there is potential for explosion due to airborne particles or fumes, and it is vital to help limit the potential for a serious accident.
- **DEKRA has announced that the StreetScooter electric delivery vehicle was expected to enter the pilot production phase soon.** Currently being performed, the tests are expected to be completed in the coming weeks.
- **Eurofins Scientific (EUFLPA) has signed a definitive agreement to acquire Boston Heart Diagnostics Corporation (Boston Heart), a portfolio company of Bain Capital Ventures, for an initial value of \$140 million, subject to post-closing adjustments, plus an earn-out payment to the sellers that is expected to be in excess of \$60 million upon achievement of certain milestones.** <http://tinyurl.com/n8xoapc>
- **Eurofins has acquired US food and environmental testing laboratory SF Analytical Laboratories for an undisclosed sum.** Based in New Berlin, Wisconsin, SFA specialises in food microbiology, food chemistry, consultative analysis and environmental chemistry. <http://tinyurl.com/ly823pa>
- **Eurofins Genomics, the genomics division of the Eurofins Scientific Group, has now achieved Good Laboratory Practice (GLP) certification for DNA sequencing services.** <http://tinyurl.com/mb4lc5r>
- **Eurofins Scientific (EUFLPA) has announced the launch of rapidust®, the first on-site test system for mycotoxins, including both representative sampling of grain lots and rapid analysis, to provide broader risk protection across the grain industry regarding mycotoxin contaminations.** <http://tinyurl.com/mfm9pzn>
- **Intertek has entered an agreement to provide analytical laboratory services to Statoil in Kalundborg, Denmark.** Under the agreement, Intertek will acquire Statoil's analytical laboratory in Kalundborg which will transfer to Intertek over the next six months. Kalundborg, on the island of Sjaelland, is a hub for North Sea crude oil deliveries, refinery processing, and increasingly for the production of new environmentally friendly 'green' fuels.
- **Intertek has acquired ScanBi Diagnostics, a Swedish company providing global high-technology DNA and protein based accredited analyses and quality services for the agro-biotech, seed, agriculture, food, and feed industries.** As part of the transaction, Intertek has also acquired 50 percent ownership of Lynx Diagnostics, a Canadian company providing testing of seed breeding and production materials for the North American market.
- **Intertek has completed the application process for an exemption, under the EU RoHS Directive, on behalf of their customer, Instrumentation Laboratory, Bedford, MA USA.** This exemption covers proprietary blood gas analytical instruments currently being supplied to hospitals, clinics and laboratory around the world, and will ensure the customer continued access to the EU market.
- **Intertek has expanded particle size distribution testing to meet industry's growing interest in nanotechnology.** Intertek can now offer dry feeder particle size testing capability, enabling direct determination of particle size in the 10nm-3mm range using laser light scattering.
- **Intertek has expanded its North Dakota Shale Oil & Gas service capabilities with a new, state-of-the-art 10,000 square foot laboratory in Bismarck.**
- **Intertek has entered into a new contract with Santos, an oil and gas producer, to provide quality assurance, technical inspection and testing services in Australasia region.**
- **Lloyd's Register Energy is launching a series of executive engagements around the globe to help facilitate industry discussion on key challenges the energy sector is facing.** In particular it has launched at Adipeq 2014 in Abu Dhabi, the largest oil and gas gathering in the Middle East.
- **SGS has announced the launch of a new, searchable web-based database of analytical methods.** The new tool contains biopharmaceutical, biosafety, and bioanalysis methods, and provides an overview of SGS's analytical development expertise and experience, enabling a quick and easy identification of suitable methods to optimize the R&D and manufacturing processes.
- **SGS has announced the opening of a new, fully equipped laboratory in Banjarmasin, South Kalimantan, Indonesia for the analysis of coal.**
- **SGS Life Science Services, the pharmaceutical analytical and bioanalytical contract solutions provider, has announced further investment in the French market, with a new facility in Villeneuve la Garenne.** The new location, which will replace an existing laboratory in Clichy, complements SGS Life Science Services' strategy to increase its Quality Control service throughput and support an ever-expanding research and development pipeline of new biopharmaceutical drugs within the country.
- **TÜV SÜD Japan Ltd. is now a partner of ESPEC Cooperation, a manufacturer and operator of environmental test chambers in Japan.** In this field, ESPEC and TÜV SÜD are currently expanding ESPEC's existing battery laboratory into a one-stop test centre for large-sized battery systems. The objective is to offer a

full range of tests for drive batteries of electric cars, making Japan a further location in TÜV SÜD's international network of battery laboratories.

- **TÜV SÜD has opened its new testing centre in Shenzhen. The new location expands the company's laboratory space to over 10,000 sqm.** The testing centre accommodates four testing laboratories for electrical and electronic products (E&E), electromagnetic compatibility (EMC), toys and chemical testing.

### Business Results

#### **DEKRA (report)**

- Revenues increase by more than 7% to €2.5 billion in 2014
- Growth by 2,000 to nearly 35,000 employees
- Service portfolio and market position expanded with acquisitions

#### **Bureau Veritas (report)**

- Q3 revenue of €1,065 million, showing solid growth of +11.4% at constant currencies
- Stronger organic growth of +3.2%
- Solid contribution to growth from acquisitions: +8.2%

#### **Intertek (report)**

- Group revenue increased by 2.5% at constant exchange rates
- Acquisitions made in 2013 and 2014 contributed 3.2% to Group revenue

#### **Eurofins**

**Eurofins has announced a strong Q3 2014 performance on continued positive trends.** Revenues increased 18.6% in Q3 2014 to EUR 370m (18.9% at constant currency exchange rates), bringing revenues in the first nine months to over EUR 1 billion.

- Group organic growth\* in Q3 2014 was 5.5% (7.5% excluding businesses in significant restructuring). For the first nine months of 2014, group organic growth stood at over 6% (over 8% excluding businesses in significant restructuring).
- Strong performance across most areas of our business.

### Policy news

### Chemicals

- The Committee for Risk Assessment (RAC) and the Committee for Socio-economic analysis (SEAC) have agreed on restriction proposals and have evaluated applications for authorisation, agreeing on 43 draft opinions for individual uses. <http://tinyurl.com/kf5pnug>
- New improved version of R4BP 3 is now available. The newly released version of R4BP 3, the central hub through which all biocides applications are made, provides significant additions and improvements. <http://tinyurl.com/nxrc5bo>
- To support innovation, especially by SMEs, ECHA has published an update to its [Guidance on Scientific Research and Development \(SR&D\) and Product and Process Orientated Research and Development \(PPORD\)](#) simultaneously with a new [Guidance in a nutshell](#) on the same subject. <http://tinyurl.com/lafufbx>
- [The Forum for Exchange of Information on Enforcement](#) has decided that its next major project will focus on enforcing REACH Annex XVII restrictions. The scope and individual restrictions to be covered will be confirmed in early 2015. The Forum has also agreed on two new smaller scale pilot projects. <http://tinyurl.com/mmwut7o>
- ECHA has prepared a proposal to update the Community rolling action plan (CoRAP). The draft plan contains 134 substances that are proposed to be evaluated in 2015-2017 by the Member States under the REACH Regulation. <http://tinyurl.com/lt5shld>
- The new work programme for the systematic examination of all existing active substances contained in biocidal products has entered into force. This new regulation updates the on-going review programme to fit the processes of the Biocidal Products Regulation and allows new active-substance/product-type combinations to be included in specific cases. <http://tinyurl.com/poz9zpf>

- ECHA has launched a new online tool, the SPC editor, to be used by companies and authorities for the authorisation of products and product families under the Biocidal Products Regulation (BPR). The new SPC format will be mandatory for new product authorisation from December 2014 onwards. It will not be mandatory for the renewal of a product authorisation. <http://tinyurl.com/o7pxurl>
- ECHA has organised a two day scientific workshop on regulatory challenges in risk assessment of nanomaterials. The purpose of the workshop was to foster discussions among academia, regulators, industry and other stakeholders on the possible regulatory impacts that the latest scientific developments may have. <http://tinyurl.com/nf6gvjo>
- ECHA has urged all companies to start preparing for the REACH registration deadline of 31 May 2018. To support this, ECHA has published new web pages with improved access to relevant information. This registration deadline concerns substances manufactured or imported in low volumes, 1 to 100 tonnes per year. <http://tinyurl.com/qh9z6o2>
- The Biocidal Products Committee (BPC) has adopted 10 opinions which concern, and support the approval of, the following active substances and their product-types (PTs): glutaraldehyde; clothianidin; 2-Methylisothiazol-3(2H)-one (MIT); N,N'-Methylenbismorpholine (MBM). The fields of application include active substances for use in biocidal products used as disinfectants, preservatives and insecticides. <http://tinyurl.com/ndrjb9x>

### Consumer Protection

- According to the [structural changes](#) communicated by Jean-Claude Juncker, the President of the new European Commission that has officially started its term of office, Directorate SANCO B (Consumer Affairs) will move from DG SANCO to DG Justice (JUST), except for Unit SANCO B2 (Health Technology and Cosmetics), which will move from DG SANCO to DG Enterprise and Industry (ENTR).
- After seven years of work, Dr. Edmund Stoiber, the Chairman of the independent High Level Group on Administrative Burdens, has handed over the group's [final report "Cutting Red Tape in Europe – Legacy and Outlook"](#) to President José Manuel Barroso.
- The conclusions and subsequent nine recommendations of a [study related to consumer protection aspects of financial services](#) have been presented by its authors from London Economics to Members of the IMCO Committee. A research team from Osnabrück University has presented a [study on discrimination of consumers in the Digital Single Market](#), which assesses discrimination from the perspective of different areas of European law and provides for several policy recommendations.

### Environment

- At the [sixth European Union-United States Energy Council](#) senior EU and US officials said that the cancellation of the South Stream pipeline project will not make the European Union more vulnerable to shortages caused by Russia cutting off gas to Ukraine.
- The International Energy Agency has published its [2014 review of EU energy policy](#). According to it, the European Union will remain dependent on Russian pipeline gas imports for the "foreseeable future".
- According to the Climate Policy Initiative report '[Global Landscape of Climate Finance 2014](#)', global investment in climate change reduction has fallen for the second year in a row, a drop of \$28 billion from 2012.
- The European Court of Auditors has published a special report '[How do the EU institutions and bodies calculate, reduce and offset their greenhouse gas emissions](#)'. It shows that green building standards and initiatives promoted by the EU for greater efficiency were not consistently employed for new buildings or major renovation projects during the period 2005-2013.
- Policy Department A has prepared a study on '[Environment and Climate Policies](#)'. Requested by the European Parliament's Committee on Environment, Public Health and Food Safety, this study reviews the state of play of on-going EU environmental legislation and pinpoints key issues for Europe in the area of environmental and climate policies for the next five years.
- European Union Heads of State and Government have agreed the headline targets and the architecture for the EU framework on climate and energy for 2030. The agreed targets include a cut in greenhouse gas emissions by at least 40% by 2030 compared to 1990 levels, an EU-wide binding target for renewable energy of at least 27% and an indicative energy efficiency target of at least 27%. <http://tinyurl.com/jweye6g>
- The European Commission has presented a first-ever analysis of the consequences of a disruption of Russian gas supplies, or even a complete halt of such imports to the Union, and neighbouring states. <http://tinyurl.com/kgthjp8>
- The European Commission has published an [interim report providing the first full dataset on energy costs and subsidies](#) for the 28 member countries across the different power generation technologies. It reveals that the largest share of public intervention in the energy sector has been in favour of solar and on-shore wind energy.

## Food

- Food Information for Consumers (FIC) legislation should allow manufacturers to choose whether to label ingredient origins to avoid costly, complicated and unnecessary changes, say suppliers. <http://tinyurl.com/jw3q4qo>
- On European Antibiotic Awareness Day, BEUC kicked off a [campaign](#) urging the EU institutions to restrict antibiotic use among livestock so as to reduce resistance. The use of antibiotics should not be a first reflex for humans when ill<sup>2</sup>, but this needs to apply to farm animals also. <http://tinyurl.com/m8ff3kj>
- The European Parliament and the Council have reached a provisional political agreement on the draft legislation on GMO cultivation. The proposal, still subject to confirmation by Coreper and by the plenary of the European Parliament, will give Member States the possibility to restrict or prohibit the cultivation of GMOs on their territory, without affecting the EU risk assessment. <http://tinyurl.com/knd6gtr>
- The European Commission has published a new foresight report '[Tomorrow's Healthy Society – Research Priorities for Foods and Diets](#)'. As main food research priorities to 2050, the study identifies the individualised diets, sustainability, integrated policy-making and consumer awareness of the link between food and health.
- As part of the European Week for Waste Reduction, Food-DrinkEurope has published a report showcasing the concrete actions being taken by Europe's food and drink manufacturers to tackle food wastage both within their own operations and up and down their supply chains. <http://tinyurl.com/n3h49b3>
- The European Parliament's Committee on Environment, Public Health and Food Safety has adopted its [draft report on the European Commission proposal for a regulation on novel foods](#). MEPs has proposed a moratorium on the use of nanomaterials in food, based on the precautionary principle. They have also added provisions for compulsory labelling of cloned food products. <http://tinyurl.com/kpshtk>
- The European Parliament's Committee on Environment, Public Health and Food Safety has adopted its long-awaited draft plans regarding the cultivation of crops containing genetically modified organisms (GMOs). MEPs have voted to remove the Council-backed idea of a phase of negotiations with the GMO companies, and supported plans to allow EU member states to ban the cultivation of GMO crops in their own territory even if it is allowed at EU level. <http://tinyurl.com/m3xvvy>
- The impact of 'sin taxes' on competitiveness and consumption habits, food prices, and sustainability were the key points on the agenda for the European Commission's High Level Forum for a Better Functioning Food Supply Chain. <http://tinyurl.com/ka5q8je>
- The ingredient list and a lack of additives or 'artificial' ingredients are the most important considerations for consumers when making a food purchase after price, says a new report on clean label in Europe. <http://tinyurl.com/o4hd7zi>
- The European Food Safety Authority (EFSA) has published scientific opinions on dietary reference values (DRVs) for [zinc](#), [selenium](#) and [chromium](#). They are part of EFSA's on-going review of existing advice on DRVs for energy, macronutrients and micronutrients.
- The European Food Safety Authority (EFSA) has published an [explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment](#). It builds on the principles set out in EFSA's previous guidance document on 90-day whole food/feed studies in rodents published in 2011.
- The European Food Safety Authority (EFSA), in collaboration with Wageningen University and Research Centre, in the Netherlands, has developed new [software which provides stakeholders with a tool for carrying out complex data analysis as part of the risk assessment of genetically modified \(GM\) plants](#). The user-friendly program can be downloaded free of charge from EFSA's website.
- The European Commission has adopted the [final report of the High Level Forum for a better functioning food supply chain](#). It describes the work conducted in the second biennium 2013-2014 and reflects the outcome of the deliberations of its members in the following areas: business-to-business trading practices, Internal Market for food and drink products (e.g. on food taxes), sustainability, social dialogue and food price monitoring.
- The European Commission has published a new document – [Taking stock of EU Public Health, Food Safety, Animal and Plant Health Policy achievements 2010-2014](#).

## Medical Devices

- The European Parliament's Committee on Environment, Public Health and Food Safety has [voted on entering into inter-institutional negotiations with the Council](#) in view of early second reading agreements on the proposals for regulations on in vitro diagnostic medical devices and on medical devices.
- [The Council has discussed progress in talks on 2 draft regulations on medical devices and in vitro diagnostic medical devices](#). The progress report, which was drafted by the Italian presidency, shows issues where further discussion is needed to hammer out the Council's position.
- The European Commission has published the [preliminary opinion of the Scientific Committee on Emerging and Newly Identified Health Risks on "The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk"](#) (2014 update) and launched a public consultation open until 30 November, 2014.
- The European Commission has published the [final opinion of the Scientific Committee on Emerging and Newly Identified Health Risks on "The safety of Metal-on-Metal \(MoM\) joint replacements with a particular focus on hip implants"](#).

## Transatlantic Trade and Investment Partnership (TTIP)

- Policy Department A has prepared a study on the 'ENVI Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations (TTIP)'. It analyses the main differences between EU and US legislation in eight areas, namely: human medicines and medical devices, cosmetics, food and nutrition, sanitary and phyto-sanitary, nanomaterials, cloning, raw materials and energy, and motor vehicles.
- At the sixth European Union-United States Energy Council US and EU TTIP negotiators have discussed the possibility of an energy chapter. <http://tinyurl.com/oox4xrn>
- The European Commission has published 2 papers: 'A draft outline for provisions on chemicals in TTIP' and 'How to put ideas for cooperation under TTIP into practice – a few examples'. The papers set out ideas for how EU and US regulators could work together in future on things like testing, classifying and labelling chemical products.
- According to Ignacio Garcia Bercero, *Director in DG Trade of the European Commission*, the EU will not change its food safety legislation under the negotiation for the Transatlantic Trade and Investment Partnership (TTIP). It means that GMOs can be marketed in the EU only once they have been authorised, and beef from the USA would be marketable in Europe only if it is hormone free. <http://tinyurl.com/12fkxft>

## Industrial Policy

- In order to move forward its plans for an 'industrial renaissance', the European Commission has to focus on creating a framework that will encourage the new industries of tomorrow, like photonics, writes Michael Martin, President of Photonics21, a European technology platform. <http://tinyurl.com/o9pjum5>
- In August 2014 compared with July 2014, seasonally adjusted production in the construction sector grew by 1.5% in the euro area (EA18) and by 0.5% in the EU28, according to first estimates from Eurostat, the statistical office of the European Union. <http://tinyurl.com/lnk7jzq>

## Transport

- A new study produced by the Transport Research Laboratory for the European Commission, DG MOVE, has found considerable potential safety benefits and low costs for the installation of Electronic Data Recorders (EDRs) in cars, vans and lorries. <http://tinyurl.com/n88bb72>
- The European Union has underestimated the greenhouse gas emissions savings offered by biofuels by as much as 50%, according to an Ecofys report. <http://tinyurl.com/px3n7kc>

## Public Consultations and Call for Tenders

- The European Commission has launched a stakeholder consultation on exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive). Deadline: 9 January 2015.
- ECHA is currently undergoing a public consultation of the restriction proposal regarding Bis (pentabromophenyl) ether (DecaBDE). Deadline: 17 March 2015.
- ECHA has launched a public consultation of the harmonised classification and labelling (CLH) for methylhydrazine. Deadline: 2 January 2015.
- The European Commission has launched a call for tenders 'Supporting study for the Fitness Check on Construction Sector'. Deadline: 23 January 2015.
- The European Commission has launched a call for tenders 'Inter-laboratory trial of textile fibres, including testing and related services for the technical analysis of 'polyacrylate' fibre'. Deadline: 12 February 2015.
- The Commission and the Scientific Committee on Emerging and Newly Identified Health Risks have launched a public consultation on the preliminary opinion on "The safety of dental amalgam and alternative dental restoration materials for patients and users". Deadline: 16 November 2014.

## The EUROLAB President, Jiří Sobola, attended the ILAC GA, AIC, ARC, LC and ILAC WG PT meetings in Vancouver, from 08 to 18/10/2014

Topics discussed:

- **ILAC IC WG 4:**

- It is necessary to assess real situation and identify what competences inspection body needs then select relevant clauses from either of standards and to resolve how accreditation certificate will look like when only some clauses from ISO EN 17025 are added to accreditation of an inspection body. This document should be informative document not a binding guidance.
- It was required by EUROLAB that specific requirements should be mentioned in an accreditation certificate for specific inspection in question.
- New logic of the document: Case studies will be reworked and EUROLAB cases will be considered / included. The new version close to final draft will be ready for Frankfurt meeting in April. Examples of the scope of accreditation should also be given in this document.

- **Inspection Committee**

- APLAC did a research on sampling as a standalone activity; only two responses were received, only one AB is accrediting sampling against ISO EN 17020 as a standalone activity.
- CNAS (China) provided a paper on the activity on inspection of pressure vessels document to be studied by EUROLAB
- Ilan Laan is not standing for re-election as IC chair. There is one candidate so far – Arne Lund from SWEDAC. Agenda will be handed over to new chair till end of this year.

- **IAAC IC Report**

- PTB project on energy will be discussed in workshop to harmonise the approach to P15. Accreditation in efficiency of energy is under discussion as some countries have programme for their area. Inspection bodies studied P15 and provided feedback to ABs on implementation of ISO EN 17020. EUROLAB should make clear position to this paper along with ILAC P10 and P9; P15 is guidance not requirement.
- EUROLAB Annual report was appreciated as nice documents and all cases where ILAC was mentioned were quoted. 2014 issue should contain review of ILAC IC activities, positions and contributions of EUROLAB to these items.

- **ILAC IC WG3**

- WG 4 Examinations and tests performed as a part of the inspection: Clause 6.3.1 implies that under certain conditions relevant requirements of ISO EN 17025 will also apply. Bridge between ISO EN 17020 and ISO EN 17025 need to be expanded via clauses like equipment, personnel, etc. EUROLAB should focus on this issue.
- We will identify applicable requirements of ISO EN 17025 like method of validation, traceability, etc. ILAC IC should identify when and how these requirements apply. EUROLAB is asked to provide examples applying to this methodology

- **Meeting ILAC IAC**

- ILAC P13 will not be reviewed
- Documents submitted by EUROLAB were quite appreciated and chair recommended to visit EUROLAB website to see interesting information.
- BIPM workshop on Carbon measurements will take place – it is new field of measurements which should expand EUROLAB interests to provide relevant information for laboratories.
- WG2: ILAC G17 – is written in a way that brings even more uncertainty to this issue. Revision is needed. It is important to validate methods and use the appropriate methodology
- **In-house calibrations** - EUROLAB may establish opinion of laboratories if they want internal calibration to be specified in the scope or not. Some ABs require labs to issue calibration certificate which is not very correct because such a calibration certificate can then be used even outside that would not be correct. ILAC is of the opinion that no ILAC guidance is necessary. ILAC G8 – guidance on reporting compliance with specifications: It is important to establish how uncertainty is to be used and included in the decision making processes. LC and EUROLAB should have view on this.

- **WG ISO EN 17025**

- The situation in LC was discussed and EUROLAB was assured of its direct membership in this group (EUROLAB can present its positions regardless LC).
- ILAC co-convenors will be nominated, 2 other members also. ILAC executive did not make decision yet.
- Some National standardisation bodies are suggesting representatives from ABs as their representatives. EUROLAB should promote laboratory representatives here.
- EUROLAB will prepare its White Paper for the revision of ISO EN 17025. Ms Mingxia Zhang will be temporary convenor for this group and will be preparing a White Paper on behalf of AIC for which EUROLAB White Paper should be the base.
- WG 3 reference materials – Lorraine Turner, membership was open for EUROLAB
- WG for converting ISO Guide 34 to standard. There should be a nomination for the representative to CASCO WG. Any comments should be sent to Lorraine before the end of October. CASCO WG is meeting in December; [lorraine.turner@ukas.com](mailto:lorraine.turner@ukas.com)
- WG5 – sampling – it is dormant WG but EA – is working on sampling as standalone activity where EUROLAB should be involved. Sampling is generating more uncertainty than measurements and tests. US are preparing big document on good sampling especially for food and feeds. It is defining size of sample for decision makers and regulators in particular. Document will handle qualification of those performing sampling.
- **APLAC:** Opinions and interpretations will be put on agenda for next meeting. EUROLAB view was in contradiction to EA report which requested special assessment and mentioning it in the scope.
- ARAC has 15 members. EUROLAB informed about the Mediterranean policy and possibilities for assistance in establishing national associations of laboratories and benefit from EUROLAB membership. ARAC representatives will assist EUROLAB in contacting proper persons.
- ILAC G11 will be revised.

- Future meetings: Frankfurt, 9-10/4 AIC, 11/4 PT

- **Laboratory Committee**

- EUROLAB amended the agenda for the issues discussed in EUROLAB GA.
- Steve Sidney was elected as a chair of LC. Candidature of Jiri Sobola did not go through. Only 8 members of LC were present but 5 proxies were decisive for vote.

- **ILAC Strategic Plan**

- It is looking into the future covering the period until 2020.
- There was no change to ILAC Vision. The mission statement was reworded but no substantial change was made.
- It is clear now that strategic plan is so ambitious that it can hardly be implemented in full.

- **ILAC/IAF Joint General Assembly**

- Meeting 2016 will be in India. It is a new development that ILAC/IAF are asking members to host the meeting (pay costs) but secretariats will decide on the venue, date, programme, etc.
- The new principle is that the host country will be responsible for logistics while secretariats will take care of the registration.

- **General assembly IAF**

- All resolutions were approved

- **Resolutions**

- Ukraine was admitted as associate member. Accreditation of RM producers and PT providers was not approved. Majority was in favour but not reaching 75% majority. It was justified that it would be better to wait for new standard ISO 17034. The main reason for voting was a letter from EC guiding EU ABs to accredit only against harmonised standard which means in reality that accreditation against ISO G34 cannot be provided by EU ABs (G34 is neither standard nor harmonised) while the rest of the world would do it and eventually offer these services in Europe. EUROLAB should monitor carefully this issue.

## **The EUROLAB President, Jiří Sobola attended the EA General Assembly in The Hague, 18-21 November, 2014**

- **During the presentation of the report, the Chairman touch upon several aspects:**

- It is necessary to harmonise EA 2/17 with Blue Guide
- The use of external (outside EU) accreditation body: R765 requires to use national accreditation body; in relation to this there were discussions on the conditions under which it is possible to use AB from third parties. This must be negotiated and explained.
- EAAB revised its expectations towards accreditation.
- There will be elections in May, the Chair will stand for re-election.
- Budget: EC projects were nearly completed. There is improvement in communication with EC in area of projects.
- There will be a regulation concerning disposal of IT technology especially export of this "waste" outside Europe.
- Minutes from these meetings will be made available after this GA.
- Closer cooperation between EA and different DGs. The secretariat will prepare one comprehensive document describing all activities toward EC. The major aim is to inform EC about EA rules and rules which EA must observe from ILAC and IAF.

- **Accreditation for notification**

- The objective is to find proper combination of standards for each directive. The WG started with 12 directives and the work will be finished in January and the remaining 16 directives will be solved.
- NBs will work according to several directives; experts are needed for vessels recreation, explosives for civil use and radio technology
- EA is preparing recommendations, not mandatory documents trying to convince that this is the way to harmonisation.
- In 2015 cooperation with stakeholders and discussions with EC will start at the same time.
- Accreditation should establish the level playing field for notified bodies. Technical discussion must be separated from political discussions. Stakeholders will be selected by EC and EAAB. EUROLAB should be in touch with EA SG and get involved in the discussions.

- **ERA Project – interoperability railways.**

- Experts were nominated from EANAC, Swedac, Latvia and SG.
- The project plan is very detailed and the project should be finalised in 2015. EUROLAB should be involved.

- **Quality Manager report**

- Peer evaluation by ILAC and IAF was finalised. The results are very good and all operations are in line with ILAC rules.
- IQNET and EEPKA asked for registration as stakeholder of EA. It was accepted. EEPKA is a certification system dealing with testing and certification of electro technical products using accreditation IEC. There is MOU between EEPKA and EA so this is just an extension of this MOU in order to become recognised stakeholder.

- **HHC**

- The main objective was to clarify unclear parts of 17011 like 4 eyes principle. The document will provide the option that 4 eyes principle is necessary. The document is not mandatory but once you decide to use it becomes mandatory.
- Benchmarking activities will continue and are the key for substantiating and justifications.
- Sampling as standalone activity - in March there will be new document on this issue
- Surveillance and reassessment – subject of revision ISO 17011.

- HHC will create the corpus of knowledge on accreditation and ISO 17011.
- EA 2/17 – has been approved by EA but disagreed by the EC, no clarity on the further steps that have to be taken.

- **International cooperation**

- It is necessary to establish WGs which will analyse ILAC issues and make proposal on how to proceed at ILAC committees' meetings. Preparation of position papers and distribution documents within EA is necessary.
- Preparations for elections at IAF/ILAC level.

- **EAAB Report**

- EAAB is of the opinion that the paper on AB accredited outside EU and providing service within EU is not necessary as it is resolved by 765 itself.
- P10 is to be properly interpreted and should not be interpreted in "must" position. There is an attempt from EA to make P10 more strict for EU and avoid option 3. EUROLAB should pay attention. EA is accepting EAAB paper on stakeholder's expectations.

- **Communication**

New programme for liaison engagement should be explored by EUROLAB. Publishing news will be improved. Publications will be available on internet with possibility of downloading.

- **EA Inspection committee**

- ILAC WG 4 - testing as part of inspection: Document will be ready for comments in April 2015. EUROLAB position is needed.
- Next IC meeting will be on 5-6 March 2015 in Bern, 8/10 in Tallinn

- **Certification committee**

- CC is handling national regulatory certification schemes. Service to authorities is main duty of ABs. ABs should be involved in establishing such schemes. New schemes are under discussion with EC where CC is involved.
- WG GHG – competence of verifiers is discussed. EUROLAB should discuss its representation in these WGs or coordination with CEOC.

- **EA LC**

- Eurachem guidance on accreditation of microbiological laboratories was adopted by EA
- EA 4/20 G :2014 – assessment against ISO 15189 – was prepared.
- EA 4/15 accreditation for non-destructive testing is in commenting period until 10<sup>th</sup> January.
- Opinions and Interpretations – it is normal requirement of ISO 17025, approach of ABs should be harmonised especially to regulatory area. There are big differences among ABs and strong positions. There was also strong discussion, new version will be ready next year. WG for ILC in testing is supporting added value for accreditation when labs are taking part in international ILC. EUROLAB TFG is to be fully involved here.
- The technical network for Food and Feed was established. DG Sanco will be involved.
- EUROLAB White Paper on revision of 17025 was appreciated and will be used by ABs
- EA should provide technical reasoning why Guidance is needed for the use of ISO Guide 34.

### **Magnus Holmgren attended the EEE-PT meeting in Rome, 29th-30th May 2014**

- **The main points tackled during the meeting were the following:**

- Guidelines in the assessment of inter-laboratory comparisons with few participants
- This document has been discussed for a long time and it has been changed dramatically several times. The present version is according to the EUROLAB representatives in the group to prescriptive and places too much burden on the laboratories. The document will be changed and recirculated to the group for discussions during next meeting.

- **PT for sampling**

- The group will develop such a document. Ian Mann will produce a draft to be circulated before next meeting. HHC acknowledged that it is the relevant forum for discussing revision of ISO/IEC 17011. HHC will set up a specific EA WG to support CASCO work.
- Next meeting, 18th and 19th November.

### **Magnus Holmgren attended the HHC meeting in Brussels, 16-17th September 2014**

- **The following points were mainly highlighted in the meeting:**

- Recognition of accreditation issued outside of the regional framework of Regulation 765/2008
- HHC approved the draft policy paper and agreed to fine-tune it based on the comments made during the meeting. The revised paper will be distributed for comments in HHC for a 2-weeks period.
- EA/HHC input to CASCO work
- HHC acknowledged that it is the relevant forum for discussing revision of ISO/IEC 17011. HHC will set up a specific EA WG to support CASCO work.

- **Revision of EA-2/17**

- HHC endorsed the final draft which was presented at the meeting. It will be circulated for EA voting.

- **Revision of EA-1/22**

- HHC endorsed the final draft of the document. The draft will be finalized to take account of the editorial suggestions made during the meeting and then circulated for EA voting.

## Manfred Golze and Irache Viviers attended the EA Laboratory Committee in Winsor, 10 – 11th September 2014

During this meeting of the EA Laboratory Committee (EA LC) two main topics were discussed in detail:

- **Opinions and interpretations (O&I) in test reports**

- EUROLAB's survey as well as an EA survey later on revealed considerably different approaches of the National Accreditation Bodies (NABs). Trevor Thompson, the convenor of the respective Task Force Group (TFG), gave a presentation and EA LC was invited to comment on his presentation by the end of November 2014.

- **Future Multilateral Agreement (MLA) for the accreditation of Proficiency Test Providers (PTP) and Reference Material Producers (RMP)**

- Mario Mosca, the convenor of this TFG, reported that the group had agreed to use ISO/IEC 17043 as basis for accreditation of PTP and that no additional guidance document would be necessary. After agreement with the EA/EUROLAB/EURACHEM Working Group on Proficiency Testing (EEE-PT) the TFG felt that they have concluded this task. The TFG was developing a guidance document, which will be submitted to the EA LC members for comments after discussion in the TFG.

- Manfred Golze gave a presentation on EUROLAB addressing among others EUROLAB's position on the revision of ISO/IEC 17011 and ISO/IEC 17025. Concerning the draft revised ILAC Guide G17 on measurement uncertainty (MU) in testing he questioned whether the situation concerning the awareness of MU and the expertise to evaluate it would be mature enough in all technical areas to strengthen the current practice.

- The EA LC approved the following draft documents and submitted them for vote or to the EA Executive Committee or the General Assembly for endorsement:

- ⇒ revised Terms of Reference of the EA LC
- ⇒ guidance document on assessment of laboratories against EN ISO 15189 and EN ISO 22870, Point of Care Testing (POCT)
- ⇒ revised EA-04/15 on Accreditation of Non-Destructive Testing (NDT)
- ⇒ paper on "Benefits and importance of the participation in EA highlighted PT schemes" as informative document

- **The EA LC decided**

- on a procedure for handling advisory documents, i.e. documents developed by recognised stakeholders or owners of recognised schemes, to compile a list of frequently asked questions (FAQ) and to publish it on the EA LC intranet, to perform a survey among EA members on the accreditation for pesticides residues analysis concerning e.g. flexible scopes, use of SANCO documents and compliance statements, to invite the two working groups on interlaboratory comparison in calibration and testing, respectively, to decide on the number of necessary meetings and to discuss the pros and cons of a merger of both groups, to compile EA resolutions on ISO/IEC 17025 and forward them to ILAC for use during the revision of the standard.

- During the next meeting elections of the chairman will take place.

- Next meeting of the EA LC will take place in Athens on 18 – 19 March 2015

## Manfred Golze attended the Eurachem General Assembly in Lisbon - 22 and 23 May 2014

- EUROLAB-Deutschland was represented in this General Assembly (GA) by Michael Koch and Rüdiger Kaus, EUROLAB aisbl by Manfred Golze.

- During the GA the former Vice-chair Wolfhard Wegscheider, Austria, took over the chairmanship from Bertil Magnusson, Sweden. David Milde, Czech Republic, was elected as new vice-chair.

- The Eurachem Memorandum of Understanding (MoU) which first was signed in 1990 was renewed for an additional three years.

- Hendrik Emons, IRMM, gave a presentation on Potential Challenges in Setting Measurement Quality Requirements from Regulatory Needs. He pointed out that an adequate estimation of measurement uncertainty and its harmonised application would be essential for proper decisions on the conformity with legislative technical specifications. But a proposal of IRMM on how to include target measurement uncertainty in technical legislation was not accepted by the member states.

- Another invited speaker was Paolo Bianco, the chairman of the EA Laboratory Committee (EA LC). Among others, he reported that the Task Force Group on the accreditation of proficiency test (PT) providers against ISO/IEC 17043 and of reference material producers (RMP) against ISO Guide 34 saw a need for an additional guidance document only in the latter case.

- Ricardo Bettencourt da Silva presented a draft guide on Setting and Use of Target Uncertainty in Chemical Measurements. In the following controversial debate it was questioned whether the use of target uncertainties would really be beneficial for laboratories in cases where other method performance characteristics as for example precision and trueness were stipulated in the regulations.

- A template for Eurachem Guides was presented by Bertil Magnusson which should provide guidance for the editors of future guides.

- The following Eurachem Guides are currently under revision:

- Quality Assurance for Research and Development and Non-routine Analysis, by a Task Force Group (including CITAC) established by the Executive Committee,

- The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics; a draft was presented by the respective WG and a new version will be distributed for comments in the middle of July 2014,

- Guide to Quality in Analytical Chemistry: An Aid to Accreditation, revision is performed by the Education and Training (E&T) WG, Traceability in Chemical Measurement, revision will be performed by the MU&T WG.

- Volunteers for participation in the revision of the guides mentioned above would be welcome. Eurachem members were requested to translate the guides into their national languages, if possible, and to promote their use, in particular towards their National Accreditation Bodies.

- POLLAB invited Eurachem to organise the next GA in Warsaw in the week 25 -29 May 2015.

- The 25th anniversary of Eurachem was celebrated with a gala dinner in Cascais on 21 May 2014

### Personal Developments

- ⇒ Luděk Drlík, Ph.D., ended his contract in SZU as Director for Testing. The activities related to the position of Director for Testing will be temporarily administered by Mr. Tomáš Hruška, Director-General of SZU.
- ⇒ Siri Revelsby has been appointed by Lloyd's Register Energy Senior Vice President, Consulting Services, reporting directly to the Energy Director John Wishart.
- ⇒ Manju Saxena has been appointed as Scientific Director at Intertek's Immunochemistry Centre of Excellence in San Diego, USA.

### Upcoming EUROLAB Events

- **EUROLAB Board meeting**, 19 January, Brussels, Belgium
- **TCQA**, 8th April 2015, Odense, Denmark
- **EUROLAB workshop & 25th Anniversary Celebrations**, 9th April 2015, Odense, Denmark
- **EUROLAB General Assembly**, 10th April 2015, Odense, Denmark
- **JTC PTC**, 27th-28th April 2015, Milan, Italy



Odense, Denmark

### International Events

- **ISRANALYTICA, CITAC, Eurachem International Workshop on Human Errors and Quality of Chemical Analytical Results**, in Tel-Aviv, 13 January 2015.
- **EPPSA's Annual Technology Evening** in Brussels, 19th January 2015
- **BMTA Medical Laboratory Accreditation Workshop** in Leeds, 5 February 2015
- **3rd SAFERA Symposium—Future Research Programming on Industrial Safety** in Paris, 9-10 February 2015
- **EA Certification Committee**, in Switzerland – (tbc), 3 – 6 March 2015
- **EA IC meeting**, in Bern, 5-6 March 2015 & in Tallinn, 8 October 2015
- **EA Laboratory Committee meeting**, in Athens, 18 - 19 March 2015
- **32nd Meeting of the EA Advisory Board**, on 3 April 2014.
- **ILAC AIC**, in Frankfurt, 9-10 April 2015
- **EA General Assembly**, in Krakow, 1 - 5 June 2015
- **8th International Working Conference "Total Quality Management – Advanced and Intelligent Approaches"** Belgrade, 2—5 June 2015
- **2015 International Congress of Metrology**, in Porte de Versailles, Paris, 21 to 24 September, 2015