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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND  
THE COUNCIL**

**Report on the implementation of the  
Measuring Instruments Directive 2004/22/EC pursuant to its Article 25  
(Text with EEA relevance)**

# REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

## Report on the implementation of the Measuring Instruments Directive 2004/22/EC pursuant to its Article 25.

(Text with EEA relevance)

### A. Introduction

#### 1. Purpose of this document

The purpose of this document is to report on the implementation of Measuring Instruments Directive (MID), inter alia, on the basis of reports provided by the Member States. Furthermore it draws from two SME surveys and a public consultation. Two external consultants provided inputs concerning the evaluation of the directive and respectively the assessment of impacts of suggestions for possible changes.

#### 2. Measuring Instruments Directive (MID)

The Measuring Instruments Directive (Directive 2004/22/EC<sup>1</sup>) has been in operation for 4½ years since 30 October 2006<sup>2</sup>.

It applies to the following instruments defined in the Annexes to the Directive:

- water meters;
- gas meters and volume conversion devices;
- active electrical energy meters;
- heat meters;
- measuring systems for continuous and dynamic measurement of quantities of liquids other than water;
- automatic weighing instruments;
- taximeters;
- material measures;
- dimensional measuring instruments;
- exhaust gas analysers.

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<sup>1</sup> OJ L 135, 30.4.2004, p. 1:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004L0022:20091201:en:PDF>

<sup>2</sup> The directive also contains a transition period of 10 years (until 29 October 2016) during which instruments conforming to old rules are allowed to continue to be marketed (Article 23 of Directive 2004/22/EC)

The main policy objective of the Directive is to facilitate and enhance the internal market for instruments required for measuring tasks for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading, where Member States consider such formal legal measurement justified.

MID guarantees a high level of confidence through essential requirements which are applicable in all Member States and is expressed by means of CE and M marking. It defines performance criteria, while giving manufacturers technological flexibility on ways of meeting them. MID offers a wide choice of conformity assessment procedures that cater for the needs of small and large producers alike.

The legislation does not define for which activities the measuring instruments need to be used. That remains a matter for national governments. For instance, practices differ between Member States on whether meters are required for water consumption or common heating systems. Similarly, factories may use many different types of meters for internal production purposes which do not need to be regulated.

However, where a formal legal measurement is required by a Member State, as in the vast majority of consumer transactions, then only instruments which comply with the Directive can be used. The Directive distinguishes categories to take account of the huge disparity of temperatures in Europe where measuring instruments placed outside need to remain accurate, between - 40 degrees in a Scandinavian winter and + 70 degrees in a Mediterranean summer.

The Directive allows to reference international standards that may be used alongside European standards by CEN/CENELEC/ETSI to demonstrate compliance with the legislative requirements. Also relying on the international standards of the 60-country strong International Organisation for Legal Metrology (OIML), for instance, helps European industry to be more competitive and penetrate global markets<sup>3</sup>.

The unit responsible for the MID is DG Enterprise and Industry, Unit G/5.

### 3. Reasons for the review

In Article 25 of the Measuring Instruments Directive<sup>4</sup> the Commission is invited to report on the implementation of the Directive as follows:

“The European Parliament and the Council invite the Commission to report, before 30 April 2011, on the implementation of this Directive, inter alia, on the basis of reports provided by the Member States, and, where appropriate, to submit a proposal for amendments. The European Parliament and Council invite the Commission to evaluate whether conformity assessment procedures for industrial products are properly applied and, where appropriate, to propose amendments in order to ensure consistent certification.”

Furthermore, Directive 2011/17/EU repeals 8 Old Approach directives in the area of legal metrology: one directive in 2011 (ship tanks) and the other seven in 2015 respectively (water

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<sup>3</sup> See for more information:  
[http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/measuring-instruments/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/measuring-instruments/index_en.htm)

<sup>4</sup> OJ L 135/1, 30.4.2004

meters, weights (2x), alcohol meters (2x), tyre pressure gauges, mass of grain) respectively. Following on the repeal the Directive foresees a 10 year transition period allowing placing on the market of instruments carrying the harmonised markings based on existing certificates, i.e. until 2021 and 2026 respectively<sup>5</sup>.

In a Joint Statement by the three institutions the Commission was invited “to report before 30 April 2011 [...] and in accordance with the principles of better lawmaking (including where appropriate impact assessment and open consultation) [...] determine whether and, if so, to what extent the scope of the Measuring Instruments Directive 2004/22/EC should be extended so as to include any of the measuring instruments currently regulated” by the repealed directives<sup>6</sup>.

## **B. Evaluation**

In this report the Commission assesses the implementation of the Directive, taking due account of the fact that it has been applicable for only 4½ years, namely since 30 October 2006.

The main purposes of the evaluation exercise undertaken are to:

- provide ballpark market estimates for each sector covered by MID;
- review the effectiveness of the Directive;
- draw conclusions for further action.

The assessment has been made using three different evaluation tools:

- small and medium size enterprises (SME) have been solicited via the Enterprise Europe Network with the aim of achieving a more SME-friendly regulatory environment following up on the Competitiveness and Innovation Framework programme;
- evaluation of the Directive has been made by external experts;
- the findings have been subject to a public consultation.

### 1. Economic weight of the measuring instruments sectors in the scope of the Directive

In their evaluation report external experts<sup>7</sup> have estimated that the MID applies to around 345 million units of measuring instruments (MIs) sold annually in the European market with a total sales value of around €3.25 billion. There are around 900 manufacturers active in the 10 sectors covered by the MID not including the large number of SMEs operating as distributors,

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<sup>5</sup> OJ L 71/1, 18.3.2011:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:071:0001:0003:EN:PDF>

<sup>6</sup> Statement by European Parliament, the Council and the Commission in Council document 6291/11 ADD1 of 14 February 2011

[http://www.cc.cec/home/dgserve/sg/sgvista/i/sgv2/repo/repo.cfm?institution=CONS&doc\\_to\\_browse=CSST/2011/06291&sw\\_inconnu=1](http://www.cc.cec/home/dgserve/sg/sgvista/i/sgv2/repo/repo.cfm?institution=CONS&doc_to_browse=CSST/2011/06291&sw_inconnu=1)

<sup>7</sup> Centre for Strategic & Evaluation Services (CSES), [Interim evaluation of the Measuring Instruments Directive](#), July 2010

importers or providers of repair services. The total number of employees occupied in the sector is estimated at 190,000.

Around 20-25% of measuring instruments in the EU27 are imported while 25-30% of the measuring instruments produced in the EU27 are exported to third countries. There is however important variation among the different categories of measuring instruments. Trade levels in both directions are particularly high (over 50% of total) for the less technology intensive categories of material measures (MI-008) and dimensional measuring instruments (MI-009) but also for electricity meters (65%). At the same time, the share of production exported is particularly high in the case of more advanced technology instruments such as Automatic Weighing Instruments (up to 42% for the sub-category of automatic gravimetric filling instruments) and in the Gas Meters category (44%) where EU firms are the world leaders.

**Table 1 – Total size of market covered by the MID**

	Market size – number of items sold annually (000s)	Market size- value of items sold annually (million €)	Share in total MIs market	Employees occupied in sector (1000s)
MI-001: Water Meters	18,000	450	13.8%	25
MI-002: Gas Meters & Conversion Devices	6,900	410	12.6%	30
MI-003: Active Electricity Energy Meters	14,000	610	18.8%	32
MI-004: Heat Meters	800	290	8.9%	18
MI-005: Measuring Systems for Liquids other than Water	31.2	240	7.4%	14-16
MI-006: Automatic Weighing Instr.	21	550	16.9%	25
MI-007: Taximeters	50	25-40	1%	1
MI-008: Material Measures <sup>8</sup>	300,000	440-490	14.3%	34
MI-009: Dimensional Measuring Instr.	300-400	70-80	2.3%	7
MI-010: Exhaust Gas Analysers	25-35	130	4.0%	17.5
<b>Total</b>	<b>345,000</b>	<b>3,250</b>	<b>100%</b>	<b>190</b>

## 2. Views by Small and Micro enterprises

End 2009 a survey was carried out by the Commission services using the SME panel consultation tool of the Enterprise Europe Network. It attracted a total of 286 responses, half manufacturers and half users, mainly small and micro enterprises with turnover of less than €10 million from most Member States<sup>9</sup>. The SMEs were active in all types of measuring instruments covered, most used CE+M marking which indicates that the instrument is in conformity with the MID, whilst 40% traded widely on the internal market, 25% only in the domestic market and 40% exported outside of the EU.

The findings of the survey suggest that in their majority SMEs do not face particular problems different from those reported from large companies in the evaluation<sup>10</sup>. Barriers to trade due

<sup>8</sup> Data refer to all material measures of length in the market. Not only MID certified.

<sup>9</sup> All Member States excepting Netherlands and the United Kingdom

<sup>10</sup> pp 35-40 in CSES, [Interim evaluation of the Measuring Instruments Directive](#), July 2010

to protection from national authorities (real or perceived), costs for conformity assessment that are higher than what would be considered adequate are reported but only from a small number of SMEs. There are also no specific categories of MIs identified with particular issues/problems. From the user side, the survey suggests that consumer protection is adequate. One issue raised by the SME survey concerns the unfair competition by non CE+M marked products. While this point should not be considered as an SME specific problem, it seems to be more prominent in comparison to the evidence provided during the interviews with trade associations and, mainly larger, companies. It could reflect transition where there are still many lower quality instruments with cheaper national approvals coming onto the market and this will resolve by itself when the transition period ends in 2016.

As regards the issue of relaxing conformity assessment procedures for inexpensive instruments, it should be noted that such instruments are usually mass produced and so conformity assessment is all the more relevant. The large choice of conformity assessment procedures available for each type of instrument should help relax bottlenecks.

Finally the Directive allows defining subassemblies but it does not allow manufacturers to define them. Should this be otherwise all kind of incomplete instruments possibly marked may appear on the market and this would complicate market surveillance.

### 3. Main findings of the evaluation

The main findings of the evaluation of the MI Directive are the following.

Innovation has not been hampered and in some cases MID is considered to be positive for innovation.

Optionality has led to close to full application with Member States requiring instruments as determined by the Directive in 90 % of possible cases. Therefore consumer protection is virtually equal across the EU and the risk of unfair competition due to differences between Member States is minimal.

The MID has helped improve 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 benefitted producers that are active on more than one market. The need was identified that such certificates should have a common format.

Stakeholders have been fully consulted at all times in the working group Measuring Instruments. They have been fully involved in the preparation of comitology proposals. The regulatory committee procedure has been used once and the advisory procedure around 10 times for publications concerning international standards of OIML<sup>11</sup> that give presumption of conformity with the essential requirements of the Directive.

The smooth running of the Directive has been enhanced by the 2004 “Commission Statement to WELMEC<sup>12</sup> on Cooperation” resulting in 40 guidance documents of conceptual nature being referenced on the Commission website after final agreement with all stakeholders in the Working group on Measuring Instruments.

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<sup>11</sup> OIML is the International Organisation for Legal Metrology

<sup>12</sup> WELMEC is the organisation of national authorities responsible for legal metrology

With the exception of taximeters there is a full coverage by standards, being either European harmonised standards or normative documents referring to international standards on which the Measuring Instruments Committee has advised positively.

The New Legislative Framework gives conformity assessment procedures which are very close to those in MID. A proposal to recast the MID adapting it to the New Legislative Framework will be presented soon.

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.

There is no evidence that the implementation of the MID has generally disadvantaged SMEs – although in some specific sectors (weighing instruments and fuel dispensers) the lack of rules distinguishing individual components (sub-assemblies) may disadvantage some SMEs.

#### 4. Outcome of the Public consultation

The public consultation on the evaluation report led to 85 reactions from firms, industry federations and Member States. The European consumer organisation declined to react because MID was not its priority.

The relatively few answers in the public consultation on the evaluation indicate that there are no major points missing nor are there any major points of disagreement with the assessment in the evaluation. The issue of failing market surveillance was not addressed by any Member State. See for details the report on the Public consultation<sup>13</sup>.

As regards the suggestions for new proposals some useful material was received but in no case was there sufficient evidence to base an impact assessment on. It concerns technical complex and detailed changes where the Commission services need to rely very much on the inputs of experts and stakeholders in order to fulfil the requirements of smart regulation. See for details the report by an external consultant<sup>14</sup>.

The evaluation of the MI Directive can be deemed to be complete as regards the evaluation and generally supported as regards its analysis. As such there is no reason to consider regulatory changes and in a Commission Services Working Document the Commission services indicated being sensitive to the risks of changing the MID in such an early stage of its application (4½ years). The possibilities of standardisation and guidance have not yet been fully utilised. Changing the directive beyond the technical adaptations allowed by the Directive in its Article 16 could lead to regulatory drift and to uncertainty in the market place.

### *C Repeal of Old Approach Directives*

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<sup>13</sup> RPA, Report on the public consultation, March 2011 (Background document 6).

<sup>14</sup> RPA, Report on suggestions for amendments and additions of new categories to the MID, March 2011 (Background document 7).

## 1. Introduction

As regards the Commission obligations stemming from the Joint Statement of the three institutions adjoined to Directive 2011/17/EU repealing the eight Old Approach Directives the Commission services have proceeded as follows:

- A letter to Member States asking for their views (June 2010) to which 6 Member States reacted.
- An SME survey via the Enterprise Europe Network (May-June 2010) to which there were 117 reactions.
- A public consultation (September – October 2010) to which there were around 20 reactions from authorities and 10 from organised industry.

## 2. Arguments presented by authorities

Some authorities bring up two arguments in favour of continued regulation:

- Replacing harmonisation by national rules would imply barriers to trade due to national approvals and diverging national regulations, thereby reducing consumer protection and competition on the Internal Market.
- Harmonisation of technical documents is needed for periodic in-service checks (the requirement and the modalities of which are national competence).

In the absence of harmonisation for these increasingly obsolete instruments, it is clearly a possibility that individual MS will develop national requirements. While those requirements do not have to comply with these directives any more, they have nevertheless to respect the basic principles of the Treaty; especially the principle of free movement of goods (Articles 34-36 TFEU). Additionally, the Mutual Recognition Regulation (EC) No 764/2008 requires a procedure of notification in the case that a product lawfully marketed in one Member State may not be marketed in another Member State on the grounds of having been produced following different technical rules to those required in the Member State of destination. Such notifications would be subject to consideration under articles 34 - 36 TFEU and the current jurisprudence by the European Court of Justice. For example, it is unlikely that only different markings would be a valid reason for banning a product. In addition, WTO-TBT commitments require Member States to legislate on the basis of international standards, which already exist in the form of OIML documents and are virtually equal to the letter to the technical specifications in each of the repealed directives. This is reinforced by the notification obligations under Directive 98/34/EC which aim to ensure full mutual recognition of equivalent products and conformity assessment procedures.

Therefore new national rules replacing the Directives will not differ in practice from the repealed Directives and there would be little ground for multiple national markings and conformity assessment if the product complies with the law in one Member State. When transition ends in 2021 and 2026 respectively, national rules will therefore not lead to change for the products currently covered by the repealed Directives. The Commission is not in any way against national rules based on international standards which are in accordance with the principles of mutual recognition, if a Member State should consider such rules necessary.



As regards the second argument about harmonisation ensuring equal technical documents needed for periodic in-service checks (the requirement and the modalities of which are national competence) international standardisation can pave the way for such documentation being equal. If needed, there is still ample time to ensure that this can be achieved before the end of transition.

The discussion of both the above arguments concerning instruments under the scope of the repealed Directives leads to the expectation that national rules will reflect international standards which will equal the content of the Directives and that there will be no additional trade barriers.

With the exception of weights, which are not subject to technological change, technically more advanced products which are outside of the scope of the repealed Directives are more important in terms of annual turnover than those within the scope of the repealed Directives.

The reasons in favour of repeal given in the Commission proposal<sup>15</sup> were that the mechanical instruments covered by the Directives are becoming obsolete and that there were no reports of significant barriers of trade for technically more advanced instruments not harmonised by the Directives. This analysis remains valid and has been confirmed<sup>16</sup>.

### 3. SME survey

The SME survey via the Enterprise Europe Network (May-June 2010) gave 117 responses, most of which were users (84) next to manufacturers (16) and distributors/importers (17). Notwithstanding the existing harmonisation, limited trade barriers with costs up to 10% due to multiple testing are reported for some instruments. This could be due to the coverage of more technically advanced instruments by additional national regulations which are allowed in parallel under the Old Approach. Manufacturers expressed a preference for self-declaration (currently not used in MID). For some instruments (irrigation meters, foul water, weights and tyre pressure gauges) users are in favour of better market surveillance and/or periodic in-service testing.

### 4. Public consultation

The public consultation (September – October 2010) received around 20 reactions from authorities and 10 from industry. Some reactions from authorities reflected the arguments already treated above whilst others indicated support for repeal and/or the prospect of new national regulation where needed. No examples were given of barriers to trade nor were there reports of notifications under the Mutual Recognition Regulation (EC) No 764/2008 in which authorities need to give evidence of the reasons for taking a product of the market in cases where mutual recognition is in force.

Reactions from organised industry were the following.

- As regards water meters, industry indicated that irrigation and foul water meters containing particles cannot be covered by the current MID provisions and that this is not needed either because there are no barriers to trade.

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<sup>15</sup> COM(2008)801

<sup>16</sup> RPA, Report on the Repeal of the Old Approach Directives, March 2011 (background document 8)

- On alcohol meters industry makes no mention of trade barriers. Spirit drinks producers expressed the same opinion as in 2008 insisting that “producers are not limited in their operational choices”, the details of which were not further specified. Wine producers do not want harmonisation and refer to the full coverage of DG AGRI regulations and international OIV standards. Neither do beer producers want harmonisation mentioning existing flexibility.
- The tyre pressure gauge (garage) industry can accept harmonisation that takes account of the forthcoming results of the 2009 mandate M/457<sup>17</sup> under which European standards are being developed which would also serve for the Car Safety Regulation (EC) No 661/2009. There are no barriers to trade reported.
- There were no reactions from industry concerning mass of grain or ship tanks.

The European consumer organisation declined to react because metrology was not its priority.

### 5. Conclusions on the repealed Old Approach Directives

At this moment, there is no reason for the Commission to propose to add sectors covered by the 8 repealed directives to the Measuring Instruments Directive 2004/22/EC.

- (1) New barriers due to new national rules are not to be expected because such national rules need to be based on international standards and therefore will in effect be equivalent.
- (2) No existing trade barriers or other overriding reasons have appeared that would justify harmonisation.
- (3) SMEs report low barriers to trade due to multiple testing which no longer would seem to be justified under the obligations of the Mutual Recognition Regulation (EC) No 764/2008.
- (4) There is virtually no support for harmonisation from organised industry and no mention of trade barriers.
- (5) Organised consumers do not consider these sectors of legal metrology as a priority.
- (6) There are no significant changes in 2010 to the impact assessment underlying the Commission proposal for repeal in 2008.
- (7) The long transition period will allow current certificates to be recognised up till 2021 for ship tanks and up till 2025 for other instruments.

### **D. Policy Conclusions and further action**

The overall positive evaluation of the MID has nonetheless shown that there exist substantial problems with the coherent application by notified bodies and market surveillance. Changes to the directive should be done carefully and fully assessed taking into account all

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<sup>17</sup> M457 Standardisation mandate to CEN, CENELEC and ETSI in the field of tyre pressure gauges for motor vehicles and tyre pressure management systems (measuring instruments)

alternatives. During this early stage of application of the Directive a stable legal framework would seem to be a benefit for the further successful development of the internal market in legal metrology.

The Commission services will pursue the following priorities

1. Introduce the New Legislative Framework into the Measuring Instruments Directive for which a legislative proposal is expected during 2011.
2. Enhance information, cooperation and guidance to notified bodies and authorities with the aim of ensuring a coherent application of the Directive.
3. Coordinate market surveillance notably in the form of common actions in order to more efficiently apply resources which are available for market surveillance.
4. Aid stakeholders in establishing guidance on transition of petrol pumps which, although formally outside of Directive, is considered to be an important point by industry.
5. Impact assess any suggestions for new proposals with stakeholders in line with smart regulation whereby full account is taken of all alternatives to regulation and where possible make any necessary changes under the terms of the Directive, i.e. by means of comitology.

#### **Background documents**<sup>18</sup>

1. RPA, Report on the Public Consultation, March 2011
2. RPA, Report on suggestions for amendments and additions of new categories to the MID, March 2011
3. RPA, Report on the Repeal of the Old Approach Directives, March 2011

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<sup>18</sup> All background documents are available on:  
[http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/public-consultation/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/public-consultation/index_en.htm)