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# Case study of Regulatory Cooperation in the context of the International Organization of Legal Metrology (OIML)

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*This case study was developed by Marc Loesewitz, student at the Nanterre Centre of International Law (CEDIN) and intern at the OIML, in the framework of the OECD project on the role of international organisations in international regulatory co-operation. It will be finalised in view of its launch, together with the report on International Regulatory Co-operation: The Role of International Organisations and four other case studies on 2 November 2016 at the OECD Headquarters in Paris.*

*Delegates are invited to submit their comments by 9 September 2016.*

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## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| **APLMF** | Asia-Pacific Legal Metrology Forum |
| **BIPM** | International Bureau of Weights and Measures |
| **CBA** | Cost/Benefit Analysis |
| **CEEMS** | Countries and Economies with Emerging Metrology Systems |
| **CIML** | International Committee of Legal Metrology |
| **CIPM** | Comité International des Poids et Mesures |
| **CIPM MRA** | CIPM Mutual Recognition Arrangement |
| **DCMAS** | Network on Metrology, Accreditation and Standardization for Developing Countries |
| **DoMC** | Declaration of Mutual Confidence |
| **EC** | European Council |
| **EU** | European Union |
| **GUM** | Guide to the Expression of Uncertainty in Measurement |
| **IAF** | International Accreditation Forum |
| **IEC** | International Electrotechnical Commission |
| **IFCC** | International Federation of Clinical Chemistry |
| **IGO** | Intergovernmental Organisation |
| **ILAC** | International Laboratory Accreditation Cooperation |
| **ILAC MRA** | ILAC Mutual Recognition Arrangement |
| **IMO** | International Maritime Organisation |
| **IO** | International Organisation |
| **IRC** | International Regulatory Co-operation |
| **ISO** | International Organisation for Standardization |
| **IUPAC** | International Union of Pure and Applied Chemistry |

| | |
|---|---|
| **IUPAP** | International Union of Pure and Applied Physics |
| **JCGM** | Joint Committee for Guides in Metrology |
| **MAA** | Mutual Acceptance Arrangement |
| **MoU** | Memorandum of Understanding |
| **NMI** | National Measurement Institute |
| **OECD** | Organisation for Economic and Co-operation and Development |
| **OIML** | International Organisation of Legal Metrology |
| **R** | Recommendation |
| **RLMO** | Regional Legal Metrology Organizations |
| **RMO** | Regional Metrology Organizations |
| **SC** | Subcommittee |
| **SI** | International System of Units |
| **SPS** | Sanitary and Phytosanitary |
| **TBT** | Technical Barriers to Trade |
| **TC** | Technical Committee |
| **TGN** | Trans Governmental Networks |
| **UNIDO** | United Nations Industrial Development Organization |
| **VIM** | International Vocabulary of Metrology – Basic and General Concepts and Associated Terms |
| **VIML** | International Vocabulary of Terms in Legal Metrology |
| **VML** | Vocabulary of Legal Metrology |
| **WELMEC** | European Cooperation in Legal Metrology |
| **WHO** | World Health Organisation |

The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organisation whose primary aim is to promote the global harmonisation of legal metrology procedures that underpin and facilitate international trade. The OIML uses a wide range of instruments to foster international regulatory co-operation, including technical standards, model laws, guidance on best practice, support for capacity building and certificate schemes to facilitate mutual recognition. This case study describes how the OIML supports international regulatory co-operation – its institutional context, its main characteristics, its impacts, successes and challenges.

## INTRODUCTION

1. The International Organization of Legal Metrology (OIML) is an intergovernmental organisation (IGO) founded in 1955, and headquartered in Paris, France. It currently has a membership of 124 countries (of which 61 are full Member States and 63 Corresponding Members). Members of the OIML are States, whose governments designate a formal representative, generally from departments or ministries responsible for legal metrology or the national legal metrology institute.

2. What makes the OIML unusual among IGOs is its highly decentralised governance and small secretariat. Consequently, much of the work of the organisation is done by its Members, which makes the OIML a very much member-driven organisation, resembling that of international standard-setting bodies. Through its Members, OIML brings together legal metrology experts to put in place effective legal metrology infrastructures, especially by developing voluntary technical standards that are mutually compatible and internationally recognised (OIML, 2011c). As an international organisation (IO) whose main aim is harmonised regulation, international regulatory co-operation (IRC) is at the heart of its activities. It operates in a very specialised field, however, and in order to understand its approach to such co-operation it is necessary to look at how metrology and more specifically legal metrology is defined and where it finds its scope of application. This case study describes how the OIML practices international regulatory co-operation (IRC), its institutional context, its main characteristics, its impacts, successes and challenges.

### Metrology

3. Metrology is "the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology".[1] It is usually categorised into three different branches: scientific, industrial and legal metrology (Annex A provides further details on the definition of metrology). Scientific metrology is the basis for establishing and developing quantity systems, units of measurements, unit systems and new measurement systems (Howarth and Redgrave, 2008 and Ramful, 2004). It is traditionally the principal area of concern of the International Bureau of Weights and Measures (BIPM). Industrial metrology, which is also under the scope of the BIPM, focuses on measurements and measuring instruments used in production and quality control. Legal metrology is the practice and process of applying statutory and regulatory structure and enforcement to metrology (OIML, 2015a). A wide view of legal metrology embraces regulation in many different areas of human life (for example, in trade, public health or human safety).

1. BIPM website: "What is Metrology?": www.bipm.org/en/worldwide-metrology/ (accessed 15 July 2016).

**IRC mechanisms within the OIML**

4. The OIML is involved in a number of activities which fall within the definition of IRC provided by the Organisation for Economic Co-operation and Development (OECD, 2013). The most important among them is the development of technical standards (referred to within OIML as "International Recommendations"). These standards are designed to be used as model regulations, by incorporation into the laws of Member States and typically establish the metrological characteristics required of certain measuring instruments, as well as specify methods and equipment for checking their conformity (OIML, 2015a). Recommendations are model regulations on metrology which are voluntary in nature; there is no enforcement mechanism within the OIML. However, Article VIII of the OIML Convention states that its Member States have a moral obligation to implement the OIML's Recommendations. The "moral obligation" in this context means that each Member State should implement the Recommendations as far as possible, but cannot be subject to sanctions by the OIML if they fail to do so. The final success of the regulatory effort thus depends on the will and/or ability of the Member States. Nevertheless, where OIML Recommendations are adopted in domestic regulatory frameworks by its Members, they are given a binding character.

5. Although Recommendations are the most important activity in regards to IRC, the OIML does engage in other activities which can also be described as IRC, notably activities such as certificate schemes, technical guidance and support for capacity building in developing countries.

6. Overall, the regulatory impact and capability of the organisation can be explained by two factors. Firstly, the OIML benefits from a political recognition of 124 Member States and Corresponding Members in total, as well as numerous liaisons with other IOs. This recognition is the result of a long development process and the continuous technical work of the OIML to strengthen its position in the complex field of international standardisation (Athané, 2001). Secondly, OIML Recommendations can be considered as contributing to the reduction of technical barriers to trade in the sense of the WTO TBT Agreement. The TBT Agreement requires WTO members to base their technical legislation on "applicable international standards". Although the Agreement does not give a definitive list of the organisations which produce these standards (unlike the WTO SPS Agreement), the OIML follows the requirements of the Agreement for the elaboration of international standards (WTO, 2000). Under the TBT Agreement, OIML Recommendations may thus be considered as "applicable international standards" in the field of legal metrology. The TBT Agreement therefore helps to ensure that OIML Recommendations gain more impact.

7. To sum up, the OIML is a decentralised, member-driven, intergovernmental organisation, which contributes to IRC by its voluntary Recommendations, certificate schemes, technical guidance and support in the field of legal metrology. OIML Recommendations in metrology have largely contributed to improve consumer protection and safety, monitor the natural environment and reduce technical barriers to trade. However, despite a strong commitment and positive developments concerning IRC mechanisms, several challenges in regard to administrative efficiency, cross-national co-operation and regulatory implementation still remain. The OIML tackles these challenges in various ways, including promotion of best practices, co-operation networks, dialogues and active stakeholder engagement.

# THE CONTEXT OF REGULATORY CO-OPERATION

## Evolution of regulatory co-operation in legal metrology

8. There is a long history of international co-operation in metrology. In fact, metrology was one of the first areas covered by formal international co-operation, dating back to the Metre Convention of 1875, which created the BIPM, one of the world's first international organisations.

9. When the Metre Convention was signed, the participants in the conference referred to the National Weights and Measures Office, which were *de facto* legal metrology bodies, since national measurement institutes did not yet exist. The participants appear to have taken the view, however that the harmonisation of national measurement standards for the kilogram and the meter would be sufficient to overcome barriers to trade without further international regulatory co-operation (Athané, 2001).

10. However, given the large number of divergences in measurements that occurred over time, the necessity for a more comprehensive regulatory co-operation became apparent. Initially there was some discussion in the General Conferences on Weights and Measures of the possibility of enlarging the responsibility of the BIPM from scientific to legal metrology. But during the first decades of the twentieth century, it was rather the creation of a new permanent international body for legal metrology, independent of the BIPM, which was discussed (Athané, 2001). A provisional committee for the foundation of such a body was meant to meet as early as in 1938 in Berlin, but owing to the politics at that time, the idea of a permanent body for legal metrology materialised only after the Second World War, on 12 October 1955, with the adoption by 24 founding states of the *Convention Establishing an International Organization of Legal Metrology*. The Convention entered into force on 18 May 1958 and the new International Organization of Legal Metrology saw the light of day.

11. The scope of the OIML's work has evolved progressively over recent decades, driven by developments in industry and society. In the early years the OIML concentrated on establishing its basis in the international landscape through its technical output, such as for example the Guide on "Factors influencing hardness measurements" (OIML, 1983).

12. By 1968, 18 international Recommendations had been published and approved, eight were in the final stages and 33 texts were being written by the various technical secretariats. But more importantly, the OIML published in that year the *Vocabulary of Legal Metrology* (VML). This document was the international basis for metrology terminology until the introduction of the *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM), which was developed in 1979 with other key international bodies (BIPM, IEC, IFCC, ISO, IUPAC and IUPAP).

13. The VIM was then used by the OIML as a basic source for its *International Vocabulary of Terms in Legal metrology* (VIML, 2013). Parallel to its technical activity, the OIML focused on encouraging the establishment of thorough legal metrology resources in developing countries.

14. In the 1970s, a new OIML work program supported a more active participation of the Member States through Project Groups and conferences on technical issues, regarding especially metrology aid for developing countries (NBS, 1970). This consequently led to a greater international acceptance of the OIML, also mirrored by the significant growth of the Organisation during that time (e.g. USA 1972, Pakistan 1973, Ireland 1979, South Korea 1987). The increasing membership went hand in hand with an important growth in activities covered in the trade and health sectors. In the 1980s, attention shifted to restructuring the Technical Committees and Project Groups to achieve greater efficiency, rapidity and flexibility. Additionally, a re-evaluation and modernisation process took place to improve the

implementation of the results, for example by the adoption of OIML Guides as a policy tool in 1980 (Athané, 2001).

15. Globalisation, starting in the 1980s, resulted in several economic, social and political changes that had a major impact on legal metrology. This period resulted in great pressure on international and regional bodies to increasingly co-ordinate their activities and take into consideration development in other areas. Most of the national metrology institutes in OIML Member States were well-established administrations, with relatively numerous technical staff interested in regulatory co-operation on the regional and international levels. Many countries had an incentive to develop standards in legal metrology to improve international trade (Athané, 2001). It was also at this time that the OIML started co-operating with the World Trade Organization and benefitted from the encouragement to WTO members to adopt "relevant international standards" as the basis of their technical regulations.

16. From the 1990s on, the OIML began developing its conformance certification schemes. The *Basic Certificate System for Measuring Instruments* was introduced in 1991 in order to ease administrative procedures. The Basic Certification System was followed in 2005 by the *Mutual Acceptance Arrangement* (OIML MAA), which aims to increase confidence in the certificates in question. As such the OIML developed a more pro-active approach in recent years in contrast to earlier periods. Recent decades have also been influenced by various new challenges and changes in environmental matters and human health.

17. To summarise, since its establishment the OIML has acted primarily as a standard-setting body that has now published approximately 103 constantly updated international Recommendations[2] laying down the metrological characteristics of certain measuring instruments, primarily those used for regulated activities. However, there are a number of other activities undertaken by the OIML in relation to IRC (OIML, 2011c). The most significant of these other activities is the creation of an international Certificate system for type evaluation of measuring instruments. In addition, the OIML seeks to provide support to, and represent the interests of, the worldwide legal metrology community, particularly in international organisations and forums concerned with metrology, standardisation, testing, certification and accreditation.[3]

**Areas of OIML work and intended objectives of regulatory co-operation**

18. According to Article I of the Convention (1955) and the OIML Strategy (2011), the main role of the OIML is:

> … to enable economies to put in place effective legal metrology infrastructures that are mutually compatible and internationally recognised, for all areas for which governments take responsibility, such as those which facilitate trade, establish mutual confidence and harmonise the level of consumer protection worldwide. (OIML, 2011c)

19. In line with its mandate, the OIML work currently covers four main areas: trade, safety, health and environment (Birkeland, 1998). These four areas reflect the purposes for which the instruments are used. Traditionally the trade area has been the most significant. Partly this is because, at the national level, regulation of instruments used for trade was the first and predominant area of legal metrology. But it is also the area where the benefits of trade facilitation – the original intention behind the establishment of OIML – can be seen most clearly. Just as the creation of an effective system of regulation of trade measurement will

2. A list of the OIML International Recommendations can be found on the OIML website: www.oiml.org/en/publications/recommendations/publication_view?p_type=1&p_status=1.

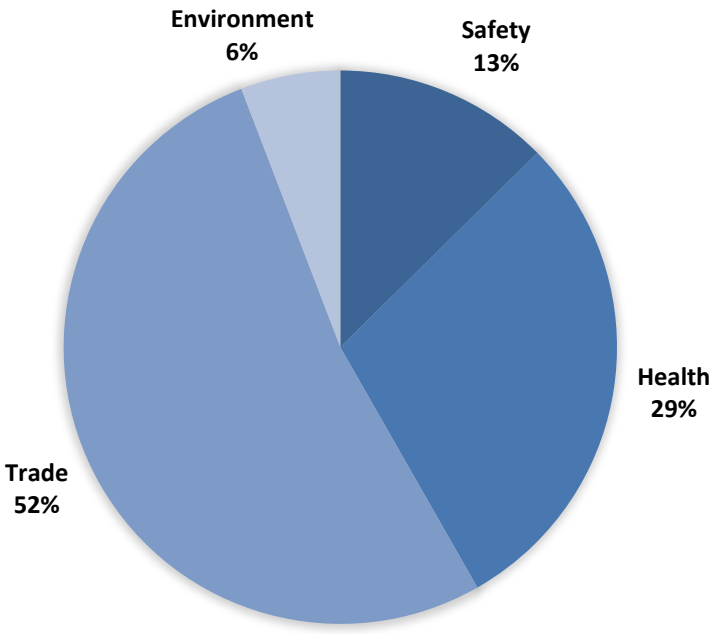
3. For example, through the World Metrology Day (20 May).

increase consumer confidence and thus volumes of trade at the national level, so harmonised regulation will have the same effect on cross-border trade. In addition, harmonised regulation facilitates trade in the measurement instruments themselves – eliminating the technical barriers that would otherwise prevent their import or use or make them costlier to sell into other markets.

20. This second effect – removing technical barriers to trade in the instruments themselves – can also be seen in the cases of instruments whose primary purpose is protection of safety, health or the environment. In addition, there are other benefits of harmonisation, unrelated to trade, since the authorities in the member states do not have to devote the same resources as they would if they were regulating in isolation. It was even predicted that these areas would grow in importance to OIML (Birkeland, 1998). However, that expansion has so far been slower than expected, possibly because Member State representatives from national legal metrology authorities have in many cases no access to policy making in the areas unrelated to trade. Arguably, also because no other international organisation comparable to the WTO endorses OIML Recommendations in the other areas.

21. The balance of activity can be seen when taking a look at the number of Recommendations published by the OIML in each area. The OIML has over time published approximately 140 Recommendations. Due to technical developments some of these have been withdrawn or superseded, which leaves 103 live Recommendations at the time of the writing of this case study. More than half of these 103 Recommendations relate to instruments used in trade, with possible overlaps to other areas. Figure 1 shows the share of Recommendations in each field.

**Figure 1. Percentage of Recommendations in the four sectors covered by the OIML (2016)**




*Source*: Author based on www.oiml.org/en/publications/recommendations/publication_view?p_type=1&p_status=1&set_language=en.

22. Some Recommendations cannot always be clearly categorised. Many fields overlap because of related interests. For instance, R 126 "Evidential breathe analysers" could be categorised in both areas of health and safety. Similarly, R 34 "Accuracy classes for measuring instruments" applies in general to all

four fields. Figure 1 can therefore only be used for a general indication of the distribution of Recommendations published for each area, since the boundaries of the areas are not always clear.

***Trade***

23. According to OECD (1999), approximately 80% of global trade is affected by national standards and regulations. Indeed, standards and regulations on measuring devices are adopted internally by states in order to protect producers and consumers. If these standards and regulations imposed by states are not backed by a functioning measurement system, sooner or later they become technical barriers to trade. The need for compatibility of systems and components is also required in non-regulated areas of trade. As a result of globalisation, components of one main system are frequently manufactured in different countries. A functioning global system of measurements improves the production of manufactured goods.

24. An integral part of the OIML's work thus consists in eliminating technical barriers to trade and reducing the barriers resulting from national and regional controls requiring conformity testing. The CIPM *Mutual Recognition Arrangement* (CIPM MRA), 2003 and the OIML *Mutual Acceptance Arrangement* (MAA), 2011 are instruments designed to promote international consistency of measurement and testing in trade. Both enable trade regulators to rely on accurate measurements. By applying these two arrangements, the time and cost of transactions can be reduced and international trade disputes are less likely to occur.

***Safety***

25. In almost every situation in everyday life, human safety depends on the enforcement of safety laws and regulations which have been put into place by regulatory institutions and national governments. Examples of measurements ensuring human safety range from radar guns, tyre pressure gauges, and breathalysers over control of medical devices and instruments to compatibility of electrical equipment. This area of work is a crossroad for all the three different types of metrology: scientific, legal and industrial. The OIML works together with the BIPM to co-ordinate arrangements between various stakeholders and maintains international references to ensure comparability in the sector of safety, for example through its *Joint Declaration on Metrological Traceability* (BIPM, OIML, ILAC and ISO 2011).

***Health***

26. As a result of longer life expectancy, population growth, international travel and trade, innovations in the medical sector, a functioning healthcare system has become more and more important. In 2005, the World Health Organization (WHO) started the World Health Regulations, an initiative to prevent, protect against, control and respond to the international spread of diseases (WHO, 2005). This collective defence system against public health risks, which is employed by 196 states, requires states to improve international surveillance and reporting mechanisms for public health events and to strengthen their national surveillance and response capacities.[4] The co-operation between the OIML and WHO is, however, not well developed. The WHO is listed as a liaison organisation of the OIML and participates occasionally as an observer in Subcommittee meetings. But there is no substantial information exchange, nor is there any extensive co-operation between the two organisations. Yet, there are a few OIML Recommendations (such as those on the determination of x-ray or scanner radiation doses) which could have the potential to play an important role to help countries implement infrastructures in order to monitor and ensure the wellbeing of their population. The extensive work of the OIML – 25% of the Recommendations are related to medical instruments – underlines its role in the health sector.

4. For further information: www.who.int/topics/international_health_regulations/en/ (accessed 15 June 2016).

27. Likewise, the improvement of modern technology demands that healthcare professionals rely on accurate health-related measurements to identify diseases and prescribe treatments. It is in the interest of practitioners that the measurement and test equipment conforms to agreed-upon standards or specifications, and produce the same results, independently of where the instruments were manufactured. The guidelines and model regulations of the OIML provide a useful tool to national governments in this respect. The *Basic Certificate System* has reassured users concerning the standards of an instrument and thus paved the way to greater credibility and a better infrastructure in the health sector.

***Environment***

28. As already noted, OIML has a small number of Recommendations relevant to environmental regulation, for example its technical standard on *Gas chromatograph/mass spectrometer systems for the analysis of organic pollutants in water* (OIML, 2006). This raises the question of whether it will have a role in the critical environmental challenge facing the modern world that is climate change. Most national environmental regulations are aligned with international agreements, such as the climate Convention in 2015, which seeks to ensure a global approach towards the challenge. A harmonised measuring system opens the possibility for governments and industry to prove compliance with regulations and obligations and is therefore essential to global acceptance of climate goals. Through its work, OIML already provides different elements to guarantee comparability of measurements. For example, its co-operation with ISO, BIPM and the International Laboratory Accreditation Cooperation (ILAC), in their *Joint Declaration of Metrological Traceability* (BIPM, OIML, ILAC and ISO 2011), underlines the importance of the International System of Units (SI), which is a cornerstone for an approach towards more traceability.

29. At the moment, the measurement challenges relating to climate change are seen primarily as scientific rather than regulatory and the BIPM has increased its work on environmental issues in recent years. As a consequence of the close co-operation between the two organisations, however, the OIML is in a position to observe and stay informed about the BIPM's work in this field. Considering the growing importance and conscience surrounding environmental change, there is a strong possibility that the work of the OIML will intensify in this area in the future, and become more important to governments who wish to implement climate conference obligations.

**Institutional landscape**

30. Being the main international organisation concerned with legal metrology, the OIML has a broad, transversal mandate which overlaps with the activities of other IOs with broad purpose, as well as IOs with sector-specific purpose. Its institutional landscape has evolved over time and is now diverse and dynamic. It co-operates on the international level as well as on the regional and national levels with different organisations and legal metrology authorities in order to reach its objective of global harmonisation in legal metrology. This interconnectivity on all levels, and the co-operation with public and private stakeholders, enables the OIML to strengthen the networks of the legal metrology community.

31. The OIML co-operates with a number of other international organisations such as the BIPM, the WTO, international accreditation bodies, other standard-setting bodies; regional organisations; and national authorities. While interactions differ in nature and extent from one organisation to another, a common aspect of co-operation is the use of consultation, observer status and information exchange, notably within joint working groups, as well as the development of joint instruments. In some cases, the OIML makes use of Memoranda of Understanding (MoUs) as a legal instrument for co-ordination. To date there are six *Memoranda of Understanding* with other IOs (IEC, ISO, UNIDO, BIPM, ILAC, IAF). Any organisation seeking to sign a MoU with the OIML or wishing to attend the International Conference as an observer simply has to demonstrate that it pursues an activity connected with that of the OIML. The OIML may enter into more MoUs with other IOs on matters of common interest with a view to ensuring further co-

operation in legal metrology. Moreover, there are additional opportunities for a wide range of organisations to participate in the more detailed work of the technical committees.

***International Bureau of Weights and Measures (BIPM)***

32. The close co-ordination between BIPM and the OIML is of great importance to the OIML in order to achieve its goal of worldwide harmonisation of legal metrology. Only the co-operation between scientific and legal metrology guarantees practical successful OIML model regulations and guidelines.

33. The BIPM has been co-ordinating the activities relating to scientific and industrial metrology since 1875. The BIPM helps to ensure uniformity of measurements and their traceability to the International System of Units (SI). It plays an important role when it comes to international comparison of national measurement standards and the calibration of instruments for the Member States.[5] The work of the BIPM therefore provides expertise in scientific metrology by which a coherent system of measurements throughout the world becomes possible. A lot of BIPM's work is undertaken through a series of consultative committees whose members are drawn from the national metrology laboratories of the Convention's Member States.

34. The BIPM focuses its efforts on the technical and organisational infrastructure of metrology (BIPM, 2013), whereas the work of the OIML concentrates on the legal aspects of metrology. OIML and BIPM consequently have a close co-operative relationship in order to combine both aspects of metrology. This co-operation is supported by various mechanisms of interaction, including a MoU, mutual observations, joint statements, information exchange and joint meetings. The main focus of the OIML/BIPM co-operative work can be divided in four areas:

- BIPM activities which may impact on legal metrology (e.g. the redefinition of SI units, in particular the kilogram);
- Co-ordinating positions on matters which may affect all branches of metrology – scientific, industrial and legal;
- Promoting the importance of metrology in a modern economy – in particular in less developed countries (what the OIML now refers to as "Countries and Economies with Emerging Metrology Systems" (CEEMS)); and
- Day-to-day administrative co-operation: both organisations are based in Paris, and have, to some extent, a shared history and membership.

35. BIPM and OIML therefore form the key elements of the international system of metrology, and the work of the two bodies is complementary.

36. In 2008, the two organisations signed a MoU guaranteeing to inform each other about their work, mainly to avoid duplication, but also to pool resources and expertise. The MoU also includes mutual prospection for new members in their respective networks and puts a special focus on developing countries. Annual meetings and joint statements (such as the *Joint Declaration on Metrological Traceability*) also underline the co-ordination between the two organisations. A further outcome of the co-operation is the joint web portal called the *BIPM-OIML Resource Centre* which has "the objective to provide metrologists and key metrology decision makers worldwide with information about metrology".[6]

5. For more information see also: www.bipm.org/en/about-us/ (accessed 15 June 2016).

6. Further information: www.metrologyinfo.org (accessed 15 June 2016).

The joint website also gives access to impact studies of both organisations and supports the information exchange on the international network of metrology. The OIML and BIPM also collaborate to promote World Metrology Day, which is the annual celebration of the signing of the Metre Convention on 20 May 1875. Both organisations work together each year on this major project, in which a large number of national metrology organisations actively participate, by promoting metrology, addressing its challenges and enforcing co-operation in this field.[7]

***World Trade Organization (WTO)***

37. Many of the OIML's Recommendations are related to international trade. Their primary objective is to dismantle technical barriers to trade, which consequently reduces costs and facilitates the flow of goods and services. The co-ordination process in international trade is implemented under the umbrella of the WTO, which introduced the Standards Code in 1979, replaced by the TBT Agreement in 1995. The TBT Agreement "sets out a code of good practice for both governments and non-governmental or industry bodies to prepare, adopt and apply voluntary standards" (WTO, 2014).[8] According to Article 2.4 of the TBT Agreement, "[w]here technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations (…)",[9] because they contribute to remove technical barriers to trade. In the sense of this article, the OIML Recommendations can be considered as relevant international standards to be used by WTO member states as a basis for domestic technical regulations.[10]

38. The reliance of WTO Members on international standards opened the opportunity for international standard-setting organisations (including ISO, IEC, and OIML) to co-operate closely with each other and with the WTO itself. Co-operation between WTO and OIML is mainly based on information exchange. Three times a year, OIML representatives attend the meetings and report to the WTO TBT Committee. Even though the OIML has only an *ad hoc* observer status, without voting rights, it has been in practice invited to every TBT Committee meeting (WTO, 2016) since 1997 (WTO, 1998).

***International accreditation bodies***

39. Accreditation bodies such as the International Laboratory Accreditation Cooperation (ILAC) or the International Accreditation Forum (IAF) play an important role in ensuring high standards in the conformity assessment activities of testing and certification bodies. For instance, the ILAC accreditation bodies, which have been accepted as signatories to the ILAC Mutual Recognition Arrangement (i.e. ILAC Full Members), use an appropriate written standard to assess the technical and managerial competence of laboratories.[11] Legal metrology regulations can then reference such standards, which help national legal metrology bodies to ensure compliance with international Recommendations. The co-operation between the OIML and those accreditation bodies is therefore important in order to demonstrate the conformity with regulatory requirements. OIML has signed MoUs with both ILAC and IAF which provide for consultation and representation on appropriate technical committees (Box 1).

7. Cf. www.worldmetrologyday.org (accessed 15 June 2016).

8. Cf. www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm (accessed 15 June 2016).

9. Cf. Art. 2.4 TBT Agreement, which includes some exceptions.

10. The obligation to adopt international standards is not absolute. WTO members may chose not to apply them "when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems" (Art 2.4 TBT Agreement).

11. For example, accredited to ISO/IEC 17025.

**Box 1. The example of the International Laboratory Accreditation Cooperation (ILAC)**

ILAC is an IO that promotes the mutual recognition of test and measurement certificates issued by laboratories accredited by national accreditation bodies. ILAC members undergo a peer evaluation process to become signatories to the ILAC Agreement. The main aim of the Agreement is to increase the use and acceptance by industry, as well as governments of accredited laboratories.

The co-operation between OIML and ILAC is materialised by a MoU signed in 2006 and revised in 2014. The co-operation ranges from shared interpretation of common issues (*e.g.* the 2011 Joint BIPM-OIML-ILAC-ISO *Declaration on Metrological Traceability*) to shared use of technical and metrological experts, and information exchange on technical matters and overall policy.

A specific example of the co-operation efforts between the two organisations is the implementation of the Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations (OIML MAA) in 2005. This arrangement is a system for recognition of test reports, by means of which the confidence in type examination testing can be increased. As a result of this co-operation, the evaluation of the testing laboratories of OIML issuing authorities can be accredited by a signatory of the ILAC Mutual Recognition Arrangement (ILAC MRA). ILAC therefore covers the scope of testing in the field of legal metrology according to the relevant OIML Recommendations.

### *Other standard-setting bodies*

40. A number of other international bodies are active in making standards which may affect legal metrology, either by setting their own requirements for measuring instruments or by setting standards for activities such as conformity assessment. The most significant of these bodies is the International Organization for Standardization (ISO), which is a non-governmental organisation and one of the largest developers of voluntary international standards (Case study of ISO, OECD *Forthcoming*). The co-operation between ISO and OIML can be characterised by the development of joint instruments (e.g. joint publications), as well as information exchange and facilitation of working procedures. Most of the mechanisms of interaction are codified in the MoU signed by the two organisations.[12]

41. The MoU dates back to 1966 and was revised in 2008. The revision is evidence of the growing international co-operation between OIML and ISO. A key intention of the MoU is the development of joint publications. Technical committees and sub-committees of both organisations can set up joint project groups under participation of the respective stakeholders. The publications developed in these project groups are later published by both organisations. This mechanism of co-operation goes beyond information exchange and aims directly at the harmonisation of the technical work. An example for such a joint publication was published by the OIML as OIML R 99-1 & 2 *Instruments for measuring vehicle exhaust emissions – Part 1: Metrological and technical requirements and Part 2: Metrological control and performance tests* and by ISO as ISO PAS 3930:2009 *Instruments for measuring vehicle exhaust emissions*. The technical requirements set in OIML R 99-1 & 2, edition 2008 and ISO PAS 3930:2009 are identical.[13]

42. The revised MoU also introduced another instrument to the toolbox of international co-operation between ISO and OIML. Since 2008, the ISO Fast-track procedure can be applied to OIML publications, whereby a document is submitted directly for approval as a draft international standard to the ISO member bodies. In this way, OIML publications can be directly converted to ISO standards without information

12. For further information: www.iecee.org/whatsnew/PDF/signed-mou-oiml.pdf (accessed 01 April 2016).

13. Further examples of joint publications of ISO and OIML: The *International Vocabulary of Basic and General Terms in Metrology (VIM)* and the *Guide to the Expression of Uncertainty in Measurement (GUM).*

loss. In 2008 nine OIML Publications were transferred to the relevant ISO technical committee, although this procedure has not been used much recently.

43. Because of the nature of many measuring instruments, the work of the International Electrotechnical Committee (IEC), which prepares and publishes international standards for electrical, electronic and related technologies, is particularly relevant for OIML.[14] The IEC also manages conformity assessment systems with which equipment, systems or components are certified to comply with international standards. Given the scope of OIML and IEC, and the fact that the IEC is also a standard-setting body in the sense of the WTO TBT Agreement, their co-operation is close and very similar with that of OIML and ISO. As with ISO, co-operation is based on a MoU which focuses on information exchange and participation in technical relevant matters.[15]

44. In practice, co-operation between IEC and OIML is based on three main pillars: technical co-operation, conformity assessment and the development and application of standards. IEC work focusses on electrical and electronic products, and the overlap in this sector with OIML activities is high, making co-operation on the technical level critical. Currently, seven technical committees and subcommittees of the OIML are in direct liaison with IEC working groups to co-ordinate closely their work[16] in order to avoid duplication.[17]

45. The standards-making process in all three organisations are very similar, the experience of both ISO and IEC in modernising the standards development process has served as an important model for some of the changes that the OIML is looking to introduce. Apart from the much wider scope of ISO and IEC, the main difference with OIML is that both of the larger organisations represent a business-led standards-making process, although involvement of national Governments is encouraged where the standards may be used in a regulated area. In contrast, the OIML is an essentially Government-led standard-setting organisation – most of the active members of the technical committees come from Government authorities, but there is significant provision for business involvement both as part of the national delegations and through international business organisations.

46. Both ISO and IEC may wish to prepare standards for measuring instruments which go beyond the metrological performance which is of interest to legal metrology authorities. It is important in such cases that the two sets of requirements do not conflict, as this could create technical barriers. This risk is managed by having cross-membership of technical committees and in some cases (e.g. water meters) having standards which are jointly developed and published. ISO is also responsible for many of the standards relating to conformity assessment (e.g. ISO/IEC 17025) and the OIML, along with the BIPM, ILAC and IAF, are included as stakeholders when those standards are developed or revised.

47. There are also potential overlaps with the work of more specialised standard-setting bodies. Possibly the most significant is the Codex Alimentarius Commission. This body "was created to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program" (FAO/WHO, 2008).[18] Possible overlapping in the scope of OIML activities exists in three fields:

14. For further information of the IEC: www.iec.ch (accessed 04 April 2016).

15. www.iecee.org/whatsnew/PDF/signed-mou-oiml.pdf (accessed 05 April 2016).

16. Technical committee: 13, 25, 38, 77; Subcommittee: 54B, 65B, 77C.

17. www.iecee.org/whatsnew/PDF/signed-mou-oiml.pdf (accessed 05 April 2016).

18. ftp://ftp.fao.org/codex/Meetings/CAC/cac31/al3104Ae.pdf (accessed 15 June 2016).

- Requirements for the quantity of product (content) in pre-packages;
- Labelling requirements; and
- Instruments used for physico-chemical measurements.

48. Formal co-operation with the Codex Alimentarius Commission is done through its status as a liaison Organisation to the OIML.

49. OIML has been reviewing the various fields covered by other international standards-setting bodies for the purposes of identifying overlapping activities, exchanging information and participating in technical activities.

***Regional Metrology Organisations***

50. Co-operation in metrology also occurs through regional metrology bodies (e.g. Europe, see Box 2, Asia Pacific, the Americas, Africa). This is the case both in scientific and industrial metrology, where the BIPM recognises a number of "Regional Metrology Organizations (RMOs)" for the purposes of its Mutual Recognition Arrangement (MRA); and in legal metrology, where the corresponding organisations are known as Regional Legal Metrology Organizations (RLMOs). In some cases, (e.g. the Americas and Africa), the same organisation acts as both RMO and RLMO. RLMOs have a wide range of activities and objectives including the development of legal metrology, the promotion of trade, comparison of metrology systems and technical support. The operation of RMOs and RLMOs is a loosely-structured process, in which the members engage directly in informal interactions. Their co-operation shows therefore many of the characteristics of Trans Governmental Networks of regulators (TGN) (Abbott, 2014 and OECD, 2013).

**Box 2. Co-operation in metrology in the European Union**

The most developed model of regional co-operation can be seen in the RLMO for Europe, the European Cooperation in Legal Metrology (WELMEC, formerly "Western European Legal Metrology Cooperation").

Europe is, however, an unusual case as the result of the supra-national approach to regulation adopted in Europe – EU Member States are all subject to EU legal metrology directives, *e.g.* on cold water meters for non-clean water. The drafting of the EU legal metrology directives took place at the same time as the development of the first OIML Recommendations, with practically the same experts working on both levels. The close consultations between the two organisations were further supported by European trade associations. The EU and the OIML likewise benefited from the co-operation between the two organisations as well as with the private sector, through industry representatives in the Technical Committees. The EU had the advantage of facilitating its trade through aligned standards in legal metrology, whereas the OIML managed to prove its usefulness through technical output and further promoted its role internationally. The regulatory developments within the European Common Market therefore show a successful regional and international co-operation.

Against this background, the Members of WELMEC are active in co-operation in a wide range of fields arising from the implementation of the EU Directives. However, because this role is the result of the supra-national approach to most forms of product regulation adopted in Europe it is not always a model that other RLMOs can follow.

51. Currently seven main regional metrology organisations[19] exist (Box 2 provides the specific example of the European co-operation). The relationships between OIML and RMLOs are complex. On the one hand, both OIML and RLMOs depend for their effectiveness on work undertaken by staff from national legal metrology authorities, working *inter alia* through Technical Committees and Working Parties. When resources are under pressure there may be an adverse effect on the work of the OIML if Member States change their focus from international to regional activities. On the other hand, in most respects, the work of OIML is complementary with that of the RLMOs. The main challenge is to find a way of co-ordinating activities which makes the most efficient use of the resources available. Striking that balance has been an important part of OIML's efforts to develop its work related to developing countries, or in OIML terminology, countries and economies with emerging metrology systems (CEEMS).

***National metrology authorities***

52. With the partial exception of the EU, direct enforcement of legal metrology requirements is a matter for national administrations. The way different countries structure their legal metrology activities varies enormously. There are usually three main components to legal metrology activities at the national level:

- Rule-making, including the decision on which activities and instruments to regulate and what specifications regulated instruments must meet. At this level, countries typically use OIML Recommendations as model regulations, incorporating them as appropriate into national law. Rule-making will normally be the responsibility of the relevant Government ministry, but countries differ greatly in the extent to which a separate national institute is involved in the process, for instance in advising on the requirements and taking part in international discussions, such as in the OIML. Moreover, where there is a separate institute it will in some countries be the single National Measurement Institute (NMI) which combines scientific, industrial and legal metrology functions, and in others it may be an entirely separate institute operating at the national level.

- Type approval controls, requiring prior authorisation of an identified model or range of an instrument before it can be used for regulated purposes. A country can undertake its own testing and evaluation at the national level – but again there are different approaches between countries where this is the responsibility of the NMI and those where it is undertaken by a separate legal metrology institute.

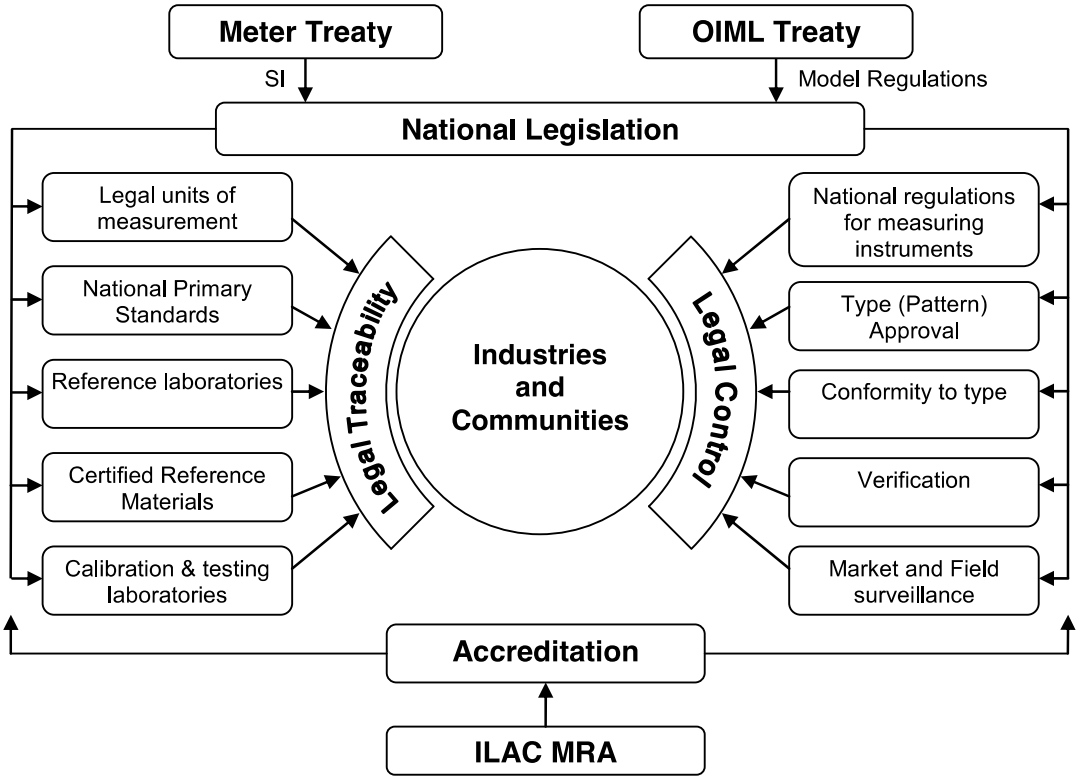
- Enforcement at the point of use of a regulated instrument, either through verification that an individual instrument meets certain requirements or through inspections of instruments in use. Verifications and inspections at the point of use are usually undertaken at a local level. They are often carried out by inspectors employed by provincial or municipal authorities. In other countries, however, inspectors are employed by a single national service. Countries also vary a great deal in the extent to which they rely on direct enforcement by state officials, checks carried out by authorised third parties or indeed declarations by the manufacturers or users of regulated instruments.

19. Intra-African Metrology System (AFRIMETS); Asia-Pacific Legal Metrology Forum (APLMF); Euro-Asian Cooperation of National Metrological Institutions (COOMET); Euro-Mediterranean Legal Metrology (EMLMF); European Cooperation in Legal Metrology (WELMEC); SADCMEL Cooperation in Legal Metrology (SADCMEL); Inter-American Metrology System (SIM).

53. Finally, countries take very different approaches to the scope of legal metrology authorities. In some cases, they are responsible only for the regulation of instruments used for trade, while other parts of governments are concerned with instruments used for other regulated purposes. Indeed, when the users of such instruments are themselves public authorities, the performance of instruments may in some cases be set through a procurement process rather than formal regulation.

54. The following diagram from the Asia-Pacific Legal Metrology Forum (APLMF) shows how the OIML, the BIPM (Metre Convention) and ILAC influence national legislation on legal metrology through their respective instruments (SI, model regulations and accreditation) (Figure 2).

**Figure 2. APLMF Guide 1 National Infrastructure for Legal Metrology**




*Source*: APLMF (2010), Guide 1 National Infrastructure for Legal Metrology, APLMF, Beijing, China.

55. One of the main challenges for the OIML lies in its interaction with national authorities (Mason, 2016). Economic difficulties in many countries have led to a significant decrease in the financial resources allocated to national legal metrology services, which then again resulted in a decrease in human resources and difficulties for regulatory co-operation between the OIML and national metrology services (APLMF, 2010).

## MAIN CHARACTERISTICS OF REGULATORY CO-OPERATION

### Governance arrangements and operational modalities

56. Unlike most IGOs, OIML is highly decentralised with a small secretariat. The work of the organisation is mainly done by its Members. OIML can thus be regarded as a member-driven organisation. Its constitutional structure is laid down in the 1955 Convention. The overall structure is modelled to a large extent on the institutions set up by the Metre Convention – a Conference of Government Representatives of Member States as the top decision-making body, a Committee to oversee the operation of the organisation (the CIML), and a permanent Bureau of staff to perform the day-to-day activities of the Organisation (the BIML). In 1968 an important amendment was made to the Convention to give each Member State the right to nominate a representative to sit on the Committee. In common with many other standard-setting bodies, much of the "technical work" of drafting Recommendations and Documents is carried out by Member States in the Technical Committees and their Project Groups rather than by staff from the Bureau. As a consequence, the work of the Member States dominates the output of the Organisation. Therefore, active participation from well-resourced Member States in the technical work is vital. Even though the "buy-in" of Member States to technical work is high, the number of Member States which show very active participation is rather small.

#### *Membership*

57. The OIML is an intergovernmental organisation. Its membership is open to any sovereign state that is prepared to ratify the Convention and pay the annual subscription. Membership is not limited to any particular region, which makes the OIML by definition a universal organisation (Amerasinghe, 2005). There are two categories of membership in the OIML: "Member States" (which are full members) and "Corresponding Members" (which can be seen as observers). Each category enjoys a different level of access to and possible influence within OIML. With only 61 countries that are full Members, the size of the organisation is smaller than many other IOs. Nevertheless, with an additional 63 "Corresponding Members" able to enjoy many of the benefits of the OIML's activities, there is coverage of most parts of the world.

*Member States*

58. At the time of its creation in 1955, the OIML had 24 founding Members with a strong regional majority of European States.[20] Since then the membership of the OIML has expanded significantly. The reach of the Organisation was expanded with the membership of the United States, Ireland, Brazil and China in the 1970s and 1980s. Kazakhstan, South Africa and Croatia joined between 1995 and 2000. Albania, Serbia, Vietnam and Turkey acceded from 2000 until 2005. Colombia joined in 2013. Thailand became the latest Member State in 2016. The number of Member States has therefore increased steadily from the original 24 countries and now stands at 61 with signs of interest from some other states that are currently Corresponding Members.

20. The founding members in 1955 (in alphabetical order) are: Austria, Belgium, Cuba, Czechoslovakia, Denmark, the Dominican Republic, Finland, France, Germany, Hungary, India, Iran, Morocco, Monaco, the Netherlands, Norway, Poland, Romania, the Soviet Union, Spain, Sweden, Switzerland, Tunisia, Yugoslavia.

59. Member States have to ratify the OIML Convention, thereby committing themselves to contribute financially to the OIML's operation, to attend the Conference and CIML meetings, and to participate in OIML technical work as much as possible (OIML, 2015a). The Member States also have voting rights in the Committee and Conference and may be selected by the President to take part in the Presidential Council. Pursuant to Article VIII of the OIML Convention, Member States are morally obliged to implement the decisions of the Conference as much as possible – since the Conference ultimately approves the international Recommendations, this is the way by which OIML standards are set.

*Corresponding Members*

60. Currently there are 63 Corresponding Members, which are almost all sovereign states. There is also one example of a grouping of states (the West African Economic and Monetary Union) joining as a Corresponding Member organisation. OIML has always envisioned a global reach. Article I of the OIML Convention provides that the purpose of the OIML is to determine necessary and adequate characteristics and standards to be approved by Member States and to be recommended internationally. An international approach, beyond the Members of the OIML, has thus been present since the establishment of the organisation. The OIML therefore provides an opportunity for states that do not yet wish to ratify the Convention and for territories that are not able to do so (for instance because they are not sovereign states) to participate in its work through the status of "Corresponding Member" (OIML, 1955). The status of a "Corresponding Member" can be compared to an "observer" status in other IOs and is designed to be a step towards becoming a Member State (the distinction between Member State and Corresponding Member makes it easier for developing countries to participate in the work of the OIML).

61. Corresponding Members may take part in the technical work of the OIML Technical Committees, Subcommittees and Project Groups as observers (*i.e.* without voting rights). There is also provision for Corresponding Members to participate in the OIML Certificate Schemes, for instance Corresponding Members can participate in the OIML's MAA by being associates in a Declaration of Mutual Confidence (DoMC) and accepting the type evaluation reports issued by Issuing Participants (OIML, 2012). It should be noted, however, that no Corresponding Member has yet opted to do so.

62. In practice all countries have access to all publications of the OIML (including International Recommendations) and the information in OIML certificates, even without becoming Corresponding Members, since the publications are publicly available on the OIML website.

*Participation of stakeholders*

63. Although the OIML primarily provides a platform for regulators or experts in legal metrology to meet and exchange information and views, civil society representatives (e.g. the manufacturing industry) are also involved in the OIML work. Stakeholders, such as business representatives, cannot become Members or Corresponding Members. They can nevertheless participate as experts or as part of national delegations to technical meetings or in the national mirror committees. Member States involved in the technical work are also encouraged to consult business or other stakeholders on their input. Business and civil society representatives are, however, only engaged in the technical (upstream) phases of the work. They are absent from the more formal activities such as the adoption of Recommendations and other OIML publications.

64. Even though there is no official "observer" status for stakeholders in the OIML Convention, some international organisations are invited to take part in OIML meetings (e.g. as foreseen in the MoUs) and therefore become *de facto* observers of the work of the OIML.[21] Those observers, so called liaison

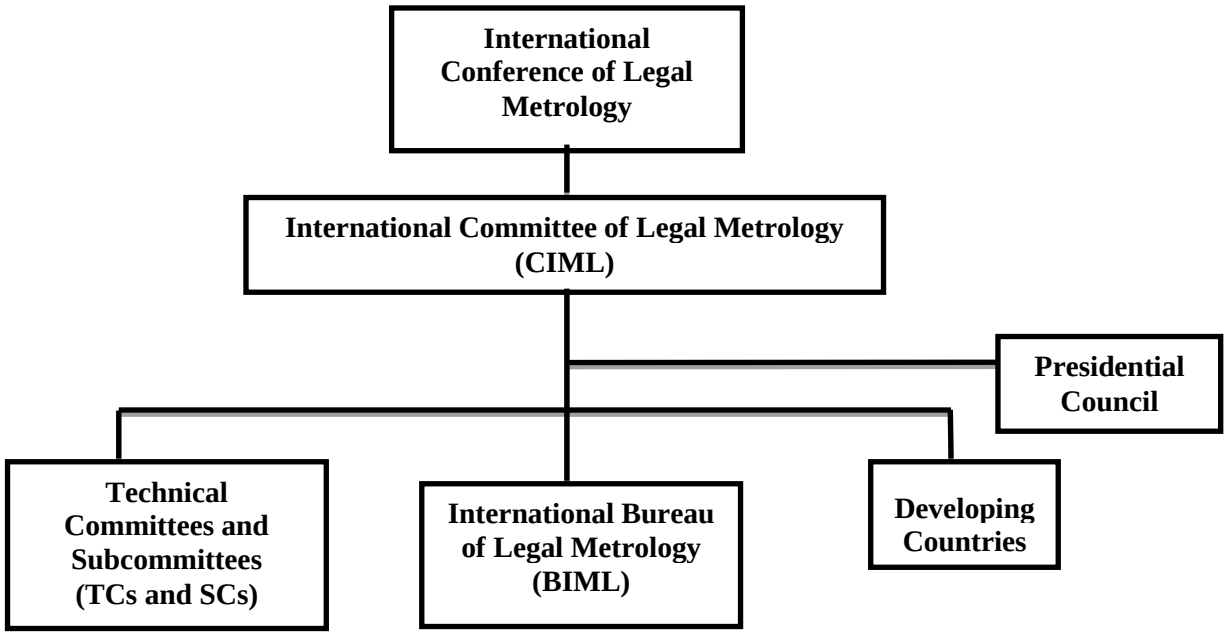
21. E.g. BIPM, IEC, ILAC, ISO and WTO.

organisations (typically other International Organisations, including those representing business) may join the Technical Committees. In that case P-Members of the Technical Committees approve the application to become a liaison in the Technical Committees in question.

***Structure of the OIML***

65. The OIML is organised around a three-layer model: The International Conference, the International Committee and the International Bureau of Legal Metrology. The important role granted to the Committee to set up Technical Committees, Subcommittees and Project Groups, makes the OIML a decentralised member-driven organisation. The Secretariat has a limited involvement and Member States carry out most of the tasks and assume responsibility for the Technical Committees (Art. VIII Convention). There is no hierarchical structure between Technical Committees which operate independently in their respective fields. Since the tasks of the Technical Committees are often of a very specific nature, not much co-operation is required amongst them.

**Figure 3. Governance structure of the OIML**




*Source*: Author, based on OIML Convention 1955.

*International Conference on Legal Metrology*

66. The International Conference on Legal Metrology is the highest decision-making body of the Organisation. Pursuant to Article XIII ff. of the Convention, the Conference consists of all the Member States, represented by delegations of technical experts designated by their respective governments. The Convention requires that it should be convened at least once every six years and in practice it meets every four years at the same time and place as the International Committee of Legal Metrology (CIML) meeting for that year. Member State representatives at the Conference are also often (but not necessarily) the CIML Members, and so transitions between the meetings are usually seamless. However, the Convention stipulates that there are certain matters that can only be decided by the Conference, such as formal approval of the OIML budget (which follows a four-yearly cycle), the OIML long-term policy and formal adoption of Recommendations and other OIML publications (OIML, 1955). Representatives from

Corresponding Members and international and regional liaison organisations may attend the Conference as observers on the same basis as they attend CIML meetings.

*International Committee of Legal Metrology*

67. The International Committee of Legal Metrology shapes the agenda of the OIML's work in the Technical Committees, Subcommittees and Project Groups, supervises the technical work and approves OIML publications which are thus issued (and used) prior to their formal sanction by the Conference (Art. XII ff. of the Convention). Furthermore, it directs and oversees the work of the Bureau and appoints the Bureau's Director and Assistant Directors.

68. The Committee, chaired by its President, meets annually to provide oversight and strategic direction for the activities of the Organisation. It comprises one representative appointed by each Member State, who are often accompanied by national experts. Representatives of Corresponding Members and of liaison organisations may also attend CIML meetings – the latter often making written or oral presentations (OIML, 1955).

*CIML President and Presidential Council*

69. The Convention provides for the CIML to elect, from among its Members, a President and two Vice-Presidents. To cater for the need for decisions between meetings of the CIML, the Convention and other constitutional documents give the President of the CIML a number of responsibilities in such cases. The President is able to call on the advice of the Presidential Council, an advisory body consisting of the President, the two Vice-Presidents, and a limited number of CIML Members appointed in a personal capacity by the President. The Director of the BIML acts as secretary (OIML, 2011d).

*Technical Committees, Subcommittees and their Project groups*

70. The technical activities of the OIML are carried out in a decentralised manner primarily through Member States which assume responsibility for Technical Committees (Art. XVIII of the Convention). Sometimes a Technical Committee is split into one or several Subcommittees and Project Groups.

- **Technical Committees** (TC) work on all activities in a specific field of metrology (e.g. length, mass, public health, etc.);

- **Subcommittees** (SC) are built within technical committees and cover specific subjects (e.g. in the area of mass: automatic weighting instruments, non-automatic weighing instruments, etc.). Not every technical committee is necessarily broken up into Subcommittees;

- **Project Groups** draw up (by way of correspondence and meetings) draft Recommendations and Documents, which are submitted through the Bureau to the CIML for approval, following which they are published by the Bureau.

71. All Member States may choose to join a Technical Committee or a Subcommittee as either a voting Participating Member (P-Member) or as an Observer Member (O-Member). Corresponding Members may also join Technical Committees as O-Members. Liaison Organisations (typically other IOs, including those representing business), may be invited to join the Technical Committees. In February 2016, 18 Technical Committees and 46 Subcommittees were registered.

72. Members of Project Groups are drawn from the technical committees or subcommittees which they report to (except for Project Groups formed by the CIML itself). Again, members act as either P-Members or O-Members. Each P-Member designates a "main contact" who is responsible for voting on behalf of the Member State where necessary, but meetings can also be attended by other designated contacts (which may include business representatives, who will also be placed on the distribution list). Liaison organisations may similarly attend meetings and receive papers.

73. The key role in both TCs/SCs and Project Groups is played by the Member State which acts as Secretariat (for TCs/SCs) or Convener (for Project Groups). Ultimately the decision on which Member State should hold a particular secretariat is made by the CIML, though as only a limited number of Member States have the resources to undertake these roles the system depends heavily on Member States being prepared to volunteer.

*International Bureau of Legal Metrology*

74. The International Bureau of Legal Metrology is the secretariat of the OIML, headed by the Director, who is *ex-officio* secretary to both the CIML and the Conference (Art. XIX-XXIII of the Convention). In comparison to other secretariats of IOs, the Bureau of the OIML is, with only 9 staff members, rather small. An analysis of the structure of the OIML reveals that contrary to most IOs (e.g. OCDE, WTO, IMO) the role of the secretariat is mainly limited to administrative work and budget matters.

75. The Bureau prepares and organises the Conference and the Committee meetings and co-ordinates the activities of the Technical Committees, Subcommittees and Project Groups. It is responsible for liaison with the Technical Committees, Subcommittees and in some cases may act as a co-secretariat or a co-convener. It also maintains liaisons with other international and regional organisations, maintains official records of all OIML activities and publishes reports on such activities, edits publications (Recommendations, Documents, the Bulletin, Guides, *etc.*), maintains the website and performs ongoing administrative functions.

76. In addition, the Bureau collects various information on subjects related to legal metrology concerning national, regional and international regulations as well as normative and technical papers of relevance to the OIML's activities. The Committee can also mandate other tasks (e.g. responsibility for Technical Committee and Subcommittee secretariats) to be carried out by the Bureau. Pursuant to the financial provisions of the Convention (Article XXIV ff. of the Convention), the Bureau prepares the budget for each four-year period. The Director of the Bureau has, with the exception of extra-ordinary expenses, full authority to manage the financial affairs of the Bureau.

77. As already stated above, the OIML operates in very decentralised manner which is further evidenced by the fact that its Bureau mainly has a co-ordinative function, only ensuring that the whole OIML system works consistently. The secretariat offers support to the work of the political and technical organs of the OIML, which may use it as a platform of organisation and communication. It does so by ensuring that the procedures are respected and that the appropriate regulations are published (e.g. the procedures on the development of regulations).

***Decision-making process***

78. The decision-making process at the OIML is an intergovernmental, member-driven process, led by the OIML Member States. Interest groups such as manufacturing industry for instance, "observers" (e.g. other IOs) or Corresponding Members may participate but do not have the right to vote in the respective bodies. As with most standard-setting bodies, every effort is made to reach decisions by agreement and the Convention sets high thresholds for most important decisions both at the Conference and in the CIML.

79. The decision-making process differs between the Conference and the CIML. Pursuant to Art. VIII of the OIML Convention, a decision by the Conference shall become effective if at least two-thirds of the Member States are present and if the decision has received a minimum of 80% of the votes cast. Abstentions, blank or null votes are not considered. The vote of the Member State whose delegate is in the chair is decisive in the event of an equal division of votes. Proxies are not permitted at the Conference.

80. The decision-making process of the Conference concentrates on the formal sanction of Recommendations. The decision-making procedure shows that OIML Recommendations do not necessarily represent unanimous agreement of all Member States. The Recommendations can therefore be adopted more flexibly than if unanimity were required, the reasoning behind this is the specific nature of legal metrology regulations which depend *inter alia* on the development of the country.

81. The decision-making of the CIML differs slightly. Art. XVII of the OIML Convention provides that a decision by the CIML is valid if at least three-quarters of the Member States are present and if the decision is supported by a minimum of four-fifths of the number of those present and represented at the session. Absent CIML Members may vote via proxies. Between sessions and in certain special cases, the CIML may make decisions by correspondence, but the majority of decisions are made at meetings. Similar voting rules are applied within Technical Committees and Project Groups.

82. Majority voting is provided for certain Conference decisions on management and administrative matters but is rarely invoked. More significantly, a small number of CIML decisions – election of the President and Vice-Presidents and approval of new projects for technical work – can be taken by an absolute majority vote.

***Budget and staff***

83. The budget of the OIML amounted to 2.1 million Euros in 2015. The OIML has a budgetary system in which the budget is discussed and approved for a period of four years – the interval of the Conference sessions. The OIML is financed via contributions from Member States according to the size of their population with some provision for less developed economies to pay reduced subscriptions on the basis of lower use of measuring instruments (declassification). This financing model means that the largest contributors to the OIML budget are also those states with the largest populations and the most developed use of measuring instruments. For example, the USA, Brazil, China, Japan and Russia alone generate more than 25% of the total budget revenue in 2015 (OIML, 2015b).

84. Like most other IOs, the OIML combines several sources of funding. In addition to the income from subscriptions, fees for specific services (e.g. Registration to the Certificate Systems) rendered to non-Member States are also possible within the business model of the OIML. It is noteworthy that the income collected for specific services is much lower in comparison to the normal subscriptions fees of the Member States. Voluntary payments of Member States to the OIML have in the past been accepted, notably for translation purposes (OIML, 2011a),[22] but are not actively used at the moment. Direct donations from other bodies are not accepted since the organisation would risk losing its financial independence. The current financial model thus guarantees the OIML a reasonable level of financial independence, since a single Member or stakeholder alone cannot control the Organisation.

22. The OIML used to have an active translation centre for the translation of documents from French to English, which stopped its work along with the increase of English as the working language of the Organisation.

85. Staffing within the Bureau consists of a Director appointed by the CIML, 2 Assisted Directors[23] and six directly employed staff. The Bureau counted eight permanent staff members and one temporary staff in 2016.

**Forms of international regulatory co-operation**

86. The International Committee and its subsidiary bodies are the main platform for regulatory co-operation. In the subsidiary bodies, Member States can work together to share experiences, discuss technical work and seek solutions to common problems as well as develop solutions (Recommendations, technical reports, *etc*.).

87. Based on Article 1 of the Convention, the main three forms of IRC employed by the OIML are:

1. Exchange of information as well as documentation on legal metrology amongst the OIML Members;

2. Discussions on good practices on a continuing basis by joint studies and projects; and

3. Development of technical standards (Recommendations) and best practices on legal metrology.

88. The OIML is therefore involved in activities that precede standard-setting, as well as the actual development of Recommendations and best practices. Except for its own Convention (1955), OIML does not produce and manage legally binding instruments. All instruments developed by OIML are non-binding. The OIML does not routinely monitor the implementation of its instruments in the national laws of its Members because of the limited financial resources to undertake such activity. Any such monitoring is also complicated by the fact that different Member States may implement Recommendations in very different ways.

89. In addition, the OIML does not employ any form of sanctions, with the exception of suspension if a Member State has not paid its contribution for three consecutive years or more. The absence of sanctions can be explained by the nature of OIML legal instruments. Although they are usually designed so they can be transposed by OIML members into their domestic "hard law", they are voluntary and non-legally binding in nature.

90. The key characteristic of the OIML method is hence an evidence-based bottom-up approach by extensive use of non-binding legal instruments and upstream activities of the policy cycle. Even though the OIML is also involved in data collection, research and policy analysis, those instruments are not used to the same extent as in some other IGOs (e.g. OECD, WTO, IMO) (OECD, 2016).

***Documentation and exchange of information***

91. The OIML collects a fair amount of information, statistical data and documentation from its Members which offer internationally comparable statistics and indicators. The OIML is the world's largest source of data on legal metrology and produces documentation in all its fields of activity.

92. The documentation and data is made available through publications (Reports, Bulletin, Guides, etc.) and an extensive online database on its website. The OIML thus offers its Members the ability to co-operate, by granting access to information arising from its technical work. This method was introduced as a comprehensive model to facilitate the process of standard-setting in legal metrology all over the world.

23. One Position is currently vacant.

***Technical analysis and dialogue on problems of legal metrology***

93. The information and data collected serves as inputs for discussions in the Technical Committee and Subcommittee meetings in order to establish international Recommendations for measuring instruments and their use. The technical dialogue takes place mainly in the Subcommittees and Project Groups using technical data and statistics although occasional seminars are held for wider audiences, in particular in conjunction with the annual CIML meeting. Member States and other stakeholders share their experiences, identify common challenges and determine necessary and adequate characteristics of measuring instruments. In order to find solutions to technical problems, Member States share best practices implemented by certain Members to respond to given challenges, through channels of communications during the committee meetings and in the Project Groups. In some cases, this can already be the end of the work chain, since Members may implement the best practices introduced in the meetings in their national legal metrology system. The OIML bulletin is also available as a means of sharing such best practices.

***Development of standards***

94. As already noted, the most important OIML activity consists of developing technical standards (referred to within OIML as "International Recommendations"). These standards, many of which are highly specific, are mostly designed to be used by legal metrology authorities as model regulations, by incorporation into the laws of Member States. Typically, they establish the metrological characteristics required of certain measuring instruments, as well as specify methods and equipment for checking their conformity. Although designed to be incorporated into legislation, they can also be used by legal metrology authorities and industry in the same way as voluntary standards. In all there are currently more than 100 international Recommendations which are regarded as "live" on the OIML database, including a small number jointly developed with ISO (e.g. R 49 and R 99) or IEC.

***Guidance Documents and Technical guidelines***

95. The OIML provides further assistance through other publications – mainly in the series of International Documents ("D" Documents) and Guides. In some cases, the OIML sets out general principles for legal metrology or guidance to legal metrology authorities of a general nature. In other cases, there may be more specific technical guidelines aimed at assisting legal metrology authorities with implementation of International Recommendations. In particular, in the 1980s, the OIML launched the publication of Guides, which are only of an informative nature, but which clarify the application of certain legal metrology requirements. Guides form part of the OIML online publications and are periodically updated. Examples of topics on which Documents or Guides have been issued by the OIML are:

- Guidance on the establishment of simplified metrology regulations for developing countries who are experiencing difficulties drafting their legal metrology regulations;

- Planning and establishing new metrology and testing laboratories at a national level.

96. Guides have proven to be successful instruments in providing assistance to developing countries in legal metrology matters. Building on this, the OIML has become more active in its involvement in training programs, mainly by providing OIML experts to offer education to national metrology authorities on the different certification systems and model regulations.

***Capacity building in metrology***

97. The Documents and Guides have proven to be successful instruments in providing assistance to developing countries in legal metrology matters and building on this, the OIML has become more active in

its involvement in training programs, mainly by providing OIML experts to offer education to national metrology authorities on the different certification systems and model regulations. This is part of a broader activity by the OIML which can be regarded as "capacity building", that is to provide support for developing countries. The OIML participates in the Network on Metrology, Accreditation and Standardization for Developing Countries (DCMAS Network). This Network has been established by the principal international organisations that have mandates to strengthen technical infrastructure and deliver capacity building in metrology, standardisation and conformity assessment (including accreditation).[24] Members of the DCMAS Network exchange information and share best practices in providing technical assistance to developing countries. Individual technical assistance work programs can be co-ordinated and synergies may be identified amongst the IOs, such as the WTO and United Nations agencies.

***Certification Schemes***

98. A rather more specialised form or International Regulatory Co-operation can be found in the OIML Certificate Schemes – the *Basic Certificate System for Measuring Instruments*, which was introduced in 1991 and the subsequent *Framework for a Mutual Acceptance Arrangement on OIML Type Evaluations* (OIML MAA).[25] The Certification Schemes provide the manufacturer with the possibility to obtain an OIML certificate and a test report indicating that a given instrument complies with the requirements of the relevant OIML Recommendation. Every designated issuing national authority in any OIML Member State that participates in the system may accept and utilise any certificate issued by a metrology service or national body in any country (OIML, 2011b). The certificates, which are issued by national authorities, aim to facilitate and harmonise the legal control of measuring instruments by national and regional bodies. The BIML registers the certificates and publishes a list of Certifications on the OIML website.[26] The purpose of the certification schemes is to simplify the type approval process for manufacturers and metrology authorities, by eliminating costly duplication of application processes and approval testing.

99. Even where there is no formal domestic regulation, instrument manufacturers can benefit from this system, which provides data regarding compliance with the requirements of the relevant OIML Recommendations in the respective state. The system helps to promote the manufacturing, marketing and use of measuring instruments which are not yet subject to legal control. For example, manufacturers can show traceability of the measuring instruments involved in packaging of goods to their customers and thereby promote their marketing.

100. The Certification Schemes require that the instruments are systematically examined and tested on their performance. The certificate may be issued to the manufacturer based on report results of tests. Once the manufacturer has obtained the certificate, he has at least the moral obligation to produce instruments that conform to those submitted to the examination. In very successful cases of implementation, Member States consider it an offence under national law to sell instruments which do not conform to the certified type.

24. Members of DCMAS: IAF, BIPM, IEC, ILAC, ISO, OIML, the International Trade Centre (ITC), the Telecommunication Standardization Bureau of ITU (ITU-T), the United Nations Economic Commission for Europe (UNECE) and the United Nations Industrial Development Organization (UNIDO).

25. The aim of this complementary scheme was to increase confidence in test and examination results. The OIML MAA is supported by the use of formal and mandatory evaluation processes of testing laboratories, using peer reviews as instruments of evaluation.

26. Registered Certificates can be found here: www.oiml.org/en/certificates/certificat_view (accessed 24 August 2016).

***Common typologies and classifications***

101. Finally, the OIML plays an important role in ensuring the stability of language in the field of metrology, through the development of classifications and typologies. This has taken the form of the vocabularies, which provide standardised terminology. The OIML has produced two principal documents of this kind: the "*International Vocabulary of Terms in Legal Metrology*" (VIML) defines the terms used in legal metrology and its first edition (1978) was a joint effort by the OIML, BIPM, IEC, IFCC, ISO, IUPAC and IUPAP. The "*Alphabetical list of terms defined in OIML Recommendations and Documents*" is also the work of the OIML. It harmonises the language used in legal metrology. The development of a harmonised terminology is essential in improving the sharing of information across Member States.

102. The OIML is moreover member organisation of the Joint Committee for Guides in Metrology (JCGM), an IO founded in 1997.[27] The task of the JCGM is to develop and maintain metrological guidance documents, such as the VIML and the *Guide to the expression of uncertainty in measurement* (GUM). The work of the JCGM includes the promotion of the worldwide adoption and implementation of its work, most of the organisation with which the OIML is in liaison take also part in this network.

**Ensuring regulatory quality**

103. The OIML has access to a variety of tools and instruments to ensure the quality of its instruments. However, particular characteristics have to be taken into account when these tools and instruments are used by a decentralised Member State driven organisation which adopts non-legally binding instruments. In the specific case of OIML, the task of evaluating and ensuring regulatory quality is shared between the Member States and the IO.

***OIML measures to ensure regulatory quality***

104. The regulatory system of the OIML does not involve direct application of legislation on Member States. There are no sanctions of any kind, nor is there a dispute settlement procedure. Regulatory management disciplines, such as *ex ante* impact assessment and *ex post* evaluation, are not used systematically by the OIML to review the development and implementation of its Recommendations, Documents and Guides in Member States.

105. However, the OIML uses the "principles for the development of international standards, guides and Recommendations" as they are enacted by the TBT Committee as a guideline for the quality of its standards and Recommendations (Kochsiek and Odin 2001). Those principles were originally introduced by the WTO in order to ensure *inter alia* transparency, openness, impartiality and to address the concerns of developing countries, taking into consideration the effect international standards can have on the market through the TBT agreement (WTO, 2000).

106. Furthermore, in order to ensure the quality of its regulatory proposals the OIML, like many other IOs, has access to a variety of tools and instruments to evaluate its work and its implementation within its Member States. The OIML does this through four different measures i) consultation and stakeholder engagement ii) take-up of its certification systems; iii) technical guidelines and expert reports iv) periodic review of recommendations.

27. Member Organisations of the JCGM: BIPM, IEC, ISO, the International Union of Pure and Applied Chemistry (IUPAC), the International Union of Pure and Applied Physics (IUPAP), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), ILAC and the OIML.

*Consultation and Stakeholder engagement*

107. An important part of the OIML's approach consists of consultation to facilitate the implementation of its instruments. Alongside Member States and Corresponding Members, a wide range of IOs have been granted a consultative status in OIML discussions and meetings. This consultative status provides the right to attend Committee meetings and to participate in the work of the OIML, though without voting rights in the final decision-making procedures. It also gives the right to receive Documents and Recommendations adopted by the OIML (Art. V of the Convention).

108. Even though the main participants in OIML activities are governments, consultations with private stakeholders (such as e.g. the manufacturing industry) are also a strong feature within the OIML system. Both are important to ensure the quality and practical use of OIML instruments. The process of drafting Recommendations benefits particularly from trade associations which have a natural interest in the outcome of possible national regulations on legal metrology. There are several ways by which private stakeholders can participate in the regulatory process:

- as technical experts in TCs/SCs and Project Groups;
- through expert reports;
- through national mirror committees;
- through public consultations with their respective government.

109. Regarding the selection of stakeholders to participate, naturally only the selection of technical experts in TCs/SCs and Project Groups, and those invited to prepare expert reports, are within the direct competence of the OIML itself. Most industry representatives and other private stakeholders are selected and agreed upon by the voting participating members (P-members) of the respective TC/SC or Project Groups. By this process, the OIML tries to balance competing group demands amongst the different private stakeholders. Individual stakeholders may also participate in the regulatory process by writing expert reports on specific legal metrology issues. Those experts in the field are chosen by the BIML, but write their reports independently.

*Certification Schemes*

110. Another indication of the usefulness of OIML Recommendations is their take-up for the purposes of the Certificate Schemes already mentioned. Broadly speaking, the greater the number of certificates issued for a particular Recommendation, the stronger the evidence that it is being widely used. Even where there is no formal regulation, instrument manufacturers can benefit from obtaining certificates which provide evidence regarding compliance with the requirements of the relevant OIML Recommendations, again providing a measure of the extent to which that Recommendation may be being used even as a voluntary standard. The OIML registers every Certificate issued by the Member States and publishes a list on the OIML website in order to monitor the take-up and implementation of Certificates.[28]

*Expert reports*

111. Additionally, the OIML makes periodic use of expert reports to facilitate the understanding of detailed regulation. Such expert reports may be written solely from the viewpoint of independent authors,

28. www.oiml.org/en/certificates/basic-certificates.

without the involvement of the OIML. These reports concentrate mainly on assisting countries in implementing a uniform and effective regulatory framework.

112. Nevertheless, expert reports can also be used to track the substantive impact of the work of the OIML by gathering information and measuring its outcomes. One case where OIML has made use of external expert reports to analyse the benefits of its work is the report by John Birch on the *"Benefit of Legal Metrology for the Economy and Society".* This report was commissioned by the OIML in 2003 in order to show the use of legal metrology and to quantify the economic and social advantages for society. Thus the main aim of the initiative by the OIML was to stimulate and increase the engagement of the legal metrology community to promote its work to governments and economists. Expert reports such as this one can for example be used as a basis for the cost/benefit analysis in the Member States to demonstrate the value of implementing OIML Recommendations.

*Stock review of Recommendations*

113. The OIML has also initiated a process of optimising the quality of its standard-setting activities for Member States, by reviewing the overall stock of Recommendations in the Organisation. The process of Recommendation review was launched in 1993 with the *Basic Publication on Directives for the Technical Work Part 1*. Within this context, it was decided that the Recommendations and Documents were to be reviewed every five years after their publication. The Bureau is responsible for initiating and co-ordinating the review process. A review can also be proposed at any time by a Member State or by the Bureau. The Technical Committee or Subcommittee which issued the Recommendation or Document then recommends whether the Recommendation or Document should be confirmed, revised or withdrawn. The results of this TC/SC review are then put to the whole CIML which makes the final decision on confirmation, revision or withdrawal. The primary criterion used in the review process is the actual use of the Recommendation in light of changes within the technology employed in measuring instruments and its importance for the national regulation (OIML, 2011b).

***Member State measures***

114. Even though the Member States are not bound by the OIML Convention to do so, many of them perform a number of measures in order to ensure the quality of OIML Recommendations in their national system. By this means the Member States fulfil their part to ensure regulatory quality, which is very important considering the fact that OIML international Recommendations are phrased in a way which enables almost direct implementation in the national law systems and illustrates once again how much the Organisation is member state driven.

*Cost/benefit analysis (CBA)*

115. Many Member States of international organisations have domestic requirements which oblige them to conduct some form of CBA before adopting the standards and other legal and policy instruments of IOs in their domestic legislation. Indeed, because of the high impact of metrology on international trade, CBA has the potential to play an important role during the decision-making process in Member States as to whether and how a standard should be developed and implemented. Such analyses are performed by the Member States, both because of the differences between countries in the factors to consider and because the OIML is not in a position to provide in-depth cost/benefit analysis for individual Member States to promote its Recommendations.

*Monitoring implementation*

116. The responsibility for monitoring the implementation of legal metrology lies entirely with the Member States. Given its limited resources and size, the OIML secretariat is unable to take part in this task. According to Article VIII of the Convention the States themselves must register and assume jurisdiction in respect of administrative, technical and social matters concerning legal metrology. Based on the completely voluntary approach of the OIML, Member States decide which Recommendations to implement and which certifications should be recognised. This approach also includes the voluntary reporting of the Member States on their progress of implementation (Art. VIII of the Convention).

## ASSESSMENT OF THE IMPACT OF REGULATORY CO-OPERATION

117. Evaluation of the impact and benefits of regulatory co-operation through the OIML remains an undeveloped field, due to the above mentioned lack of monitoring. In order to get a clear cut picture, a more systematic exchange of information with Member States on the impacts and the implementation of OIML instruments domestically would be needed. The perceived benefits may include the reduction of transaction costs (in particular those associated with disputes), consumer protection, effective stock control, the reduction of fraud, the enforcement of fair trade practices, as well as knowledge flow. Challenges include the "buy-in" of Member States, the lack of regulatory flexibility, the difficulty to keep up with the rapid technological challenges and implementation issues.

### Benefits, costs and challenges of regulatory co-operation through OIML

118. Quantified evidence of the benefits, costs and challenges of the co-operation of members through OIML is limited and non-systematic. However, the average system for filling pre-packaged products provides an example for an OIML Recommendations which led to greater transparency, consumer protection and economic benefit in the processing of food. Recommendation R 87, currently under revision, gave birth to a widely-used definition of average packing system, which is perceived as being widely recognised within the legal metrology community.

119. The benefits for the society should also not be underestimated. Due to *inter alia* the enforcement of legal metrology regulations, safety standards around the world are generally good and constantly improve over time. Road fatalities, for instance, have considerably decreased since the 1970s. Better roads, driver education and compulsory seat belts have contributed significantly to that result. Legal measuring instruments such as vehicle speed measuring devices and breath analysers are also a reason for the decline in road fatalities. The implementation of key OIML Recommendations has led in many cases to a decline in accident rates according to an expert report conducted in 2003 (Birch, 2003). More significantly, measuring devices have increased the likelihood of apprehension and confidence in their accuracy. A major study of the WHO in 2015 suggests that road traffic accidents cost countries approximately 3% of their gross national product, with that number increasing to 5% in low- and middle-income countries. Consequently, legal metrology also benefits countries economically.[29] The change in driver behaviour is additional evidence that legal metrology can be a cost-effective method of social engineering (Birch, 2003). However, as already stated above, the evidence is rather fragmented. The extent to which OIML Recommendations lead to a positive result greatly depends on the degree of implementation and use by the Member States.

### Assessment of success

120. Two aspects need to be looked into, in order to assess the success of the regulatory co-operation of the OIML: the scale of impact, and the level of implementation. The OIML is widely accepted as an international standard-setting organisation, with a growing membership and strong non-member engagement in its activities. The well-recognised quality and accessibility of its technical work is further underlined by the growing use of the Certificate systems. Furthermore, and more importantly, the endorsement of OIML Recommendations by the WTO through Art. 2.4 of the TBT agreement is a key factor for successful implementation (OIML, 2015a).

29. WHO, N°358, for further information: www.who.int/mediacentre/factsheets/fs358/en/ (accessed 04 April 2016).

***Scale of impact***

121. The scale of impact of the OIML can be understood by analysing three different factors: the geographic coverage, the sectors in which the regulations are involved and the importance of measurement within the respective sectors.

122. The geographic coverage of OIML Recommendations is rather comprehensive, with all regions represented in OIML membership. Altogether, Member States cover 96% of the world economy (IMF, 2016) and 86% of its population (United Nations, 2015). This being said, the involvement of new Member States and partners is essential for OIML Members to maintain their interest in the work of the Organisation, and to reach the overall goal of harmonisation. Ultimately, the status of "Corresponding Member" is to be understood as a stepping stone towards full membership.

123. In regards to the areas in which OIML Recommendations find their applicability, the majority, as shown above, concern instruments used for trade. Even though the coverage of the Recommendations within the other three areas (health, safety and the environment) is de facto not as universal in comparison to trade, the potential to cover all aspects of human life through OIML Recommendations is aspired by the OIML. The areal coverage is therefore also quite universal but has naturally, because of the OIML's history and the prevailing interest of Member States in trade-related matters, different intensity. If the OIML is to address the challenge to improve the coverage of other areas apart from trade, it will have to establish closer co-operation with other IOs in the respective areas, e.g. Codex Alimentarius.

124. When it comes to the importance of measurement within the sectors, the well-known benefits of legal metrology (such as e.g. cost reduction, fairness in trade, consumer protection, *etc.*) underline the importance of measurement regulations. A further indicator for the importance of measurements in these sectors is the fact that the OIML benefits greatly from strong support by its Member States, as shown by the large number of Member States that pay their contributions on time and engage actively in the work of the OIML.

125. In conclusion, the scale of impact of the OIML is quite comprehensive due to the wide geographical coverage, the different areas Recommendations are involved in and their importance for the user-community.

***Level of implementation***

126. The question of adoption of international standards is a very important one and often goes to the heart of the matter when it comes to effectiveness of IOs. As mentioned above, the OIML has no tools to enforce its standards directly. The level of implementation by States is dependent on their willingness to transpose the Recommendations into law or find other ways to recognise them for regulatory purposes. Beyond voluntary reporting, no standardised methodology has yet been introduced to measure the degree of implementation and compliance of the Recommendations and Documents of the OIML. Due to the fact that some countries may lack the infrastructure to use the Recommendations or may chose a different way of regulation while others may adopt OIML Recommendations without an explicit reference, there is not much quantifiable evidence of the level of implementation of OIML instruments.

127. One area where the level of implementation can be accurately measured is in the use made of the OIMLs MAA certificate scheme, where countries have the opportunity actively to sign a "Declaration of Mutual Confidence. In fact, there has been a disappointingly level of "buy-in" of Member States in the MAA and the OIML is currently remodelling both certification schemes (MAA and Basic Certificate System) into one single system, in order to tackle that problem.

128. Despite the above-mentioned challenges, however, it is clear that countries (not just Member States) do recognise OIML Recommendations and other activities of the OIML in their national legal metrology systems. Different OIML projects, such as for instance the OIML *International Vocabulary of Legal Metrology* are widely accepted (Athané, 2001) and the 2 840 certificates issued by the end of 2015 are evidence of successful use of OIML instruments.

129. The situation of the OIML therefore gives rise to the question of how a highly decentralised, Member State-driven organisation can uphold and improve the level of implementation, bearing in mind that its legal instruments are non-binding. The OIML does that by on the one hand relying on its own measures (a) and on the other hand taking advantage of the WTO framework (b).

*OIML measures*

130. The voluntary strategy chosen by the OIML relies on three main pillars. Firstly, the OIML exercises a high degree of transparency and accessibility of its work. Every Document and Recommendation is free to download from the website. Second, the character of the OIML's work is technical and specific, which makes stakeholder involvement easier and furthermore fosters common interest amongst both Members and non-members. Third, the OIML employs a consistent dialogue not only with Member States, but also with non-member states and private stakeholders.

*WTO framework*

131. The WTO framework is the second aspect that encourages the implementation of OIML Recommendations. Indeed, more so than the "moral obligation" of OIML instruments, the WTO TBT Agreement is the main driver for the implementation of OIML Recommendations into national legal systems (OIML, 2015a). Due to the fact that OIML Recommendations can be considered as 'relevant international standards' according to the WTO Agreement on Technical Barriers to Trade (TBT), their adoption may also be considered as an obligation under WTO law. Since the majority of OIML Members are also members of the WTO, the enforcement mechanisms of the WTO therefore apply to them. There are hence strong incentives for Member States to implement the trade-related OIML Recommendations. It is firstly only natural for the Member States to implement trade-related regulations for their greater benefit. And secondly, the stronger legal framework of the WTO has a powerful incentive not only to endorse OIML Recommendations, but also to achieve their implementation in the national systems.

**Factors of success**

***The institutional architecture***

132. As already noted, the implementation of OIML Recommendations depends highly on the Member States. However, implementation is largely facilitated within the OIML framework by the interplay of the stakeholders (trade associations, industry organisations and national laboratories) that provide incentives for companies and state administrations to push the harmonisation process forward. The institutional structure therefore allows non-members and Members alike to join in the debate on Recommendations on every level of the decision-making process. Furthermore, every Technical Committee may establish Subcommittees and Project Groups on every subject matter, which grants the Organisation a lot of flexibility. This institutional flexibility is very much needed in the never-ending race to catch up with technological developments.

***Strong industry support***

133. The OIML benefits from strong support from industry actors in different areas. This support can be explained by the extensive consultations and participation of stakeholders *via* national mirror

committees in the different bodies of the Organisation. Stakeholders make systematic use of the opportunity to comment on proposed actions, thereby playing an important role in the drafting of the Technical Committee and Subcommittee work. For instance, EU trade associations take part in the process, channelling back and forth between the EU institutions and the OIML on regulatory matters. The revision of Recommendation R 35 on material measures of length for general use (with its 2014 amendment) is an example of the co-operation between industry and the OIML that took place as a result of consultation between the TC/SC secretariat and industry representatives. Another important factor is that all main OIML bodies are composed of legal metrology representatives with engineering backgrounds, which ensures practical approaches to challenges. This gives a fair chance to successful implementation by national administrations and industry.

***Quick procedures and transparency***

134. Even though the voting rules in some of the bodies do not require unanimity, the general aim of the OIML is to achieve a high level of agreement in order to push the harmonisation of legal metrology forward. The relatively small membership and good links between the leading representatives of the Member States enable the OIML to reach agreements relatively quickly. Given that the voting procedures come with high transaction costs for secretariats and for participants, the OIML has devoted a lot of attention to improving the use of new technologies to increase efficiency and lower costs. For instance, since 2011, the Bureau has improved the mechanisms and shortened the time required to complete technical work by improving the features of the website for Member States and Corresponding Members, for example through online voting procedures. In doing so, the OIML has not only introduced more transparency into its work, but has also achieved an increase in the acceptance of Recommendations.

***High technical skills and solid scientific competences***

135. The technical format in which the Recommendations are drafted, as well as the easy practical adaptability of the model regulations into national regulations, demonstrates the practical approach of the OIML. Two examples are the guideline for the *Establishment of simplified Metrology Regulations* and the Guide on *Planning of Metrology and Testing Laboratories*. The latter has by its practical approach been particularly useful for developing countries. The accessibility of all the OIML's activities and legal instruments enables private stakeholders in both developed and developing countries to use the OIML's work to the most suitable extent in line with different national circumstances. This paves the way to harmonising legal metrology, one step at the time.

***Recognition by user-community***

136. Many OIML Recommendations have been widely accepted by the international community to constitute an international legal metrology standard on a particular issue. OIML Recommendations and Documents are therefore considered to be a reference and find broad application beyond the OIML membership. For example, the Recommendation on pre-packaging of goods has become a main reference point in its field and the definitions it contains are generally accepted. Furthermore, the *International Vocabulary of Legal Metrology* is evidence of the successful adoption of a common terminology in the field of legal metrology (Athané, 2001). Besides that, the standard-setting capacity of the Organisation is underlined by the consistent use of Recommendations and reference to the OIML by the EU and the WTO. Beyond the standard-setting activity of the OIML, activities such as the Certification System and the support network for developing countries (DCMAS) through technical support in the areas of testing and accreditation are increasingly recognised by the international community. The various activities in different contexts strengthen and underline the legitimacy of the Organisation in the field of legal metrology and beyond.

***Co-operation in case of overlapping regulations***

137. There can be overlaps between international organisations which regulate metrology and standardisation of measurement, when definitions and standards of different organisations are related. The co-ordination between the different organisations has relatively recently increased in order to avoid confusion. The wider international metrology policy is exercised by the OIML and BIPM. The infrastructure policy, however, is split between different specialised agencies (IEC, ISO, OIML, BIPM, ILAC, IAF). This is due to the nature of the international standard-setting bodies and legal metrology network of specialised agencies as sectorial agencies, with headquarters in different locations. Due to this fact, inter-agency co-ordination can be challenging. However, co-operation emerged right from the beginning in the form of consultations and incorporation of different policies and information provided by various organisations. In addition, there are joint project groups established by ISO, IEC, BIPM and ILAC concerning regulatory and technical co-operation, as well as *Memoranda of Understanding*. This way, all the organisations in the general framework of legal metrology avoid duplication and benefit from the input of their partner organisations in the drafting process of their work.

138. In this regards, the co-operation and regulatory overlap between the OIML and the EU is the strongest. This is potentially because the European Commission has the most widespread competence on regulatory responsibilities of all regional organisations. This has nevertheless not led to conflict between the two organisations. On the contrary, the EU uses most of the OIML Recommendations and helps with its unique structure by unanimous implementation in the European market. The working relations between the EU and the OIML are therefore generally good. The co-operation between the OIML and the EU has worked well with the establishment of the *European Directive 2004/22/EC on Measuring Instruments*, because the OIML has provided the definitions and technical work and the EU has the means to ensure the necessary implementation.

## CONCLUSION

139. Legal metrology is an excellent area for studying international regulatory co-operation because of its worldwide reach, impact and potential for technical regulation.

140. This case study has identified the factors leading to success within the structural architecture in the OIML, including the ability to reach quick and relatively stable agreements, the relatively small community involved in progressing the most important work, and common interests. Another key factor of success is the flexibility of voluntary technical standards, which facilitate the buy-in of Member States. Depending on the level of technical development of the country, many of the Recommendations have comprehensive coverage and appear to be rather well-enforced.

141. The OIML as an international standard-setting organisation for legal metrology has acquired credibility and legitimacy in metrology, owing to its widespread use of consultations, technical assistance and guidance on best practices and its sponsorship of activities such as certification and capacity-building. Its reputation has supported a broad acceptance of Recommendations and definitions developed by the Organisation, including by countries outside of its formal membership.

142. In addition, the practical approach in the development of Recommendations – the development of technical assistance, training programs and expert reviews – is evidence that the instruments are successful. Direct consultations with experts and private stakeholders as well as their involvement in the development of Recommendations help to strengthen trust and provide the necessary support from the private sector for regulatory implementation. The success in regulatory co-operation is therefore also due to the strong interplay of public and private incentives as well as other international organisations in the field. Overall, international regulatory co-operation in legal metrology can therefore be considered a relative success.

143. Nevertheless, this case study also identifies a number of challenges faced by the OIML. In order to show the economic and social gains as well as the increased administrative efficiency of the OIML's work, systematic and structured evaluation through Expert Reports has in the past proven to be a successful tool, which ought to be used more frequently, to create greater momentum for Member States to implement OIML Recommendations into national law.

144. Similarly, the Certification schemes, in particular the Mutual Acceptance Arrangement, have not made as much impact as had been expected because of a low "buy-in" from the Member States. There appears to be a lot more potential for both schemes to be further realised and promoted to Members and non-members of the Organisation. Indeed, in 2016 the Organisation is working on a complete overhaul and the development of a single integrated System in order to address this concern.

145. Due to the relatively small size of the Secretariat, almost no monitoring mechanisms are operated by the OIML. Peer reviews and peer pressure could improve the monitoring process of implementation and would also take the costs and limited capacities of the Bureau into account. By these means, evaluation of the work could take place and the needs of developing countries, for instance, could be met to a much greater extent.

146. This case study has shown that the OIML's work is most successful in regard to international trade facilitation, especially thanks to the incentive for implementation of OIML standards provided by the WTO TBT Agreement. However, the other areas of interest to metrological regulation fall short in comparison to trade. A closer co-operation with other specialised IOs developing standards in the other areas of safety, health and environment, would increase impact and success of OIML Recommendations in those fields.

147. The technological change propelled by globalisation leads to the increasing need to speed up the standard-setting process in order to keep up with rapid developments. The flexible institutional structure of the OIML does provide a good basis in order to address this challenge. However, there is still scope for the procedures to be optimised to reach their maximum potential. Greater use of the OIML web-site for online development of OIML technical work is already a feature of the OIML Strategy. With the continuous developments in IT and communications, this will need not only to continue but to accelerate. In turn it is necessary to keep under review the structures and policies which govern OIML's technical work. OIML has already made a conscious decision to look for models among other IOs which might be emulated, so recognising that the structure, policies and experience gained by other IOs can be of great assistance in tackling these challenges. Bearing in mind the limited resources available both to the OIML and to its Members, concentrating the efforts where the greatest added value can be achieved would lead to mutual benefit and possibly more successful implementation of OIML international Recommendations.

## ANNEX A. DEFINITION OF METROLOGY

148. Metrology comes from the Greek words "metron" and "logos" which means (literally translated) the study of measurement (Goldsmith, 2010). The BIPM, defines metrology as "the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology".[30]

This wide definition extends to all "units of measurement and their standards, measuring instruments and their field of application and all theoretical and practical problems relating to measurement" (Ramful, 2004).

149. Metrology is usually categorised into three different branches: scientific, industrial and legal metrology.

***Scientific metrology***

150. Scientific metrology, also sometimes referred to as fundamental metrology, concerns itself with problems common to all metrological questions in general. It searches to solve theoretical and practical problems of all kinds, including uncertainties and errors in measurement. Scientific metrology is the basis for establishing and developing quantity systems, units of measurements, unit systems and new measurement systems to develop standards in industry and society (Howarth and Redgrave, 2008 and Ramful, 2004). It is traditionally the main focus of the BIPM.

***Industrial metrology***

151. Industrial metrology focuses on measurements and measuring instruments used in production and quality control. Through these activities, the correct use of measurement science in manufacturing processes and in other applications not subject to regulation is assured. The main focus lies in the calibration procedures in industry, to ensure compliance with the market-driven requirements (Howarth and Redgrave, 2008 and Ramful, 2004).

***Legal metrology***

152. The *International Vocabulary of Legal Metrology* defines legal metrology as the practice and process of applying statutory and regulatory structure and enforcement to metrology (OIML, 2013). In other words, legal metrology "concerns activities which result from statutory requirements and concern measurement, units of measurement, measuring instruments and methods of measurement and which are performed by competent bodies" (Ramful, 2004 and OIML, 2013). This area is the main focus of the OIML.

153. The legal metrology systems differ enormously from country to country, influenced by the legal and administrative traditions of different countries and the level of economic development. Regulations, based on legal metrology standards, affect our daily lives in various ways. Most countries have legal metrology regulations regarding trade. A sound legal metrology system facilitates the trading of goods by ensuring quality and quantity as well as fair trade practices. A fair and competitive marketplace is therefore ensured by the application of international standards based on legal metrology in trade (Ramful, 2004).

30. For more information, see BIPM website: "What is Metrology?": www.bipm.org/en/worldwide-metrology/ (accessed 15 July 2016).

154. The control of measurements concerned with public health and human safety is also essential for the protection of citizens: an inappropriate dose of x-rays, for instance, may lead to accidents or incorrect diagnosis and treatment. Studies have also shown that the consistent use of legal metrology has led to a decrease in road facilities (Birch, 2003).

155. As a further example of the application of sound legal metrology practices across the world, tackling the environmental challenge of our planet can only be thoroughly done if pollution is accurately measured and monitored. Countries are expanding their efforts to regulate environmental issues, which will be important areas of work for legal metrology practitioners in the future (Ramful, 2004).

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