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Country follow-up to Economic Commission for Europe studies on regulatory and procedural barriers to trade

Follow-up on Economic Commission for Europe countries studies: Republic of Moldova

Submitted by the secretariat

Summary

In 2017, the Economic Commission for Europe (ECE) conducted a study on regulatory and procedural barriers to trade in the Republic of Moldova. The recommendations were integrated in their entirety into the country’s National Action Plan for Trade Facilitation, which was adopted by the Government in November 2017 to fulfil the country’s commitments under the World Trade Organization Agreement on Trade Facilitation.

This document provides an overview of the National Accreditation Centre of the Republic of Moldova (MOLDAC) capacity building efforts to achieve international recognition, and highlights progress in implementing the study recommendations.

The document was prepared jointly with MOLDAC and its development partner the Italian National Accreditation Body (ACCREDIA), with the aim of singling out best practices and approaches that could be replicated in countries facing similar challenges. It is presented to the Steering Committee on Trade Capacity and Standards for decision.
I. Introduction

1. A public institution, the National Accreditation Centre of the Republic of Moldova (MOLDAC) is responsible for implementing national policies on accreditation and conformity assessment. It provides guidance in the areas of accreditation and certification (without including them in consultation services for obtaining/maintenance of accreditation and technical competence certification) in accordance with the European Union (EU) common framework for accreditation (EC Regulation 765/2008). MOLDAC operates the following accreditation schemes:

• Testing laboratories
• Calibration laboratories
• Medical laboratories
• Inspection bodies (including metrological verification laboratories)
• Product certification bodies (including ecological)
• Management system certification bodies; and
• Food safety management systems certification bodies

2. The Centre is a member of Eurasian Interstate Council for Standardization, Metrology and Certification (EASC) of the Commonwealth of Independence States, a full member of the International Laboratory Accreditation Cooperation (ILAC), associate member of the European Cooperation for Accreditation (EA) and full member of the International Forum for Accreditation (IAF). It also has established cooperation agreements with its counterparts in Belarus, Bosnia and Herzegovina, Cyprus, Czech Republic, Estonia, Kazakhstan, Kyrgyzstan, Macedonia, Poland, Romania, Slovakia, Turkey and Ukraine.

3. This paper provides an overview of MOLDAC’s experience in achieving international recognition, with the aim of singling out best practices and approaches that

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1 The National Accreditation Body was created as an independent, impartial, unique and separate structure by Law no.186-XV from 24.04.2003 regarding the product conformity assessment and by Government Decision no. 1646 from 31.12.2003 about the set up of the accreditation system in the field of product conformity assessment. The State Enterprise “Accreditation Centre in the field of Product Conformity Assessment” (CAECP) was designated as a Sole Accreditation Body. The Statute of CAECP was approved by Decision no.38 of 28.06.2004 of the Ministry of Economy and Trade. In May 2005, CAECP signed the Collaboration Contract with European Co-operation for Accreditation (EA). In November 2011, CAECP signed the Associated Member Contract with European Co-operation for Accreditation. Law no.235 on the accreditation activities and the conformity assessment was adopted on 01.12.2011, replacing Law no.186-XV/24.04.2003. Law no. 235/2011 transposes the requirements of Regulation (EC) 765/2008, and designates as a sole accreditation body the National Accreditation Centre, abbreviated MOLDAC. The Law No.235/2011 was amended subsequently by Law No. 9 of 26.02.16, Law No.160 of 07.07.2016 and Law No.122 of 30.06.2017. The State Enterprise “Accreditation Centre in the field of Product Conformity Assessment” (CAECP) placed under the monitoring of the Ministry of Economy by Government Decision (GD) No.77 of 25.01.2013. The said GD covered the regulation on the organization and functioning of the National Accreditation Centre (MOLDAC). GD No.77 of 25.01.2013 was amended by GD No. 961 of 08.08.2016 and GD No. 411 of 08.05.2018. Law 235 “On Accreditation and Conformity Assessment” of 1 December 2011 is available at:
can be replicated in other countries. In The paper also highlights progress made in implementing the recommendations emerging from the ECE study.\[^2\]

4. This introduction is followed in section two by an overview of the main capacity efforts implemented to achieve compliance with the applicable rules for the accreditation activities, before becoming a signatory member of EA Multilateral Agreement (MLA). Sections three and four highlight achievements and success factors and are followed in section five by lessons learnt.

II. Capacity building efforts

5. Until 2017, MOLDAC’s capacity building efforts have been mainly focused on joining the European EA BLA, ILAC Mutual Recognition Agreement (MRA), and IAF Multilateral Agreement (MLA). To achieve this, MOLDAC set forward the following objectives:
   
   • Identify strengths and weaknesses in the accreditation process
   • Improve existing accreditation procedures and processes
   • Improve existing accreditation schemes
   • Develop new accreditation schemes and sub-schemes for, among others, forensic field, medical devices, GHG verification, proficiency testing (PT) providers, Protected Designation of Origin (POD) certification and Protected Geographical Indication (IGP) certification schemes
   • Improve the technical knowledge and expertise skills of personnel involved in the accreditation process

6. Developing new certification schemes was difficult not only due to capacity shortfalls within MOLDAC but also because the Government did not accord this task sufficient attention. Moreover, mutual recognition of conformity assessment procedures and certificates was impossible in the absence of reliable and accepted measurements and analyses to demonstrate compliance.

7. There was also a need to further improve existing accreditation procedures and processes. As explained in ECE study, line Ministries accredited their own testing laboratories, and it was often the case that accreditation schemes were not in line with international standards and best practices. For example, some schemes did not contain clauses for ensuring the independence of the accreditation processes and for withdrawing the accreditation certificates in cases of non-compliance.

8. These shortfalls along with the concerns noted in EA Peer Evaluation for supporting MOLDAC membership in the EA Bilateral Agreement (BLA)\[^3\]. In particular, the EA evaluation noted the following gaps, which MOLDAC was required to address in order to achieve full compliance with the EA requirements in the areas of testing, inspection, calibration, and certification. The below gaps, related to the applicable ISO/IEC 17011 standard, were rated as “concerns” that should be addressed as a pre-requisite for obtaining MLA recognition:

\[^2\] [https://www.unece.org/fileadmin/DAM/trade/Publications/ECE_TRADE_433E.pdf](https://www.unece.org/fileadmin/DAM/trade/Publications/ECE_TRADE_433E.pdf)
\[^3\] MOLDAC formally applied for becoming a signatory to the EA BLA in December 2013. The Peer Evaluation process commenced in 2015 with a pre-peer evaluation conducted on 26-27 January.
Concern 1: The current rules and legislation for the Accreditation Council indicates that they "approve" some of the operations of MOLDAC. This suggests that the council is more than a structure that safeguards impartiality (ISO/IEC17011: 2004, Clause 4.3.2);

Concern 2: The current pricing/assessment time formulas are detailed in the accreditation law. The way that it is structured may limit MOLDAC's ability to allocate sufficient time to CAB assessments on a case by case basis. (ISO/IEC17011: 2004, Clause 7.5); and

Concern 3: Currently MOLDAC are in the process of accrediting the National Metrological Institute (NMI) however not all of the NMI reference standards are fully linked at the International CMC Level. This is mitigated by the fact that the relevant reference standards (Mass, Volume, Length, Liquid Density and Gas Flow) are in the process of recognition at the regional level (COOMET). (ISO/IEC17011: 2004 Clause 7.1.1 supported by ILAC P10).

To address these concerns, MOLDAC partnered with ACCREDIA\(^4\) within the context of a twinning project, which was implemented over the period October 2015-April 2016.\(^5\) The project involved two components, with the first focusing on completing an in-depth assessment of MOLDAC’s accreditation process and competence in the various accreditation areas. The assessment was geared to ensuring a strengthening of MOLDAC management system, including documentation, and equipping it with the required expertise skills on the implementation of EU and international standards. The second component featured mock peer evaluations by ACCREDIA peer evaluators and direct support by the ACCREDIA experts to help MOLDAC address the above-mentioned concerns.

Throughout project implementation, a special focus was dedicated to training both the personnel involved in accreditation and key staff from the conformity assessment bodies (CABs). The training delved into subjects of major importance for accreditation process and conformity assessment in the Republic of Moldova, such as, for example, measurement traceability assurance, development of new accreditation areas (forensic, certification of DOP and IGP products). In delivering support, ACCREDIA experts followed a rigorous methodology: (i) assess documents of accreditation process, files of accredited conformity assessment bodies, and competence of personnel; (ii) find any other gaps other than the ones identified by EA (weaknesses and opportunities for improvement) with respect to the applicable EU standards; (iii) correct the immediate effects (whenever possible); (iv) analyze the root causes which generated the gaps; (v) identify and implement proper corrective actions to remove the causes; and (vi) check the effectiveness of the corrective actions.

In more detail, efforts to address the first two concerns were directly related to the national law 235 of 2011 on accreditation, which included articles that were “not compliant” with the requirements of the standard ISO/IEC 17011, due to: (i) improper responsibilities attributed to the members of the Accreditation Council; and, (ii) the lack of flexibility in the price/assessment time formulas, which limited the ability to allocate the needed assessment time case by case.

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\(^4\) ACCREDIA (www.accredia.it) is Italy’s sole national accreditation body on the basis of Regulation (EC) No 765/2008, signatory member of EA-MLA, IAF-MLA and ILAC-MRA for all scopes: laboratories of testing, calibration and medical analysis; certification bodies of products, management systems and persons; inspection bodies; verification bodies; proficiency testing providers; and, producers of reference material. As of March 2019, it has accredited 1800 conformity assessment bodies in Italy and beyond.

\(^5\) The project, titled “Support for the National Accreditation Centre MOLDAC to successfully undergo the EA Peer Evaluation Process”, Twinning Light Project No. MD14/ENPI/TR/20, was financed by the EU. The original project duration was six months. The project was extended to eight months.
12. The law was revised to ensure compliance with the requirements of independence and impartiality of the international accreditation standards: (i) the Accreditation Council now “examines” and “may recommend actions” but does have the responsibility to “approve” the MOLDAC accreditation activities, since the Council shall act as an independent 3rd party with the responsibility of safeguarding the impartiality (first concern); and, (ii) the pricing policy for accreditation assures now a clear correlation between the costs and time needed to perform all kinds of assessments (initial, periodical, reaccreditation, in-office and witness assessment, for every accreditation scheme) and flexibility of contracts to allocate additional time for the assessments in case of need (second concern).

13. Simulations of application of the new law were undertaken to test the rules for calculating the duration of the assessments. The two concerns were closed with the publication of the revised law, which came into force in April 2016.

14. As regard the third concern, the issues were directly related to the traceability of measurements for laboratories in the Republic of Moldova. MOLDAC was in the process of accrediting the National Metrological Institute (NMI), but not all the NMI reference standards were fully linked at the International Calibration and Measurement Capability (CMC) Level. Thus, efforts centered on amending MOLDAC Policy P-03 on Traceability in conformity with the ILAC mandatory standard P10:2013.

15. It was necessary to report that the limited “quantities” now accredited by MOLDAC in the framework of NMI and CMAC activities, left still open gaps to be recovered regarding the status of traceability in the Republic of Moldova, since such quantities did not cover the spectrum of all the 97 testing laboratories already accredited by MOLDAC in the previous years.

16. Aware of the impossibility of filling such historical gap during the project period, a survey was carried out to establish the status of compliance to the amended Policy P-03, of all the 97 testing labs that were accredited according to the previous rules. The survey demonstrated that 12 testing labs could assure the required traceability through the use of calibration services offered (according to route 1 and/or 2). Addressing concern 3 required more time and efforts:

- The Policy P-03 on Traceability of Measurement was finally amended to comply with requirements of ILAC P10:2013; and
- A review of files of the 2 calibration labs (NMI and CMAC) accredited by MOLDAC confirmed that their certificates have been issued in compliance with the standard, since they cover only the “quantities” for which they assure the metrological traceability, and not all the other quantities they initially applied for (NMI Moldova is accredited for Mass, Length, Humidity, and CMAC is accredited for Mass, Length, Temperature).

17. It was proven that in both cases the traceability was assured by calibration services provided by foreign metrology institutes (Czech CMI, German NMI PTB, Rumanian NMI, BIPM-KCDB France). The following conclusions were reached in relation to the third concern:

- The actual situation is compliant since MOLDAC has put in place an accreditation process managed by competent personnel in compliance with the international rules, which was experimented on a significant number of testing laboratories;
- the historical situation is under control since MOLDAC prepared and started to implement an Action Plan to progressively recover the status of the remaining laboratories; and
MOLDAC could demonstrate to have the control of the situation of the traceability in Moldova, since this was considered satisfactory on the way to progressively fill the historical gaps related to traceability, assuming that MOLDAC will implement the recovery plan till its completion, monitoring the results with all the tools of its management system.

18. Two additional project activities were originally planned for assessing the Moldova’s situation regarding the challenges ahead for MOLDAC to work in new accreditation areas such as medical devices and forensic laboratories and train the personnel involved in the related accreditation processes:

• The area of certification of medical devices according the standard ISO 13485 was covered by ACCREDIA experts who performed a gap analysis of the MOLDAC system, identified the training needs regarding the new accreditation process and trained the personnel during dedicated sessions, also supporting MOLDAC in reviewing the related system; and

• A team of ACCREDIA experts in the area of forensic laboratories conducted an assessment to identify existing needs and to assess the compliance or the needs for improvement of the MOLDAC system documentation in this new accreditation. MOLDAC personnel involved in this area have been coached in interviewing personnel of a CAB interested in accreditation in forensic field and trained by the expert.

19. Even if the activities in these new areas have been considered encouraging for a future prosecution, MOLDAC finally decided not to proceed given the lack of sufficient previous experience and/or applications by the local market.

III. Achievements

20. The project delivered the below results: (i) EA peer evaluation, conducted on 15-25 February 2017, ended with a positive assessment, testifying MOLDAC’s successful addressing of the above-mentioned concerns; (ii) on 5 October 2017 MOLDAC become a signatory of the EA Bilateral Agreement (EA BLA) for the accreditation of testing and certification laboratories, laboratories of medical analysis, conformity assessment bodies for inspection and for certification of product and management systems; (iii) on 11 October 2017, based on the EA recognition, MOLDAC signed the ILAC MRA for the accreditation of testing and certification laboratories, laboratories of medical analysis, and conformity assessment bodies for inspection; and (iv) on 31st of January 2019, MOLDAC became signatory of IAF MLA, for following accreditation schemes: product certification and management systems certification. The results involved the delivery of:

(a) 13 project activities completed through several missions;
(b) 13 trainings sessions and seminars for over 170 attendees;
(c) Several Joint Assessments and follow up workshops with lessons learned;
(d) More than 15 technical experts from ACCREDIA covering all the project areas;
(e) More then 140-man days and 30 travels and of ACCREDIA experts and managers;
(f) 5 EA Peer Evaluators for conducting 3 mock peer evaluations;
(g) Study tours to Italy for 5 MOLDAC delegates;
(h) All the project material uploaded in cloud (Dropbox) for making documents and information available to all interested parties, included EU;
(i) Publication on the ACCREDIA website and of relevant information and educational materials presented during the activities of MOLDAC project, available for download;
(j) Roll down banner stand, flyers and brochures for Opening and Closing Conferences;
(k) Interest of media (new papers, radio and TV) in Moldova; and
(l) Final expenditures amount: about € 200,000

21. The approval of the Moldovan Accreditation law was another major success, which even exceeded the expectations, considering that the proposed benchmark of the project was related to the identification of the gaps and weaknesses of the Moldovan legislation on the Accreditation. MOLDAC and ACCREDIA were able to not only propose changes and improvements to the draft of the new accreditation law but to also contribute to the draft law and support its final approval and publication before the conclusion of the project.

22. MOLDAC is a signatory to EA BLA in the following areas of accreditation:
   • Product Certification Bodies (ISO/IEC 17065)
   • Management Systems Certification Bodies (ISO/IEC 17021)
   • Calibration laboratories (ISO/IEC 17025)
   • Testing laboratories (ISO/IEC 17025)
   • Medical laboratories (ISO 15189)
   • Inspection Bodies (ISO/IEC 17020)

23. Moreover, as shown in the annex, MOLDAC has successfully implemented a number of the study recommendations and is playing a key role in improving the economic competitiveness of the Republic of Moldova.

IV. Success factors

24. MOLDAC’s partnership with ACCREDIA was met with success due to the below factors:
   • The diverse specializations provided by ACCREDIA experts made it possible to cover all the areas of competence, with sound expertise in each applicable IAF, ILAC and EA standards, included the availability of 5 EA peer assessors qualified in the 4 areas of interest.
   • The willingness to share the experience accumulated by ACCREDIA, in its pluriannual background as MLA signatory in all the EA scopes.
   • The regular communication and prompt document sharing via cloud provided by ACCREDIA.
   • A flexible approach assured by the ACCREDIA management which has been closely oriented to the MOLDAC training needs, through availability on site and remotely of the expertise of ACCREDIA on demand as needed.
   • All the findings identified during the previous EA peer assessment have been effectively closed.
   • All the gaps and opportunities for improvements identified by the ACCREDIA experts during the project activities have been discussed, corrected and/or implemented.
   • All the experts have completed their missions according the project work program.
V. Lessons learnt

25. MOLDAC’s experience point to several best practice approaches of relevance for countries facing similar challenges:

- Training should be specific to ensure thoroughness and revised as needed. Indeed, an unexpected project result was the improved competence of MOLDAC staff in food standards, even as the project did not provide a specific focus on this. Training on the requirements of the new version of EA, IAF, ILAC documents were replaced, upon the request of MOLDAC, with training on Global Gap, ISO 22003, BRC and IFS standards as well in illustrating EU regulation on organic farming;

- Mock peer-evaluations were critical for ensuring due diligence, as well as the learning by doing approach adopted by ACCREDIA experts to help MOLDAC progressively address the gaps identified by the EA. Three mock evaluations were conducted: 09-13.11.2015, 18-22.01.2016 and 11-15.04.2016, including the evaluation of MOLDAC Management System on compliance with ISO/IEC 17011:2006, Reg.(EU)765/2008, during which were identified weak points and correction measures were taken. Moreover, a study tour was organized to ACCREDIA premises, for 5 of MOLDAC staff. The staff were not only trained at ACCREDIA headquarters, but also participated in assessment teams, as observers;

- Assessments should be conducted for every accreditation scheme, based on face to face interviews with staff, evaluation of files for accredited CABs;

- Evaluation of how EA, ILAC and IAF documents were applied was critical for ensuring the sustainability of achievements as well as the financial monitoring (calculation of service costs) and continuous reflection on progress made; and

- A major challenge was the extensive and numerous project activities, which stretched MOLDAC. MOLDAC is a small body and has planned accreditation activities and self-management. ACCREDIA was flexible and separated the missions based on MOLDAC’s proposal. MOLDAC worked overtime, with much motivation.

26. The experience gained point to several factors that need to be taken into account when designing and implementing similar twinning project in countries with comparable challenges:

- The time allotted by the project to evaluate and implement all the new areas of accreditation (e.g. forensics, medicine, environment, etc.) and complete the training of internal and external staff, should have been longer to improve skills in such areas, where there until now there had been poor opportunities to make significant experiences, because the limited national market

- Efforts should focus on strengthening accreditation staff competence in all the international proprietary certification schemes of the food sector (such as BRC, Global GAP, IFS, etc.) considering the strategic role played by agriculture and agroindustry in such countries

- The competence of national accreditation bodies (NABs) personnel should be strengthened with particular reference to CE mark

- Relationships with national CABs should be carefully developed, paying particular attention to adopting an approach that is tuned with the practical needs of these bodies.
Annex

Table 1. Progress in implementing Recommendations emerging from ECE study

<table>
<thead>
<tr>
<th>Area</th>
<th>ECE Recommendations</th>
<th>Project’s contribution to implementing ECE recommendations</th>
</tr>
</thead>
</table>
| Conformity assessment | 1. Develop the competence of the National Accreditation Centre (MOLDAC) in new areas, including:  
1.1. Certification of persons and verification bodies and further improve existing competences as follows:  
- Proficiency testing according to the general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes (ISO/IEC 17043).  
- Verification bodies according to the principles and requirements for bodies that undertake verification of greenhouse gas (GHG) assertions (EN ISO 14065:2013).  
- Inspection according to the requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities (ISO/IEC 17020:2012).  
- Product certification according to the requirements for bodies certifying products, processes and services (EN ISO/IEC 17065:2012).  
1.2. Product certification bodies. New accreditation schemes are needed to allow for covering all the products under the European Cooperation for Accreditation (EA) Multilateral Recognition Arrangement (MLA).  
2. Further improve accreditation procedures and processes  
Improve accreditation schemes by line Ministries to ensure compliance with international best practices, with a special emphasis on allowing for withdrawing certificates in cases of non-compliance and on ensuring the independence of the accreditation processes.  
3. Further develop conformity assessment bodies (CABs) under government agencies  
3.1. The National Food Safety Agency (NFSA), the Ministry of Health and Customs as well as the newly established SE National Centre for Verification and Certification of Vegetable Products and Soils need to be equipped with modern testing equipment and expertise knowledge on the application of international and/or European standards and technical regulations. In the case of the NFSA, training should feature a focus on consolidating overall administrative/management systems and ensuring robust the monitoring and evaluation processes. | The following actions were undertaken:  
- 17043 – MOLDAC initiated the process of development for this scheme, but because of lack of clients – the scheme was not developed.  
- 14065 – at this moment, MOLDAC is at the stage of national market analysis and of standard requirements.  
- 17020 – the scheme is fully developed.  
- 17065 – the scheme is fully developed.  
The line Ministries only give some improvement proposals for accreditation schemes but has no right to withdraw accreditation.  
Within National Food Safety Agency (NFSA) there is the Republican Veterinary Diagnostic Center, which is accredited by MOLDAC. Within the Ministry of Health, there is also one accredited CAB, namely |
<table>
<thead>
<tr>
<th>Area</th>
<th>ECE Recommendations</th>
<th>Project’s contribution to implementing ECE recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>auditing of the activities throughout the country.</td>
<td>the National Agency for Public Health. The National Centre for Verification and Certification of Vegetable Products and Soils has also accredited laboratories. Respectively, all the mentioned laboratories are equipped.</td>
</tr>
</tbody>
</table>
5.2 Area ECE Recommendations

In accordance with SR EN ISO 9000: 2006, and equip it with a quality management center and research facilities in the four areas of metrology, including engineering measurement, physical measurement, material and chemical measurement and analytical instrumentation measurement.

5.3 Consider diversifying NMI services to allow for achieving a certain degree of self-sufficiency. This is important for enabling the institute to retain qualified staff.

Table 2: Updated list of CABs accredited by MOLDAC6

<table>
<thead>
<tr>
<th>CAB</th>
<th>Scope</th>
<th>No. of accredited CABs</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratories</td>
<td>Testing</td>
<td>80</td>
<td>SM SR EN ISO/IEC 17025</td>
</tr>
<tr>
<td></td>
<td>Calibration</td>
<td>3</td>
<td>SM SR EN ISO/IEC 17025</td>
</tr>
<tr>
<td></td>
<td>Medical examination</td>
<td>2</td>
<td>SM SR EN ISO 15189</td>
</tr>
<tr>
<td>Certification bodies</td>
<td>Product certification</td>
<td>13</td>
<td>SM SR EN ISO/IEC 17065</td>
</tr>
<tr>
<td></td>
<td>Ecological products</td>
<td>3</td>
<td>SM SR EN ISO/IEC 17065</td>
</tr>
<tr>
<td></td>
<td>Quality management systems</td>
<td>2</td>
<td>SM SR EN ISO/IEC 17021</td>
</tr>
<tr>
<td></td>
<td>Food safety management systems</td>
<td>1</td>
<td>SM SR EN ISO/IEC 17021</td>
</tr>
<tr>
<td>Inspection bodies</td>
<td>Inspection</td>
<td>6</td>
<td>SM SR EN ISO/IEC 17020</td>
</tr>
<tr>
<td></td>
<td>Metrological verification</td>
<td>9</td>
<td>SM SR EN ISO/IEC 17020</td>
</tr>
</tbody>
</table>

6 The registry of accredited CABs is available at: www.acreditare.md