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European Cooperation in Legal Metrology
W E L M E C



Directory of European Union legislation in force
<http://eur-lex.europa.eu/en/legis/20110701/index.htm>

13 Industrial policy and internal market
13.30 Internal market: approximation of laws
13.30.12 Metrology

➤ **Non-automatic weighing instruments (NAWI)**

Directive 2009/23/EC - codification of Directive 90/384/EEC and Directive 93/68/EEC

Codification is the process of bringing together a legislative act and all its amendments in a single new act. The new act passes through the full legislative process and replaces the acts being codified.



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➤ **Measuring instruments (MID)**

Directive 2004/22/EC and its amendment the **Commission Directive 2009/137/EC** in respect of exploitation of the maximum permissible errors, as regards the instrument-specific annexes MI-001 to MI-005

In the process: Introducing New Legislative Framework (**Decision No 768/2008/EC**) into MID.

Legislative proposal to recast MID is expected during 2011

Unlike codification, **recasting** involves new substantive changes, as amendments are made to the original act during preparation of the recast text.



- **Definitions**
- **Obligation of economic operators (manufacturer, the authorised representative, the importer and distributor)**
- **Conformity of the product (conformity assessment procedures)**
- **Notification of CABs**
- **Safeguard procedures (products presenting a risk to health and safety)**
- **CE marking**



Recital (6)

“ Whenever legislation is drawn up, the legislator may depart, totally or partially, from the common principles and reference provisions laid down in this Decision on account of the specificities of the sector concerned. Any such departure should be justified. ”



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➤ **Directive 2009/34/EC** relating to common provisions for both measuring instruments and methods of metrological control (recast) - Directive 71/316/EEC with several amendments

➤ **Units of measurement**

Directive 2009/3/EC amending Council **Directive 80/181/EEC** on the approximation of the laws of the Member States relating to units of measurement



The repeal of technically outdated Old Approach Directives

- **Directive 71/349/EEC on the calibration of the tanks of vessels
with effect from 1 July 2011**
- **Directive 71/347/EEC on the measuring of the standard mass
per storage volume of grain**
- **Directive 75/33/EEC on cold-water meters**
- **Directive 76/765/EEC on alcoholometers and alcohol
hydrometers**
- **Directive 76/766/EEC on alcohol tables**
- **Directive 86/217/EEC on tyre pressure gauges for motor
vehicles**
- **Directive 71/317/EEC and Directive 74/148/EEC on accuracy
weights
with effect from 1 December 2015**



The repeal of technically outdated Old Approach Directives

- Transitional period of 10 years – current certificates to be recognised till 2021 for ship tanks and up till 2025 for other instruments
- No existing trade barriers that would justify harmonisation
- New barriers to trade due to new national rules are not to be expected
- No support for harmonisation from industry or consumers
- The Mutual Recognition Regulation (EC) 764/2008 ensures full mutual recognition of equivalent products and conformity assessment procedures



Pre-packaging

Directive 2007/45/EC on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC

Directive 76/211/EEC relating to the making-up by weight or by volume of certain pre-packaged products

Directive 75/107/EEC relating to bottles used as measuring containers

Directive 2009/34/EC relating to common provisions for both measuring instruments and methods of metrological control (Recast) - Directive 71/316/EEC with several amendments



MID instruments specific annexes

MID is fully operational since 30 October 2006

- **Utility Meters - Clean Water (MI-001), Gas and volume conversion devices (MI-002), Electricity (MI-003), Heat (MI-004)**
- **Systems for the continuous and dynamic measurement of quantities of liquids other than water (MI-005)**
- **Automatic Weighing Instruments (MI-006)**
- **Taximeters (MI-007)**
- **Material measures (MI-008)**
- **Dimensional Measuring Instruments (MI-009)**
- **Exhaust Gas Analysers (MI-010)**



Report from the Commission to EP and the Council on the implementation of MID on the basis of Article 25 of MID - 17 June 2011

- Reports provided by Member States
- WELMEC proposals (44 proposals among them 26 changes to the text of MID and 18 proposed new sectors)
- SME survey on possible sectors for inclusion in MID from 21 May to 30 June 2010
http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/public-consultation/index_en.htm
- Interim Evaluation report by external experts – Centre for Strategic & Evaluation Services (CSES), July 2010
- Public Consultation on the Review of MID from Sept. to Nov. 2010
- Impact Assessment Study on the review of MID – RPA Report (Risk & Policy Analysts Limited), March 2011



SME survey on possible sectors for inclusion in MID

from 21 May to 30 June 2010

298 replies to the survey - more than 60% users of MI, manufacturers represent less than 25%, the remainder are distributors, installers or importers

- **None of the respondents had their products withdrawn from the market due to a decision by a Member State under the MRR**
- **Approx. half of the respondents did not experience any barriers to trade. For those who experienced barriers, the associated costs rarely exceeded 25% of the company's turnover and for many companies amounted to less than 10%**
- **Over half of the users (55%) identified a need for more legal metrological control**
- **Most of the respondents were in favour of a manufacturer declaration and half of them identified the need for involvement of the notified body**



Impact on SMEs - findings of the CSES evaluation

- Overall impact appears limited but may vary across sectors
 - SME survey indicates that conformity assessment procedures are not particularly burdensome (85% considered adequate)
 - Less than 15% of SMEs referred to the presence of barriers to trade
 - Certification costs probably increased for SMEs active only in domestic or only a few markets
 - SMEs producing only components may be disadvantage in the case of MI-005 and MI-006 due to absence of modular approach



10 year of transitional period

from 30 October 2006  30 October 2016

Measuring instruments with pre-MID type approvals may be placed on the market and put into use until the expiry of the validity of the type approval or in the case of indefinite validity, **for the period of maximum of 10 years from October 2006**

Updating of pre-MID type approvals should be **administrative** and should **not lead to any technical updating or upgrading** of metrological performance of the instrument

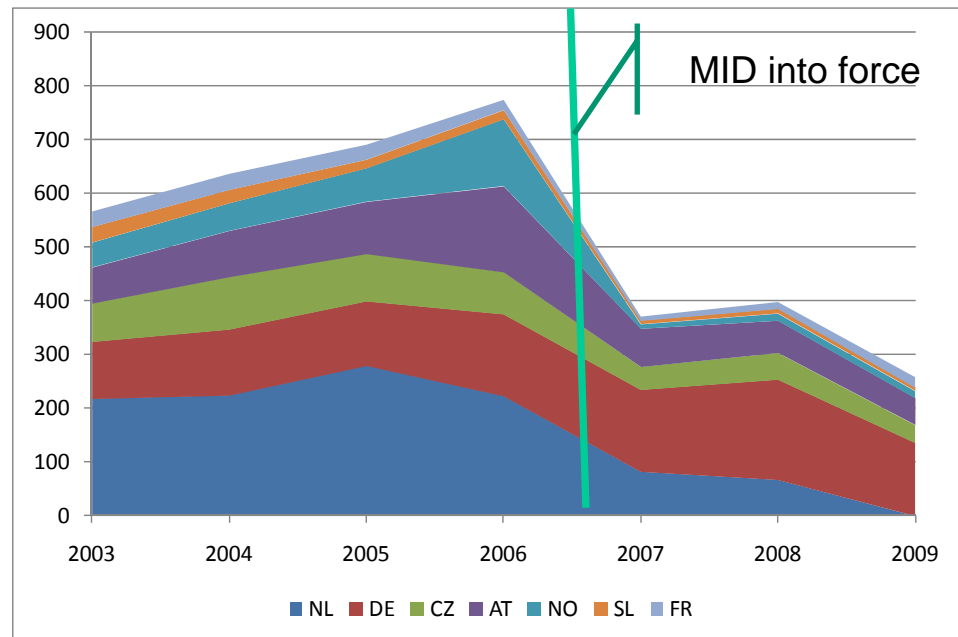


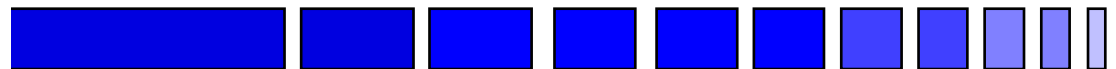


Transitional period - findings of the CSES evaluation

- Overall considered appropriate and adequate
- Used by large number of manufacturers that were not prepared
- Some evidence of rush prior to 2006 based on available data
- But too early for any conclusions

Number of type certificates (national and EC) before and after the entry of MID into force (data from seven countries)





Overall findings of the evaluation – Effectiveness

- MID provides the basis for the development of a more efficient internal market through the use of a single certificate
- Significant improvement in relation to the pre-MID period

Main parameters that affect effectiveness

- Problematic/poor market surveillance:
 - Reported that MSs are generally limited to typical CE+M and document checks
 - Examples of absence of any level of surveillance and complaints of unfair competition (taximeters, fuel dispensers and AWI)
- Inconsistency of notified bodies in conformity assessment and certification procedures
 - Varying level of quality and experience – contradicting decisions
 - Varying use of WELMEC guidance documents (more or less strict approach and limitation of options to manufactures)
 - Varying fees charges (although this is not necessarily bad from competition side)

MID - Market data ballpark figures

	Market size – No of MIs sold annually thousands)	Market size- value of items sold annually (million €)	Firms (with MID certificates)††	Employees occupied in sector (1000s)
MI-001	18,000	450	20-30	25
MI-002	6,900	410	15-20	30
MI-003	14,000	610	25	32
MI-004	800	290	10	18
MI-005	31	240	50-60	14-16
MI-006	21	550	350	25
MI-007	50	25-40	50-60	1
MI-008a†	130,000	290	40	14
MI-008b	175,000	150-200	250	20
MI-009	300-400	70-80	20-30	7
MI-010	25-35	130	50-60	17.5
Total	350 million	€3.5 billion	900	200

† Data cover both MID and non-MID certified instruments

†† Do not include SMEs operating as distributors or importers



The principle of Optionality means that Member States decide which MID instruments to regulate - the provisions of the MID are not universally binding

For 90% of the total category of MIs a national legislation in accordance to the MID is in place

17 countries have opted out from the Directive for one or more Instruments

The main reasons for selecting to opt out concern either the absence of specific categories of legal metrology instruments from the market or the consideration that the administrative burdens imposed would be much higher than the level of consumer protection provided

No problems in terms of unfair competition or a two-tier market



The principle of Subsidiarity requires that Member States remain responsible for their legal metrology control

The MID therefore leaves it to the Member States to decide whether to issue regulations, but if they do, the regulations must comply with the provisions of the MID

The obligation of Member States to communicate to the Commission the reasons for not prescribing the use of measuring instruments



Main findings of the evaluation

- Innovation has not been hampered and in some cases MID is considered to be positive for innovation
- The operation of the internal market with the use of a single conformity assessment certificate, which, being about 10-15% more expensive than the former national certificates has been improved. The need was identified that such certificates should have a common format
- The consumer protection is virtually equal across the EU and the risk of unfair competition due to differences between Member States is minimal
- With the exception of taximeters there is a full coverage by standards, being either European harmonised standards or normative documents
- The quality of market surveillance appears as an important concern of industry and it is an area where most authorities recognise that their effort until recently has been limited
- There appear to be inconsistencies among the notified bodies in terms of interpreting MID requirements and other guidance as well as differing levels of capacity; as well as the rather restrictive interpretation by notified bodies of the guidelines of WELMEC posing constraints to using alternative approaches to conform to the essential requirements



Recommendations on the basis of evaluation

- No major changes necessary in the main provisions of the Directive at this stage
- Optionality principle should be maintained
- Support information exchange and training to notified bodies to increase consistency and quality
- Increase availability and exchange of information among MSs in relation to approved and rejected instruments
- Strengthen market surveillance on the basis of multi-annual plans by MSs
- Increase awareness of applicability of MID by manufacturers and importers
 - Targeted awareness raising campaign through cooperation with trade associations at European and national level
- Invite additional stakeholders to participate (e.g. EGEA –MI-010, FEVE- MI-008b)
- Issues related to the modular approach and sub-assemblies should be addressed
 - existing representation bodies (WELMEC and wgMID) are the appropriate forums

Country	Notified Bodies	Link to National Database	Contact
Austria	0445	http://www.metrologie.at/index.html/homepage_mess-eichwesen_196.htm	benannte.stelle@bev.gv.at
Czech Republic	1383	http://brno.cmi.cz/hk/index.pl?lang=en	jkalandra@cmi.cz
Denmark	0199, 0200	http://webtool.danak.dk/Plone/metrologi/english/midcertificates-engelsk/	krm@sik.dk
Finland	0424	http://www.tukes.fi/en/Toimialat/Measuring/MID-certificates/	
France	0071	http://www.lne.fr/fr/metrologie/metrologie_legale/listes-certificats-delivres	Corinne.lagauterie@finances.gouv.fr thomas.lommatzsch@lne.fr



Main Strengths of the MID

- Single certificate provides basis for development of internal market
- Flexibility provided by optionality principle with no adverse impacts
- Technologically neutral requirements in most areas
- Overall decrease of administrative costs for firms with presence in multiple markets
- High level of representation and involvement of non-government stakeholders
- Positive role of WELMEC as a mechanism for identification, discussion and possible solution of issues

Main Weaknesses of the MID

- Poor market surveillance in a number of MSs leading to cases of unfair competition and possible issues of consumer protection
- Inconsistent interpretation of MID requirement and WELMEC guidelines by notified bodies
- Limited awareness by manufacturers and importers in some sectors or countries
- Problematic level of information exchange among authorities and notified bodies – contributes to problems in market surveillance and inconsistency



New Legislative Framework

Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State

Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance to the marketing of products

Decision No 768/2008/EC on a common framework for the marketing of products



A **Directive** shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods'

A **Regulation** shall be binding in its entirety and directly applicable in all Member States. In this context, 'direct applicability' means that the Member States usually do not have to enact implementing measures. Regulations are therefore legislative acts which may be relied on before the courts in all Member States, without the need for national measures to be adopted by Member States



Regulation (EC) No 764/2008 on mutual recognition

Scope: products which are not subject to Community harmonisation measures

applicable from 13 May 2009

binding and directly applicable in all Member States

Member State cannot prohibit the sale of products on its territory provided that they were lawfully placed on the market in another Member State of the EU, in the countries of the EEA or in Turkey without proper justification of a legitimate overriding national interest.

Regulation concentrates on the burden of proof by setting out the procedural requirements for denying mutual recognition



Products from EU Member States and EEA are treated as equivalent

- if the products meet the test and inspection requirements in the member state,
- if a comparable level of protection is sustainably given

By virtue of the Regulation, a uniform procedure is being introduced for all Member States concerning:

- the burden of proof
- consultation
- rights and
- justification

which is to be followed if the authorities wish to prohibit or restrict access to sell or market a product which is not subject to Community legislation, even where the product is lawfully marketed in another Member State.



Product Contact Points in each Member State

The main task of the Contact Points is to provide enterprises and authorities in other Member States with information on the national technical rules in force. In addition to this, the Regulation lays down rules on the submission of a yearly report to the Commission detailing the application of this Regulation in the Member States.



Regulation (EC) No 764/2008 on mutual recognition

Mandatory prior authorisation

non-discriminatory and proportionate procedures established by the law

Before a product or type of product may be placed on the market, the competent authority should give its formal approval following an application

Any intended decision to reject the application on the basis of a technical rule should be taken in accordance with this Regulation

The competent authorities should no longer refuse test reports and certificates issued by an accredited conformity-assessment body on grounds related to the competence of that body



WELMEC Strategy

WELMEC is prepared to facilitate the application of Regulation 764/2008/EC by providing the structured overview on nonharmonised instruments on the Welmec website in order to get the information which instruments are regulated in what country and their contact addresses for information

If necessary WELMEC will start to draft guidance on the application of the Regulation in relation to legal metrology



Thank you for your attention

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