The role of WELMEC in Europe

Anneke van Spronssen

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欧州におけるWELMECの役割

Anneke van Spronssen
Content

- Legal Metrology in Europe
- European Directives
- WELMEC
目次

欧州における法定計量
欧州指令
WELMEC
The EU is an union of independent states

- The member states (MS) have delegated only part of their power to the EU
- Decisions are taken at an appropriate level ➞ subsidiarity

Units of Measurement have been harmonized

- (SI-system)

Common market for products ➞ also for legally regulated measuring instrument (MI)

- Measuring instrument directive (MID)
- Non-automatic weighing instrument Directive (NAWID)
  ➞ Manufacturer’s Declaration of Conformity/Notified Bodies
EUは独立国の連合である

- 加盟国 (MS)は、各国の権限のごく一部をEUに委譲している
- 決定は、適正な水準で行われる ⇒ 権限委譲

測定単位は、整合化されている

- (SI系)

製品の共同市場 ⇒ 法規制対象の計量器(MI)についても

- 計量器指令 (MID)
- 非自動はかり指令 (NAWID)

⇒ 製造事業者の適合宣言/通知機関
Differences in regulated areas between member states.

- The use of MID instrument is optional! But if MI is regulated then MID requirements. e.g. Germany broader regulated area of measurement than Sweden or UK.

NAWID harmonizes all stages of the MI lifecycle.

- Also after it has been taken into use.

MID harmonizes early stage of MI lifecycle

- Until the MI has been placed on the market and put into use.
欧州連合（EU）における法定計量

加盟国間での規制分野の違い。

- MID計器の使用は任意となっている！しかし、MIが規制対象であれば、例えば、スウェーデン又は英国よりも広範なドイツの規制分野など、MIDの要件の対象にもなる。

NAWIDは、MIのライフサイクルの全段階を整合させている。

- MIが使用に付された後も

MIDは、MIのライフサイクルの初期段階を整合させている

- MIが発売され、実際に使用されるまで
Surveillance procedure for MI in service has not been harmonized.

- MS have their own surveillance system ⇒ Subsidiarity principle
- Significant differences exist between the MS systems
- In most MS the surveillance on MI in use are based on a Mandatory periodic Verification by competent third party
- Some MS like UK and the Netherlands have an inspection approach by public authority.
欧州連合（EU）における法定計量

使用中のMIに対するサーベイランス手順は、未だ整合されていない。

- MSは、各国独自のサーベイランスシステムをもっている ⇒ 権限委譲原則
- MSの制度間には、大きな違いが存在する
- ほとんどのMSでは、使用中のMIのサーベイランスは、適格な第三者による義務的な定期検定に基づいている
- 英国、オランダなどいくつかのMSには、公的機関による検査の取組みが行われている。
Conformity Assessment procedures
適合性評価手順
Conformity Assessment procedures

A: Internal product control
A1/A2: Internal production and supervised product checks
B: Type examination (design)
C / C1: Internal production control
D / D1: Quality assurance production process
E / E1: Quality assurance product inspection
F / F1: Product verification
G: Unit verification
H: Full quality assurance
H1: Full quality assurance + design

+: taking into account extra requirements for testing, product related knowledge or ability to decide on conformity
適合性評価手順

A : 内部生産管理
A1/A2: 内部生産チェック及び
  監督下での製品チェック

B : 型式審査（設計）

C / C1: 内部生産管理

D / D1: 品質保証生産プロセス

E / E1: 品質管理製品検査

F / F1: 製品検定

G : ユニット検定

H : 完全な品質保証

H1 : 完全な品質保証 + 設計
  審査

+: 試験の追加要件、製品関連の知識又は適合性を決定する能力を考慮に入れる

17025+, 17020+又は17065+
17025+, 17020+又は17065+
17025+, 17020+又は17065+
17021+又は17065
17021+又は17065
17025+, 17020+又は17065+
17020+又は17065+
17021+
17020+, 17021又は17065
2004: Stocktaking exercise by EUC on experience with new approach.

New Approach legislation is at large successful:

- internal market for goods is a reality.
- protection of public interests at a high level (health safety, consumer protection, etc)
- free movement of goods due to harmonised conditions.

Shortcomings:

- Significant number of non-compliant products
- Unsatisfactory performance of certain notified bodies
- Application unnecessarily complicated by inconsistency in the legislation.

Conclusion: new instruments needed to strengthen and complete existing rules ⇒ New Legal Framework.
新たな法的枠組み

2004：新たな手法（ニューアプローチ）を用いた経験に基づくEUCによる見直し

ニューアプローチ法令は、全体として成功している：

- 商品の域内市場は、一つの現実である。
- 高い水準の公益保護（健康安全性、消費者保護、その他）
- 整合状態による商品の自由な移動

欠点:

- 著しい数の不適合品
- 特定の通知機関の不十分な実績
- 法令の不整合により、適用が不必要に複雑化している

結論：既存の規定を強化し、完全なものとするために新たな手段が必要である⇒新たな法的枠組み
Main changes due to NLF

- Alignment procedures MID and NAWID
- Obligations manufacturer and authorised representative more explicit
- Importer and distributor are introduced
- Technical documentation should include risk analyses
- Declaration of Conformity must contain all applicable directives.
NLFによる主要な変更

- MIDとNAWIDとの整合手順
- 製造事業者及び正式な代表者の義務のいっそうの明確化
- 輸入業者及び販売業者を新たに加える
- 技術文書には、リスク分析を記載することが望ましい
- 適合宣言には、適用される指令をすべて含まなければならない。
Any questions about the New Legal Framework?

Consult the Blue Guide

新たな法的枠組みに関する質問があるときは？
ブルーガイドを調べること

Normative documents in MID

Manufacturer must proof conformity with the essential requirement and may use any technical solution that complies with the essential requirements.

Presumption of conformity only by the use of:
- Harmonised standards (MID + NAWID)
- Normative documents. (MID)

What is a **normative document**?

List of requirements of OIML recommendations which covers the essentials requirement of MID
製造事業者は、必須要件への適合性を証明しなければならず、また必須要件を遵守するあらゆる技術的解決方法を使用することができる。

次のもだけを使用することによる適合性の推定：

- 整合規格 (MID + NAWID)
- 規準文書 (MID)

規準文書とは何か？

MIDの必須要件を収めるOIML勧告の要件のリスト
Legal metrology

Legal metrology is the science of measurement. It is very important for trade and our everyday lives. No market can function without correct measuring and without common units of measurement. The EU’s legislation on legal metrology is one of the pillars of the single market for products. EU requirements aim to promote technological innovation, protection of health, public safety, protection of the environment and fair trade.

Units of measurements

The European system of units of measurement starts from the International System of Units (SI). The SI serves as a global standard. More on units of measurement.

Measuring instruments

Measuring instruments harmonised by EU law range from weighing scales and utility meters to thermometers. In 2013, the annual turnover of the sector was estimated at €7 billion.

The European Commission carried out a study on the life cycle costs of measurement instruments. The costs include the purchase, installation, operation, and maintenance of the instruments. The study found that the average life cycle cost of a measurement instrument is between €100 and €200. The cost of maintaining a measurement instrument is between €20 and €50 per year.

The study also found that the cost of measuring instruments is influenced by the quality of the instrument, the frequency of use, and the level of maintenance.

Free movement in harmonised and non-harmonised sectors

International aspects of the single market

Pre-packaging and pack size

The EU’s pre-packaging legislation defines the quantity contained in pre-packaged products. It helps guarantee the net quantity in pre-packed and the volume of product in bottles or jars. EU law requires national authorities to do regular market surveillance. EU laws prohibit EU currencies to be legal on any and it bans fixed prices for wine and spirit drinks.

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Measuring instruments harmonised by EU law range from weighing scales and utility meters to thermometers. In 2010, the annual turnover of the sector was estimated at €7 billion. The European Commission measures (712 MB) to OH, CEN/ISO and ETSI in the field of measuring instruments is leading to the creation of European standards that will enable interoperability of utility meters (water, gas, electricity and heat) and enhance energy efficiency and user empowerment. The ETSI draft EN441 concerns new European standards for the non-regulation of errors of water and heat meters, metering small-scale delivery of active electricity to the grid and use of energy by electrical vehicles. The new standards are expected to be delivered by the end of 2017.

More on measuring instruments

Pre-packaging and pack sizes

The EU pre-packaging legislation defines the quantity contained in pre-packed products. It helps guarantee the net quantity in pre-packed and the volume of product in bottles or cans. EU law requires national authorities to monitor market practices. EU law prohibits EU countries to regulate on packs and it bans fixed sizes for wine and spirits drinks.

Measuring instruments

Measuring instruments range from water meters to weighing machines. They are important for trade, consumers and industry as they ensure accuracy of measurement, transparency and fairness.

Evolution of the legislation

- Covers 10 categories of measuring instruments, and abolishes the corresponding previous legislation, depending on Framework Directive 2009/13/EC amending Directive 71/315/EEC.
- Adopts a decisively modern regulatory approach, leaving much more room for technological innovation and more choice for manufacturers in conformity assessment procedures.
- Aligns Community legislation on international standards, in particular the 0101 and covering the electronic resolution that has characterised measuring instruments since the 1870s.
- Directive 2014/31/EU on Non-Automatic Weighing Instruments (NAWI) follows the same approach replacing Directive 2008/98/EC, the codification of the original Directive 90/384/EEC.

Implementation of these Directives takes place in close cooperation with WEMEC, the Western European Metrology Cooperation, which serves as a platform for cooperation among its European members' authorities.

Report on MID

In 2010 the Commission held a public consultation on the Measuring Instruments Directive 2004/22/EC. The aim of the consultation was to gather feedback on the implementation of the Directive and on the reasons and impacts of possible changes.

- All reactions to the Public Consultation of September - November 2010 (8 MB)

Background documents on MID

Legislation on measuring instruments

European standards

Normative documents
Normative documents and guidance

<table>
<thead>
<tr>
<th>Essential requirements in MID (Annex 1 and MI-002)</th>
<th>OIML R 137 (2012)</th>
<th>Comment</th>
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<tbody>
<tr>
<td>8</td>
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<td>9.1.4.2</td>
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<td>8.3</td>
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Guidance to normative document: Corresponding tables
(WELMEC website)

http://www.welmec.org
規準文書及び手引き

規準文書

(委員会ウェブサイト)

規準文書の手引き：対応表

(WELMECウェブサイト)

http://www.welmec.org

<table>
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| 8.2                                              | 9.1.1            | Covered |
|                                                  | 9.1.3            |         |

| 8.3                                              | 1.1.1            | Covered |

(1) 2004/23/EC: Essential requirements of Annex 1 and Annex MI-002

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<tr>
<td>8.1 The metrological characteristics of a measuring instrument shall</td>
<td>5.13.8</td>
<td>“Gas meters provided with ancillary devices shall be designed such that</td>
<td>Covered</td>
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<td>not be influenced in any inadmissible way by the connection to it of</td>
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<td>all functions of the ancillary devices (e.g. provisions for</td>
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<td>another device, by any feature of the connected device itself or by</td>
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<td>communication purposes) do not affect the metrological behavior.”</td>
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<td>any remote device that communicates with the measuring instrument.</td>
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<td>“Ancillary devices shall not affect the correct operation of the</td>
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<td>instrument. If an ancillary device is not subject to legal metrology</td>
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<td>control this shall be clearly indicated.”</td>
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<td>“For gas meters of which parts may be disconnected, the following</td>
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<td>provisions shall be fulfilled:</td>
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<td></td>
<td></td>
<td>a) Access to the parameters that contribute to the determination of</td>
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<td>results of measurements shall not be possible via a disconnected port</td>
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<td>unless the provisions in 9.1.4 are fulfilled.</td>
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<td>b) Interposing any device which may influence the accuracy shall be</td>
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<td>prevented by means of electronic and data processing securities or, if</td>
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<td>not possible, by mechanical means.</td>
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<td>c) Moreover, these gas meters shall be equipped with provisions</td>
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<td>which do not allow the meter to operate if the various parts are not</td>
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<td></td>
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<td>configured according to the manufacturer’s specifications.”</td>
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<tr>
<td>8.2 A hardware component that is critical for metrological</td>
<td>9.1.1</td>
<td>“Protection of the metrological properties of the meter is accomplished</td>
<td>Covered</td>
</tr>
<tr>
<td>characteristics shall be</td>
<td></td>
<td>via hardware (mechanical) sealing or via electronic sealing.”</td>
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</table>
RESPONSIBILITIES

European Union → Directives

Member States → Implementation
National Law

Common Interpretation

Common Application

WELMEC

Stakeholders Participation (manufactureres)
責任

欧州連合

加盟国

Common Interpretation

Common Application

指令

施行 国内法

WELMEC

利害関係者の参加
(製造事業者)
Aim of legal metrology: correct measurement

Responsibilities in Legal Metrology

- European Commission
- Member states
- European/international organizations (OIML, EA, CEN/CENELEC)
- Notified bodies
- Market surveillance
- European trade organizations

WELMEC brings all parties together in order to find a harmonized implementation of European legislation, respecting the individual responsibility.
WELMECの協力

法定計量の目標：正しい測定

法定計量に対する責任

- 欧州委員会
- 加盟国
- 欧州/国際機関
  (OIML, EA, CEN/CENELEC)
- 通知機関
- 市場サーベイランス
- 欧州の業界団体

WELMEC は、個々の責任を尊重した上で、欧州法令の統一的施行方法を見つけるために、全関係者をまとめている。
WELMEC AT PRESENT

31 Members
28 EU + 3 EFTA

7 Associate Member
Albania, Bosnia and Herzegovina, FYROM, Kosovo (under UNSCR 1244/99) Montenegro, Serbia and Turkey

Observers
EUC, OIML, EURAMET, EA

Corresponding organisations
Industry federations like CECIP, CECOD, AQUA, ESMIG etc.
WELMECの現状

31加盟国
28 EU + 3 EFTA

7 準加盟国
アルバニア, ボスニア・ヘルツェゴビナ, FYROM, コソボ（UNSCR1244/99に基づく）モンエネグロ, セルビア及びトルコ

オブザーバー
EUC, OIML, EURAMET, EA

準加盟団体
CECIP, CECOD, AQUA, ESMIGなどのような産業連盟。

2017年2月24日
WELMEC’s vision:
- to be the primary source for trusted advice on legal metrology issues in Europe

WELMEC’s mission:
- develop and maintain confidence in European legal metrology

WELMEC objectives:
- Driving further harmonization and improve common understanding across members.
- Adapting to new developments (i.e. new desires, insights, technologies, legislation).
- Effectively exchanging information across members, and with stakeholders.

GAIN AND SHARE KNOWLEDGE

January 2015

WELMEC Strategy
2015 - 2020
WELMECの戦略

WELMECの未来像:
- 欧州での法定計量問題についての信頼できる助言の主要な情報源となること

WELMECの使命:
- 欧州の法定計量に対する信頼を深め、維持すること

WELMECの目的:
- 加盟国間での整合化を推進し、共通の理解を深めること
- 新たな進展（すなわち、新たな要求、見識、技術、法令）に適応すること
- 加盟国間で、及び利害関係者との間で、効果的に情報交換を行うこと
- 知見の獲得と共有
WELMEC STRUCTURE

- Chairperson’s Group
  - Common Working Groups
    - Metrological Supervision
    - Software
    - General Aspects Measuring Instruments Directive
  - Product Specific Working Groups
    - Weighing Instruments
    - Multidimensional Instruments
    - Prepackages
    - Measuring Systems for liquids other than water
    - Utility Meters
    - Taximeters

Observer and Corresponding Organizations
WELMEC products

- European network of legal metrology consisting of all parties involved
- Identification of OIML recommendations as normative documents (together with OIML)
- Guidance to the normative documents
- Guides to the regulated instruments in MID and NAWID (harmonized interpretation of European legislation)
- Cooperation in market surveillance
WELMECの成果

- 全関係者で構成される法定計量の欧州ネットワーク
- 規準文書としてのOIML勧告の確認（OIMLと共に）
- 規準文書の手引き
- MID及びNAWIDの規制対象計器のガイド（欧州の法令の統一解釈）
- 市場サーベイランスでの協力
Status guidance documents

The guidance documents are not a legally binding interpretation of the directive. The legally binding text remains that of Directives 2004/22/EC and 2009/23/EC, which is the codification replacing 90/384/EEC. However, the guidance documents represent a reference for ensuring consistent application of the directives by all those involved. Guidance documents are conceptual in their set-up and give a general context allowing to answer any questions of application that may arise.


2017年2月24日
状況の手引き文書

手引き文書は、指令についての解釈であるが、法的拘束力をもたない。法的拘束力をもつ文書は、今も指令2004/22/EC及び2009/23/ECであり、これらの指令は、90/384/EECに換わって編纂されたものである。しかし、手引き文書は、すべての関係者がこれらの指令を一貫性をもって適用することを確実にするための参考に相当する。手引き文書は、その仕組み上、概念的であり、適用について生じる可能性のあるあらゆる疑問に答えることができる一般的状況を示している。


2017年2月24日
Guide structure is under revision!

Current WELMEC WG2 Guide Structure:


- 2.1
- 2.2
- 2.3
- 2.4
- 2.5
- 2.6
- 2.7
- 2.8

- Evaluation / Technical Criteria
ガイドの構成は現在改訂中である！

現在のWELMEC WG2でのガイドの構成:

- 2.1
- 2.2
- 2.3
- 2.4
- 2.5
- 2.6
- 2.7
- 2.8

NAWI指令2009/23/ECの解釈

評価 / 技術基準

2017年2月24日
WELMEC WG 2: AWI’s and NAWI’s

WG2 New Guide System under development:

- **NAWI/MID: Common Application**
  - “New Guide 2” (Guide 2.10)

- **Modular Approach: Technical Implementation** (Guide 2.11)

- **Technical Guides**
  - 2.1x Load cells
  - 2.1x Indicators
  - 2.1x EPoS
  - ... 2.1x

- **Interpretations of NAWI and MI Directives**

- **Evaluation / Technical Criteria**

2017年2月24日
WG2 作成中の新規ガイドの体系:

NAWI/MID: 共通の適用
“新規ガイド2” (ガイド2.10)

モジュール手法:
技術的実施 (ガイド2.11)

技術ガイド

ロードセル 2.1x
指示器 2.1x
EPoS 2.1x
... 2.1x
... 2.1x

NAWI及びMI指令の
解釈

評価 / 技術基準

2017年2月24日
WELMEC WG 5: Market Surveillance

When: after the product is placed on the market
Why: to prevent placing on the market of non-compliant goods to secure level playing field.

ToR WG 5:

- ....... to promote equivalent, effective and sufficient levels of metrological supervision across the EU
- ......... the exchange of information and guidance on metrological supervision matters, including market surveillance and field inspection

Products:

- Guides: e.g. guide 5.2 Market surveillance guide (NAWID and MID)
- Shared project between market surveillance authorities
- Discussion platform
時期: 製品の発売後
理由: 不適合品が市販されることを防ぎ、公平な条件を確保するため

ToR WG 5:

- .......... EU全体にわたって同等で、有効かつ十分なレベルの計量取締を推進すること
- .......... 市場サーベイランス及び現場検査を含め、計量取締案件についての情報交換及び手引き ....

製品:

- ガイド: 例 ガイド5.2 市場サーベイランスガイド (NAWID及びMID)
- 市場サーベイランス当局間での共同利用型プロジェクト
- 議論のプラットフォーム
WELMEC WG 7: software

- Subgroup New technologies:
  - monitor new technological challenges
  - develop filter to identify new technologies with future impact on legal metrology

- Subgroup Risk assessment is developing a risk assessment procedure for software

- New Cross section subgroup (with WG 2) on Software matters in NAWI’s.

Workshop Software and ICT related Challenges in Legal Metrology.

WELMEC WG 7: ソフトウェア

下位部会 新規技術:
- 新たな技術的挑戦を監視する
- 法定計量に将来的に影響を与える新規技術を特定するためのフィルターを作成する

下位部会 リスク分析は、ソフトウェアのリスク分析手順を作成している

NAWIのソフトウェア問題に関する新たな部門をまたぐ下位部会（WG 2と共に）

ワークショップ 法定計量におけるソフトウェアとICTに関連する課題

New technologies go very fast
New technologies should be incorporated in legal metrology
Don’t get behind
Use OIML and APLMF/WELMEC
Team up together
Support each other

YOU ARE THE FUTURE
未来へ向けて

- 新規技術はめざましい勢いで開発されている
- 新規技術は法定計量への組み込まれるべき
- 取り残されない
- OIML, APLMF/WELMECの活用
- 共に協力し合う
- お互いをサポートする

皆さんが未来です！

2017年2月24日
Thank you for your attention

Are there any questions?
ご静聴ありがとうございました。

質問はございますか？