







# EA REPORT to IAF/ILAC and REGIONS

STATUS
JULY - DECEMBER 2017











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# I - Compositional state of play in December 2017

# 1 - EA Membership

EA has 36 Full Members and 14 Associate Members.

The last national accreditation body (NAB) having joined the EA membership is AZAK, the Azerbaijan Accreditation Centre, which became an EA Associate Member in November 2017.

The complete list of EA Members together with their details is available on the EA website at <a href="http://www.european-accreditation.org/ea-members">http://www.european-accreditation.org/ea-members</a>.

# 2 - Signatories to the EA MLA

34 Full Members and 7 Associate Members are signatories to the EA MLA.

It is worth highlighting that ALGERAC and MOLDAC, respectively the Algerian and Moldavian NABs, have become new signatories to the EA MLA in October 2017.

### Recapitulative table of signatories by EA MLA scope

	Full Member signatories to the EA MLA	Associate Member signatories to the EA MLA	Total signatories
Calibration	33	7	40
Testing	34	7	41
Medical Examination	31	2	34
Inspection	33	7	40
Management Systems	30	3	33
Products	31	3	34
Persons	28	2	30
Validation and Verification	24	0	24
Proficiency Testing Providers	15	0	15







# **EA Multilateral Agreement Signatories**

	CALIBRATION LABORATORIES	TESTING and MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION & VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALBANIA - <b>DPA</b>		√**						
AUSTRIA - AA	V	V	V	V	V	V	V	
BELGIUM - BELAC	V	V	V	V	√	√	V	√
BULGARIA – BAS	V	V	V	V	V	V	V	
CROATIA - HAA	V	V	V	V	V	V	V	
CYPRUS - CYS	V	V					V	
CZECH REPUBLIC - CAI	V	V	V	V	V	V	V	√
DENMARK - DANAK	V	V	V	V	V	V	V	√
ESTONIA - EAK	V	V	V	V	V	V	V	
FINLAND - FINAS	V	V	V	V	V	√	V	√
FRANCE - COFRAC	V	V	V	V	V	√	V	V
FYROM - IARM	V	V	V				V	
GERMANY - DAkkS	V	V	V	V	V	V	V	
GREECE - ESYD	√	V	V	V	V	V	V	√
HUNGARY – <b>NAH</b>	√	V	V	√	√	V	V	
IRELAND - INAB	V	V	V		V		V	
ITALY - ACCREDIA	V	V	V	V	V	V	V	√
LATVIA - <b>LATAK</b>	V	V	V	V	V	V	V	
LITHUANIA - LA	√	V	V	√	<b>√</b>		V	
LUXEMBURG - OLAS	V	V	V		V		V	
MALTA – <b>NAB-MALTA</b>	V	√**					V	
NETHERLANDS - RvA	V	V	V	V	V	V	V	√
NORWAY - NA	V	V	V	V	V	V	V	√
POLAND - PCA	V	V	V	V	V	V	V	√
PORTUGAL - IPAC	V	V	V	V	V	V	V	
ROMANIA - RENAR	V	V	V	V	V	V	V	√
SERBIA - ATS	V	V	V	V	V		V	









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	CALIBRATION LABORATORIES	TESTING and MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION & VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
SLOVAKIA - SNAS	√	V	V	$\checkmark$	V	$\checkmark$	$\checkmark$	
SLOVENIA - SA	√	√**	V	V	V	$\sqrt{}$	V	
SPAIN - ENAC	√	V	V	V	V	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
SWEDEN - SWEDAC	√	V	V	V	V	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$
SWITZERLAND - SAS	√	V	V	V	V		V	
TURKEY – TURKAK	, √	V	V	V	V		√ √	V
UNITED KINGDOM - UKAS	√	V	V	V	V	V	V	V

<sup>\*\*</sup> Signatory for testing laboratories only; not signatory for medical laboratories.

# **EA Bilateral Agreement Signatories**

	CALIBRATION LABORATORIES	TESTING & MEDICAL LABORATORIES	CERTIFICATION BODIES - PRODUCTS	CERTIFICATION BODIES - PERSONS	CERTIFICATION BODIES - MANAGEMENT SYSTEMS	VALIDATION & VERIFICATION BODIES	INSPECTION BODIES	PROFICIENCY TESTING PROVIDERS
ALGERIA – ALGERAC	√	√**					$\checkmark$	
BOSNIA & HERZEGOVINA - BATA	√	√**					√	
GEORGIA - GAC	√	√**	V	V			V	
ISRAEL - ISRAC	√	√					$\sqrt{}$	
REPUBLIC OF MOLDOVA - MOLDAC	<b>V</b>	√	V		V		V	
UKRAINE – <b>NAAU</b>	√ V	√**	V	V	V	_	V	
TUNISIA - TUNAC	√ V	√**			V		V	

<sup>\*</sup>Accepted as associate member by the EA General Assembly in November 2011 (Resolution 2011(28)03).

<sup>\*\*</sup> Signatory for testing laboratories only; not signatory for medical laboratories.









# 3 - EA Recognised Stakeholders

EA cooperates with about 40 Recognised Stakeholders, identified on the EA website at <a href="http://www.euro-pean-accreditation.org/ea-relationships#3">http://www.euro-pean-accreditation.org/ea-relationships#3</a>

FSSC 22000 (food safety and quality management system certification scheme) and UILI (Union internationale des laboratoires indépendants) are the last two organisations that signed the EA Recognised Stakeholder Agreement in November 2017 in accordance with EA-1/15: *EA Policy for Relation with Stakeholders*.

# II - EA MLA and peer-evaluation issues

# 1 - Latest developments relating to the EA MLA

Upon decisions made by the EA MLA Council in October 2017, LA, the Lithuanian NAB, while remaining an EA MLA signatory for testing, became a signatory to the EA MLA in the field of medical examinations according to ISO 15189. Regarding EA Associate Members, ALGERAC, the Algerian NAB, became a BLA signatory in the fields of testing (excluding medical examinations according to ISO 15189), calibration and inspection, while MOLDAC, the Moldavian NAB, became a BLA signatory in the fields of testing (including medical examinations), calibration, inspection, product certification and management systems certification.

It is worth recalling that EA launched its MLA for Proficiency Testing Providers (EN ISO/IEC 17043) in April 2017 when, upon decisions by the EA MLA Council, ACCREDIA, CAI, COFRAC, DANAK, ENAC, ESYD, FINAS, NA, PCA, RvA, TURKAK and UKAS became the first 12 signatories of the EA MLA for PTP accreditation. BELAC, RENAR and SWEDAC joined the signatories for PTP scope in October 2017.

In May 2017, the EA General Assembly, acting upon the recommendation from the Executive Committee and considering EA Resolution 2010(25)13, approved to expand the scope of the EA MLA for Reference Materials Producers (RMP) as new level 2 conformity assessment activity using EN ISO 17034 as a new level 3 normative document. Subsequently, acting upon the recommendation from the EA MAC, the EA General Assembly also approved the launching of the EA MLA for RMP during the MAC meeting in April 2019, provided that at least three members were successfully peer-evaluated by that date.

The MAC project to reengineer the peer-evaluation system is progressing.

At its April 2017 meeting, the MAC appointed 10 TFGs to further develop the proposals agreed at the meeting. The issue of evaluator resource is currently a priority issue on the MAC agenda. In order to support further development of EA's pool of evaluators, an additional newcomer session was held in June 2017 and two refresher activities dedicated to new ISO/IEC 17011 have been performed in December 2017 (see below). The 2018 training plan has also been reinforced. How to improve monitoring of transition to standards, how to better manage the process for dealing with changes notified to the MAC by NABs' members, how to translate the IAF resolution adopted in New Delhi on peer evaluation of IAF sub-scopes in the EA peer evaluation system are also being discussed in the MAC.









# 2 - Latest developments relating to the EA peer evaluations

#### 2.1 - Peer evaluations in 2017

All peer evaluations scheduled for 2017, i.e. a total of 18 peer evaluations, were carried out, including:

- 3 initial evaluations;
- 1 initial evaluation for extension of MLA signatory status to PTP accreditation;
- 2 re-evaluations with extension of MLA signatory status to PTP accreditation;
- 1 re-evaluation with extension of MLA signatory status to certification of products;
- 1 re-evaluation with extension of MLA signatory status to inspection, certification of persons and to certification of management systems;
- 1 re-evaluation with extension of MLA signatory status to management systems;
- 1 re-evaluation with extension of MLA signatory status to medical examinations;
- 6 re-evaluations;
- 2 extraordinary evaluations.

The MAC Secretariat assigned 121 evaluators to carry out those 18 peer evaluations.

At its meeting held in October 2017, the EA MLA Council endorsed a paper aimed to support harmonisation of practical issues in peer evaluations dedicated to the launch of EA MLA for Reference Materials Producers (ISO 17034). First peer evaluations for extension of scope to RMP accreditation will start in 2018. For this purpose, a survey on MLA for RMP was conducted in January-February 2017 to estimate how many accreditation bodies provide accreditation for RMP or plan to offer this service.

## 2.2 - Peer-evaluator trainings

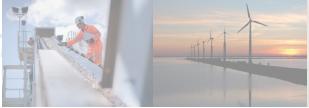
The EA Laboratory Committee (LC) organized a workshop on accreditation of Reference Materials Producers (RMP) against ISO 17034:2016 in May 2017 in Milan, Italy. This workshop was intended to support the expansion of the EA MLA to include ISO 17034 and specifically targeted to potential ISO 17034 peer evaluators.

The EA MLA Council also organized a training workshop dedicated to potential new evaluators in June 2017 in Utrecht, Netherlands, in order to support further development of the EA pool of evaluators.

Recently two refresher trainings were held on 6-7 and 14-15 December 2017 in Utrecht, The Netherlands, for Team Leaders and Deputy Team Leaders in order to be well prepared and able to perform evaluations according to the new ISO/IEC 17011. The objective of these workshops was to exchange information with the aim to enhance harmonisation and use of best practices between evaluators.









# III - Status of EA's recognition in ILAC/IAF

It should be noted that EA has been successfully peer-evaluated by ILAC/IAF for extension of its MLA/MRA signatory status to accreditation of Greenhouse Gas (GHG) verifiers and Proficiency Testing providers. In addition to on-site and witnessing activities, ILAC/IAF evaluators were in Paris for the evaluation of the EA Secretariat on 25 and 26 May 2017. In autumn 2017, a TFG has been appointed by ILAC/IAF to review the evaluation report; a decision is expected for beginning of 2018.

The EA General Assembly in May 2017, acting upon the recommendation from the EA MAC, agreed that EA applies to ILAC for extending the scope of EA as a recognized region for the scope "Reference Material Producers – ISO 17034".

EA's application has been accepted by the ILAC Arrangement Management Committee (AMC) in January 2018.

In parallel, the application process for IAF management systems sub-scopes has been reopened according to the new IAF process.

The full re-evaluation of EA by ILAC/IAF is planned for July 2018. All regional evaluators have already been appointed.







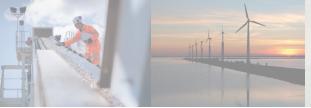


# IV - Status of EA's documents

Withdrawn since July 2017	Document under revision	New documents under development	Published since July 2017
EA-3/04 Use of proficiency testing as a tool for accreditation in testing	EA Articles of Association (AoA)	EA Guidance document for the Accreditation of Pesti- cide Residues Analysis in Food and Feed	<b>EA-1/06</b> EA MLA. Criteria for Signing. Policy and procedures for development
EA-3/11 Food Safety Management Systems – Scope of Accreditation	EA-1/17 S3 Supplement 3 to EA-1/17 EA Rules of Procedure – EA Procedure for the Investigation and Resolution of Complaints and Appeals	EA policy for the Accreditation of Certification Activities under (EU Regulation 1151/2012) PDO/PGI/TSG; (EU Regulations 606/2009, 607/2009 and 1308/2013) Wine Products; (EU regulation 110/2008) Spirits and (EU Regulation 251/2014) Aromatised Wine Products	
	EA-1/17 S5 Supplement 5 to EA-1/17 EA Rules of Procedure – Levying of Membership Fees		
	EA-2/02 EA Procedure for evaluation of a NAB		
	EA-2/13 EA Cross Border Accreditation Policy and Procedure for Cross Bor- der Cooperation between EA Members & its Supplement 1 EA-2/13 S1: Interpretation of terminology used in clause 5.1 and guidelines to assessment focus		
	EA-3/01 Use of Accreditation marks and reference to MLA signatory status		









Withdrawn since July 2017	Document under revision	New documents under development	Published since July 2017
	EA-3/12 EA Policy for the Accreditation of Organic Production Certification		
	EA-4/17 EA position paper on the description of scopes of accreditation of medical laboratories		
	EA-4/20 Guidance for the Assessment of Laborato- ries against EN ISO 15189 and EN ISO 22870 Point- of-Care Testing (POCT)		
	EA-6/03 EA Document for Recognition of Verifiers un- der the EU ETS Directive		
	EA-6/04 EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites		









# V - Activities to promote the IAF MLA and/or ILAC MRA

EA continued to contribute to ILAC and IAF newsletters in October and December 2017, respectively.

On 17 June 2017, two EA Communications and Publications Committee (CPC) members participated in the joint workshop on "Decoding how accreditation can be a global tool to support public policy" organized by the APLAC Public Information Committee (PIC) and PAC Communications and Marketing Committee (CMC) during the 4<sup>th</sup> Joint Annual Meetings of APLAC, the Asian Pacific Laboratory Accreditation Cooperation, and PAC, the Pacific Accreditation Cooperation, in Bangkok, Thailand.

Sébastien Laborde from COFRAC, the French NAB, gave an oral report on how accreditation gave credibility to classification of hotels in France, while Jon Murthy from UKAS, the UK NAB, focused on how accredited food assurance schemes guaranteed defined standards of food safety.

This workshop enabled to raise the profile of the <u>Public Sector Assurance website</u> and to share how it can promote and support the use of accreditation by regulators and policy makers.

EA, as a recognized regional cooperation body of ILAC and IAF, is willing to develop and maintain close and active relationships with its sister organizations, such as APLAC and PAC, to promote accreditation at an international level and enhance a global confidence in accredited conformity assessments results.

Another workshop took place at the last EA CPC meeting held in October 2017 in Dublin, Ireland, to discuss on how the EA website should be refreshed in 2018 to improve in particular the promotion of the EA MLA. Moreover regular information is published through the EA website, Twitter and e-news to keep EA Members and the whole accreditation-related community updated on EA activities, the EA MLA and the transitional arrangements for revised conformity assessment standards.

# VI - Major other developments in EA

#### **Last EA General Assembly for Thomas Facklam**

Thomas Facklam, whose chairmanship of EA came to a close at the end of 2017, chaired his last EA General Assembly meeting on 22-23 November 2017 in Berlin, Germany, where EA Members paid him great and warm tribute for his outstanding contribution to EA.

Thomas served various positions in the EA Executive Committee for 17 years: after being the EA Vice-Chairman from 2000 to 2005 and the Chair of the EA Multilateral Agreement Council (MAC) from 2010 to 2013, he became the EA Chairman from 2014 to 2017. Thomas was a key player not only in the professionalization of EA, by developing closer cooperation with the European Commission and increasing EA's voice in a global network, but also in the reorganization of the German accreditation system, which culminated with the setting up of DAkkS, the German national accreditation body, in 2009. Thomas was the Chief Executive Director of DAkkS during 2010 and 2011.

Furthermore, Thomas Facklam was elected the Vice-Chair of the International Accreditation Forum (IAF) from 1998 to 2002, when he became the Chair of it until 2009. He has also been very much committed as DAkkS and German delegate in numerous national and international standards committees and working groups.









#### New EA Executive for the 2018-2020 term

Regular elections took place at the EA General Assembly on 23-24 May 2017 to renew the Executive Committee in full. A new tandem as EA Chair and Vice-Chair was elected, as well as all EA Committee/ Council Chairs elected or re-elected for a two-year mandate starting on 1 January 2018, together with additional members:

EA Chair: Peter Strömbäck, SWEDAC Ignacio Pina, ENAC EA Vice-Chair:

EA Multilateral Agreement Council Chair: Paulo Tavares, IPAC EA Horizontal Harmonization Committee Chair: Gabriel Zrenner, DAkkS EA Communications & Publications Committee Chair: Lucyna Olborska, PCA EA Laboratory Committee Chair: Laurent Vinson, COFRAC EA Certification Committee Chair: Kevin Belson, UKAS

EA Inspection Committee Chair: Rolf Straub, SAS

Four additional members of the Executive Committee: Maria Papatzikou, ESYD

Emanuele Riva, ACCREDIA

Jiří Růžička, CAI Ed Wieles, RvA

Note: Because he has been appointed from the Swedish government in December 2017 as the Director General for the Swedish Patent and Registration Office, Peter Strömbäck will not be able to act as the EA Chair. Therefore a new EA Chair shall be elected at the EA General Assembly in May 2018, until when the EA Vice-Chair, Ignacio Pina, will take over from January 2018 all the functions of the EA Chair.

#### Revision of EA Articles of Association

The EA Articles of Association (AoA) are being revised with respect to membership criteria.

The EA Executive Committee identified the need for this revision because there might be NABs not fulfilling the existing criteria for being EA Members, whereas EA itself has a specific interest to have such NABs as members. The EA AoA shall be revised in order to allow that a European NAB can be a member of EA. This revision has been triggered by the Brexit issue.

#### EA's contribution to revision of ILAC Articles of Association

Pursuant to the ILAC Articles of Association (AoA), voting will be conducted in the General Assembly, unless otherwise specified, on the basis of one vote per economy as exercised by the fully paid-up Full Members and Associates only. Where there is more than one Full Member or Associate eligible to vote in a particular economy, its vote will be exercised by a nominee elected by all eligible Full Members and Associates in that economy. This provision takes inter alia into account that, in more than 90% of economies, only one accreditation body has been established due to the status of accreditation as the last level in the conformity assessment chain.









ILAC was informed that the present voting rules would not be in compliance with the Dutch Civil Code (DCC) and advised to amend the provisions.

In order to solve the discrepancy with the DCC, the first proposal of the ILAC Executive Committee was to provide each Full and Associate Member a vote in the General Assembly. But this proposal does not consider that the vast majority of economies has for good reasons only one accreditation body established and the risk that one country may dominate the association in the future.

As agreed by ILAC in October 2017 during the Vancouver meetings, the EA Executive Committee is preparing an alternative proposal for the revision of the ILAC Articles of Association that would maintain the existing principle of having one vote per economy, but which would be in compliance with the DCC.

Note: EA provided this proposal in January 2018 to the ILAC Executive Committee.

#### EA Strategy 2025

The *EA Strategy 2025* was adopted in November 2016. To be a world reference for accreditation that enables an open and global market for competitive business and provides reassurance to consumers in a sustainable society, EA has to ensure confidence in accredited conformity assessment results through harmonised operation of accreditation activities, in support of European and global economies. The implementation plan of the *EA Strategy 2025* has been approved in May 2017 by the EA General Assembly, which mandated the EA Executive Committee to monitor the implementing actions entrusted to specific TFGs. The Strategy will involve all EA Committees and the Secretariat.

To achieve EA's vision and mission, 3 strategic objectives based on core values have been defined to support the implementation of the EA Strategy, enabling the EA Membership to speak with one voice and reach the desired position in 2025. EA's core values, as indicated below, highlight the expected principles on which all work of EA is based to support the implementation of the EA Strategy.

#### We are harmonized

- By being transparent in our rules and actions
- By being coordinated in word and deed
- By being accessible both internally and externally
- By having and promoting a common understanding of NABs promise to the market and society

### We are responsible

- By involving and listening to regulators, industry and other stakeholders
- By being loyal and dedicated and work for the public interest
- By being proactive
- By maintaining our integrity

#### We provide confidence

- By establishing consistent deliverables
- By being open, impartial and independent
- By being non-discriminating
- By practicing what we preach
- By being democratic

#### We are competent

- By being efficient and professional
- By using our resources
- By exercising leadership
- By supporting development and innovation
- By continuously improving









One of the objectives of the *EA Strategy 2025* is to foster the merger between ILAC and IAF. From EA's point of view, the international structure (ILAC/IAF) for accreditation should consist of one body covering all areas of accreditation and acting as the focal point for all issues to be solved at the global level.

The full text of *EA Strategy* 2025 – *From Good to Great* is available on the EA website at <a href="http://www.european-accreditation.org/brochure/ea-strategy-2025-full-document-v2">http://www.european-accreditation.org/brochure/ea-strategy-2025-full-document-v2</a>

#### FPA 2018-2021 with European Commission (EC) / EFTA

The EA General Assembly on 22-23 November 2017 has approved the EA Action Plan 2018-2021. EA has been negotiating the next Framework Partnership Agreement for the period 2018-2021 with the EC / EFTA, whose conclusion is expected by autumn 2018.

### Memorandum of Understanding between EA and A2LA

EA signed a Memorandum of Understanding with A2LA (American Association for Laboratory Accreditation) on 15 August 2017 regarding the final rule 40 CFR Part 770 of the Environmental Protection Agency (EPA) on Formaldehyde Emission Standards for Composite Wood Products (Federal Register / Vol. 81, No. 238 / Monday, December 12, 2016 / Rules and Regulations) and the related EPA TSCA Title VI Third-Party Certification Program to ensure that composite wood panel producers comply with the statutory formaldehyde emission limits.

Pursuant to the EPA TSCA Title VI Third-Party Certification Program, a prerequisite for ABs for being recognized by EPA is that ABs designate an Agent for service in the United States in their applications for recognition. A2LA agreed to be the "Agent" for EA National Accreditation Bodies according the EPA TSCA Title VI Third-Party Certification Program under the conditions described in the Memorandum of Understanding.

#### Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada

The Standards Council of Canada (SCC) signed a bilateral cooperation agreement in 2016, which will enable the implementation of the Conformity Assessment (CA) Protocol provided for in the CETA agreement, allowing for the mutual acceptance by Canada and the EU of conformity assessment results delivered by each other's recognized accredited conformity assessment bodies. This will help facilitate trade and open doors for EU and Canadian companies.

A pilot project, based on the very similar EU Directive ATEX and Canadian Regulation HAZLOC for equipment for potentially explosive atmospheres, is nearing completion. Assessments of Canadian and EU-located CABs according to ISO/IEC 17065 and HAZLOC or ATEX requirements were respectively observed by EA and SCC; the Canadian and European requirements were thoroughly analyzed.

The next step is actual recognition of NABs and CABs according to the CETA CA Protocol with the first assessments to start in March-May 2018.

To get detailed information on the bilateral cooperation agreement signed between EA and SCC, please read the brochure "CETA Agreement and Conformity Assessment Accreditation: a tool to enhance trade between the European Union and Canada". Further information is also available in the Comprehensive Economic and Trade Agreement (CETA).









#### 2017 CIM

EA took an active part in the organisation of the International Congress of Metrology (CIM) held in Paris on 19-21 September 2017. EA notably co-organised and facilitated a round table on 19 September dedicated to "Measurement and conformity declaration: ISO/IEC 17025, what's new?".

Both the EA Laboratory Committee Chair and Vice-Chair, respectively Laurent Vinson (COFRAC, the French NAB) and Trevor Thompson (UKAS, the UK NAB), who was also BSI (British Standards Institution) member of ISO WG 44 in charge of revision of ISO/IEC 17025, were key contributors to the discussions aiming to highlight the changes made to the standard – in particular in terms of scoping including sampling associated with subsequent calibration and testing, alignment of the standard with others in ISO/IEC 17000 series or ISO 9001, incorporation of use of new technologies for electronic records and results, and introduction of risk management for considering new version of ISO 9001:2015.

# VII - EA meetings

Please visit the EA website <a href="http://www.european-accreditation.org/events">http://www.european-accreditation.org/events</a>



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