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**COMMISSION STAFF WORKING DOCUMENT**

**Accompanying the**

**Proposal for a Directive of the European Parliament and of the Council  
on the repeal of 8 metrology directives**

**Impact Assessment**

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**Lead DG:** Enterprise and Industry

**Other involved services:**

**Agenda planning or WP reference:** CWLP 2008/ENTR/015 - measuring instruments: Extension of the scope of Directive 2004/22/EC on measuring instruments and repeal of 8 "old approach" metrology Directives

This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

## **1. EXECUTIVE SUMMARY**

In the key issues document the Commission services presented three options:

1. "Old approach" Directives exist next to national rules (current situation)
2. Repeal of directives, no harmonisation, national rules continue to exist
3. Harmonisation via the Measuring Instruments Directive and repeal of directives.

From the public consultation and an external study it appears that there are no obstacles to trade in the 6 sectors covered by the 8 old approach directives. It is also apparent that the directives are less and less used and have not hampered technological advance. Where there is additional national legislation it apparently fully takes into account mutual recognition.

Based on the assessment of impacts there is no option that stands out. As there are no barriers to trade, harmonisation does not have any benefit that cannot be achieved either by the market in an unregulated context or by national regulation based on international standards taking the concept of mutual recognition fully into account. What is more, a substantial number of Member States have indicated that they will opt-out of harmonisation which effectively compromises the very aim of harmonisation.

For reasons of simplification and subsidiarity, therefore, the option of repeal without reregulation could be deemed the most appropriate.

## **2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES**

### **2.1. Organisation and timing**

This impact assessment accompanies a proposal to repeal 8 "Old Approach" metrology Directives (CLWP 2008/ENTR/015). The work on this impact assessment has started in April 2007 by means of a meeting with national experts. No inter-service steering group has been set up since no cross-cutting impacts were expected to materialise and no comments were received from other DGs in the ISC on the key issues document in May 2008 (AGRI, ENV, MARKT, SANCO, TAXUD, TRADE and TREN).

### **2.2. Context**

This impact assessment concerns 8 metrology directives in the following sectors:

- Cold Water Meters for Non-Clean Water (Directive 75/33/EEC)
- Alcohol Meters and Alcohol Tables (Directive 75/765/EEC and 75/766/EEC)
- Medium and Above-Medium Accuracy Weights (Directive 71/317/EEC and 74/148/EEC)
- Tyre Pressure Gauges for Motor Vehicles (Directive 86/217/EEC)
- Standard Mass of Grain (Directive 74/347/EEC)
- Calibration of Ship Tanks (Directive 71/349/EEC)

All but directive 75/766/EC are of the so-called optional type. The instruments described in each directive must be accepted by Member States and this was useful in the 1970's when there were trade barriers due to differing Member State regulation. Next to applying the directives, Member States are allowed to keep their own national laws containing technical specifications. These national laws have often been further developed to keep pace with technological progress and are based on international or European standards and contain mutual recognition clauses giving the requirement that instruments with similar level of performance are accepted as well. It should also be noted that both international and European standards are voluntary and do not require national law or harmonised directives in order to be applied by manufacturers.

## **2.3. Consultation and expertise**

### **2.3.1. *Public consultation 21 May -15 July 2008***

Commission services have published a key issues document for public consultation until 15 July 2008. Next to repeal, the option of reregulation is outlined, namely to include one or more of these sectors in the Measuring Instruments Directive (Directive 2004/22/EC). In the key issues document the concern was expressed that currently the old directives are not easily adaptable to technological progress and therefore risk hindering innovation. The key issues document was subject to an inter-service consultation involving 10 Directorates-General.

Publicity about the start of the public consultation was sent to 28.000 subscribers of Enterprise e-news, by means of 'Your voice in Europe' website to the general public and by e-mail to the national experts as well as to the consultant for mention in his contacts with stakeholders. Nonetheless, only 14 reactions were received in the public consultation during the 8-week period up to 15 July 2008. From the reactions it did not emerge that there are barriers to trade that would require harmonisation under Article 95 of the Treaty. Nor was any other consideration of an overriding policy need brought up.

### **2.3.2. *External study by RPA Ltd. – 26 March till 16 July 2008***

The consultant RPA Ltd. was commissioned for a study among stakeholders. The study was kicked off on 26 March 2008 and the final report delivered to the Commission services on 28 July 2008. The study contains comprehensive outlines of each of the sectors.

The main findings of the RPA study are:

- The 6 sectors covered by the 8 directives are small, with annual output amounting to €120 million, mostly in tyre pressure gauges and weights.
- There is no mention by stakeholders of any barriers to trade.
- Apparently only a minority of Member States require legal metrological control based on the directives by instruments which in practice are less and less used.
- There is widespread use of alternative technical specifications (European, international and industry standards), notably in ship tanks, alcohol production and cereals.
- Technological progress is being taken into account by means of voluntary international and European standardisation.
- EU regulations for alcoholic drinks and cereals reference these standards, not the directives.

### **2.3.3. *Meetings with national experts***

The Commission services have discussed with national experts in meetings on 18 April 2007 and 24 July 2008. Member States, expressed varying views the essence of which will be described in the following. Some Member States have chosen to be transparent by expressing their views in the public consultation and these contributions have been published in their

entirety on the Commission website. The conclusion was that in most cases either half the Member States or a majority are in favour of repeal.

The directives contain technical descriptions for non-electronic instruments. Conformity assessment under the directives is the responsibility of the national authorities. The same conformity assessment system will sometimes be used for instruments under national law which are technically more progressed, i.e. electronic and digital, as long as there is a non-electronic part which is covered by the directive. Such conformity assessment documents allow authorities an easy way of checking who has been responsible for conformity assessment.

For tasks where Member States require legal metrological control there is often also a requirement for periodic verification of the instruments that are in-service. This is always a national responsibility even where there has been harmonisation under the New Approach, i.e. for non-automatic weighing instruments (Dir 90/384/EEC) and measuring instruments (Dir 2004/22/EC). National experts say that they need full knowledge about the certification history of an instrument in order to perform the appropriate periodic verification in metrology.

It was, however, pointed out that this rather specific issue of the certification history of an instrument relevant for periodic verification, mentioned above, is already fully addressed in the WELMEC Type Approval Agreement, which concerns the non-harmonised area, i.e. technologically more advanced instruments outside of the directives. In 1993, the cooperation of national authorities WELMEC (The Western European Legal Metrology Cooperation) decided to seek to reduce barriers to trade in measuring instruments by an agreement which would remove the need for multiple type approval testing against various national legal requirements, i.e. the non-harmonised field. This agreement consists of a declaration on the part of the signatories (the members of WELMEC, i.e. authorities of all EU Member States and Norway, Iceland and Switzerland) of their intention to accept conformity with an OIML Recommendation as the basis for a national type approval with little or no further examination where the instrument has already been granted approval in another signatory country<sup>1</sup>.

On the one hand, some experts indicated that transposing the directives had been imposed as a condition for EU membership and that there was no choice for new Member States but to have these directives in national law. On the other hand, other experts indicated that New Approach harmonisation would allow a wider number of routes to conformity assessment than currently allowed in national laws (although they agree that Member States do not need EU regulation to allow more sophisticated forms of conformity assessment in national regulation.)

#### **2.3.4. Conclusion from consultation and expertise**

The public consultation and external study have informed the impact assessment. Both point to an apparent lack of trade barriers, the limited use of the directives and the availability of voluntary alternative standards which are widely used. The current situation does not seem to pose any problem and the repeal of the directives would not affect the market place. Voluntary standardisation and mutual recognition already cover market needs also those related to technological innovation.

The key issues document, report on the public consultation and all contributions to it as well as the study report by RPA are available on the Europa website:  
[http://ec.europa.eu/enterprise/prepack/ms\\_inst/mi\\_directives.htm](http://ec.europa.eu/enterprise/prepack/ms_inst/mi_directives.htm)

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<sup>1</sup> WELMEC European cooperation in legal metrology – An Introduction, p.9  
[http://www.welmec.org/publications/5thIssue\\_Introduction.pdf](http://www.welmec.org/publications/5thIssue_Introduction.pdf)

Main conclusions per sector are outlined in the Annex to the document.

### **3. PROBLEM DEFINITION**

#### **3.1. What is the issue or problem that may require action?**

The Old Approach directives had the aim of allowing harmonised goods to penetrate the trade barriers existing under differing national regulations in the pre-Cassis de Dijon era. Operators could be sure that the technical specifications in the directives would be accepted.

Since then national regulations encompassing technological progress have been based on international standards due to obligations of membership laid down by international (treaty) organisations like ISO and OIML<sup>2</sup> as well as of European Standardisation Organisations and eventually also by the WTO-TBT agreement. Since 1983 mutual recognition clauses concerning instruments and conformity assessment procedures have been entered into national rules, also in the context of the notification procedure of Directive 98/34/EC. In addition since 1993 the WELMEC type approval agreement has given a framework for inter-governmental cooperation regarding the mutual recognition of conformity assessment specifically of non-harmonised measuring instruments based on international standards.

As there exist international standards, also for the outdated technologies, it would seem reasonable to expect that Member States, who as a consequence of subsidiarity choose to re-regulate in case the Directives were repealed, would by so-doing not resurrect new barriers to trade. The expectation is that there would be no change compared to the current situation.

It should be noted that Article 2 of the Measuring Instruments Directive (2004/22/EC) allows an opt-out to Member States in the sense that for tasks where they require legal metrological control it may only be by means of instruments complying with the directive, whilst in other cases they may not have any requirements. Given the expressed preferences of national experts, it is to be expected that a substantial number of Member States will apply the opt-out in each of the sectors.

#### **3.2. What are the underlying drivers of the problem?**

The underlying driver of the problem common to all sectors is that there no longer is a need for EU legislation to create an internal market for these instruments and that the existing directives are less and less used. Due to technological development the existing directives are less and less applied. In some cases they may still have practical value, e.g. weights, where there is no technological development for the weights although there is a trend away from manual weighing. In all cases (except the very diverse non-clean water meters) the existing directives are covered fully by existing international standards, as indicated in the third column of Table 1. The Member States arguing in favour of regulation motivate this by pointing out that they would need to regulate nationally. However, if a Member State should decide to regulate it is obliged to base its laws on international standards under the conditions of WTO/TBT agreement of 1995, the outcome of such national regulation would be identical to the current one based on the directives.

**Table 1: EU legislation and standards applied in the sectors**

Sector	Current Directive	Related Standard	Other EU regulation	Related Standard
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<sup>2</sup> Organisation Internationale pour la Métrologie Légale of which all Member States are member and which is recognised under the TBT agreement as an international standards setting body.

Non-clean water meters	75/33/EEC	None	none	none
Alcohol meters	76/765/EEC	OIML R44/1985	Regl.2676/1990 Regl.2870/2000	ISO 4801:1979 ISO 4805:1982 ISO 3507:
Alcohol tables	76/766/EEC	OIML R22/1975	Regl.2676/1990 Regl.2870/2000	
Weights	71/317/EEC 74/148/EEC	OIML R111/2004		
Tyre gauges	86/217/EEC	OIML R23/1975		
Mass of grain	74/347/EEC	OIML R15/1970	Regl.824/2000	ISO 7971/2:1995
Ship tanks	71/349/EEC	OIML R95/1990		ISO 4269:2001 ISO 4512:2000 ISO 5024:1999 Phoenix API/EI

(Source: Study for the Commission of July 2008 by RPA Ltd.)

Under the conditions of WTO/TBT agreement of 1995 Member States that choose to regulate are obliged to base their laws on international standards. National laws will therefore be based on international standards, which often have also been transposed into European standards. On top of this the ‘Cassis de Dijon’ jurisprudence by the European Court of Justice prohibits disproportionate national requirements and obliges mutual recognition of products legally marketed in other Member States.

When barriers to trade exist or there is a large risk of them appearing, harmonisation is justified on the basis of Art 95 of the Treaty. In the case of a harmonising directive, the obligation to base the law on international standards is assumed by the EU. Under New Approach harmonisation, any technical specification that complies with the essential requirements in the Directive is allowed. Therefore innovation can occur without any need to change the law. Under Dir 2004/22/EC European standards and international standards are always voluntary but give presumption of conformity, which for manufacturers can be an efficient option of complying with the essential requirements of the directive. The so-called blue guide<sup>3</sup> gives a comprehensive explanation of the New Approach harmonisation.

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1.1.1. <sup>3</sup> The Guide to the Implementation of Directives Based on New Approach and Global Approach is available on:  
<http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm>

### **3.3. Who is affected, in what ways, and to what extent?**

Even though the sectors are small in turnover, the instruments and measures are used to give indications on many products. For example, tyre pressure gauges are needed to inflate the 1 billion tyres on EU roads.

There do not seem to be any parties that would be affected by a repeal as identified in the problem definition. The existing directives are virtually not applied and have been superseded by national laws based on international standards which take into account technological progress and these national laws are subject to mutual recognition. Where needed, consumer protection is thereby assured, whilst mutual recognition relieves manufacturers of multiple conformity assessment. It should be noted that the mutual recognition principle (concerning non-harmonised goods, i.e. products subject to national laws not based on harmonising EU directives) has recently been further clarified when the European Parliament and the Council adopted Regulation (EC) No 764/2008, which will apply from 13 May 2009.

Repeal of the directives would not affect the producers of technologically more advanced products because their products are either currently subject to national law or not regulated at all, depending on the Member State. Manufacturers do not report barriers to trade that would justify additional harmonisation through EU regulation. Consumers and buyers of instruments would not be affected by the repeal because either there are national laws in place or there is currently no protection. Consumers did not report lack of protection. National authorities would not be affected because most of the directives are less and less used. Authorities currently can use the WELMEC type approval agreement in order to exchange information for purposes of market surveillance in the non-harmonised field and periodic in-service controls and this would, of course, also be the case if the directives were repealed without new harmonisation.

### **3.4. How would the problem evolve, all things being equal?**

Mutual recognition is already the rule for these sectors and this is not expected to change.

Without any new EU action, the old Directives would still exist until technical progress has completely overtaken the technological specifications.. The old directives concern mostly outdated (non electrical) technology. According to the RPA study, it is expected that the market will evolve quickly to products more technologically advanced no longer covered by the old directives.

### **3.5. Does the EU have the right to act – Treaty base, ‘necessity test’ (subsidiarity) and fundamental rights limits?**

Given the apparent lack of constraints and trade barriers, it would appear that there is no need to replace current outdated harmonisation by new Community law.

There are no apparent barriers to trade that would require harmonisation on the basis of Article 95 of the Treaty.

Only the Community can repeal existing Directives, therefore action at Community level is necessary and fully in line with the subsidiarity principle.

## **4. OBJECTIVES**

In line with the Commission’s approach to simplification (COM(2005)535) the general objective is to simplify the acquis of European law by repealing obsolete legislative acts, which have little or no practical impact and therefore have become irrelevant.



The specific objective is to simplify the EU acquis in the areas covered by eight old approach metrology Directives while maintaining the free circulation of the measuring instruments in the internal market and not hindering technological progress.

These objectives are fully in line with the Community policy of better regulation and simplification, and are in line with the Lisbon strategy. The objectives aim to continue free circulation of goods and services on the Internal Market consistent with international standards. In line with better regulation and simplification, changes are kept to the minimum and where needed continuity of enforcement is best ensured. The objectives are to maintain conditions that have proven to be conducive to competitiveness of European enterprises.

## **5. POLICY OPTIONS**

### **5.1. What are the possible options for meeting the objectives and tackling the problem?**

The options under consideration have been set out in the Key Issues Document (for the public consultation) as follows:

**Option 1:** Maintain the current regulatory framework unchanged. This option will act as the baseline for assessing the impacts of adopting either Option 2 or 3.

**Option 2:** Repeal the eight existing Directives without proposing any new Community legislative instrument to replace them. Under this option the free movement of measuring instruments within the Internal Market would implicitly rely on the Mutual Recognition Principle and horizontal legislation framing its correct functioning. Rather than national regulation Member States could rely on the voluntary application of European standards. For the updating and development of such standards the Commission could, if needed, give a mandate to the European Standardisation Organisations. Member States wanting to keep national regulation would need to base their laws on international standards. For most instruments international standards exist. Under WTO/TBT obligations, international standards would be the basis for national regulation as well as for European standards. Option 2 is the repeal of the Old Approach directives without any change to the MI Directive 2004/22/EC.

**Option 3:** Replace the current Directives by new harmonising legislation added into the Measuring Instruments Directive 2004/22/EC, the latter already providing a legal framework for certain measuring instruments under the New Approach. This option implies the inclusion of these new sectors into this New Approach Directive. It does not allow any national rules, although Member States remain free to choose the tasks for which they want to prescribe legal metrological control. For these tasks they may only allow instruments conformity assessed on the essential requirements in the directive to be used on their territory. New Approach harmonisation prescribes essential requirements and allows any technological specification that complies with these requirements. Option 3 is to add new annexes for each instrument to the MI Directive 2004/22/EC.

#### ***Which options have been discarded at an early stage and why?***

No option has in principle been excluded beforehand.

## **6. ANALYSIS OF IMPACTS**

### **6.1. What are the likely economic, social and environmental impacts of each of the short-listed options?**

It was originally hoped that sufficient data would be obtained by the study consultant or otherwise to enable robust estimates to be made of the administrative costs associated with each of the options (outlined above). Although this has not proved to be possible, attempts have been made to suggest (qualitatively at least) whether administrative costs are likely to increase or decrease (with respect to the existing regulatory framework) for each of the sectors under each of the options. It should be noted that given the nature of the initiative (simplification) and the very limited or even non-existing impacts as indicated by the consultation and the study, the analysis of impacts is carried out in line with the principle of proportionate analysis.

#### **6.1.1. Impacts of option 1 (No action)**

Option 1 is used as the baseline case and represents the current situation

Scenario 1A is a limitative interpretation that only the old approach directive applies and so no new technology may be sold on the market. It would probably be at odds with mutual recognition in the non-harmonised sector. As there were no complaints about such a situation, scenario 1A probably does not exist anywhere.

Scenario 1B is the case where national rules exist parallel to the old approach directive in order to cover technological advances. Such national rules can be based on international standards (required since 1995 by WTO /TBT) (scenario 1B) and offer a high level of protection but at the cost of national conformity assessment. Mutual recognition allows uninhibited entry into other Member States, due also to the WELMEC type approval agreement.

Scenario 1C would be the case of national specifications diverging from international standards which could lead to a barrier to trade. As no information was received from stakeholders about barriers to trade it would seem that scenario 1C probably does not exist anywhere either.

Scenario 1D is the case of no national rules. In this case the Old Approach directive is on the national rule book but it is nowhere required and is therefore completely voluntary. It is left up to consumers to decide what they need. It means that there are no administrative costs but there may be sub-standard instruments on the market, which would be difficult to take off the market, failing a law. This problem has only been mentioned by a UK authority in the public consultation in the case of tyre pressure gauges. Such abuse would normally be a reason for a Member State to propose national legislation, but only half of Member States wanting to regulate these sectors.

Summarising, it would seem that only scenarios 1B and 1D are actually encountered and these two are the baseline relative to which impacts are analysed. Both of these scenarios are fully in line with the principle of mutual recognition. They will allow products to freely circulate, whereby the WELMEC type approval agreement will provide information about conformity assessment needed for appropriate market surveillance.

According to a UK local authority in the public consultation most firms are relatively small and already operating in various markets. It would seem that both scenarios 1B and 1D would be equally conducive to cross border expansion by small and medium sized businesses, notably due to the lack of barriers to trade afforded by mutual recognition.

### **6.1.2. Impacts of option 2 (Repeal the directives)**

Option 2 would continue to allow regulation by Member States as is already the case now.

If a Member State would choose to regulate based on international standards, there would be minimal costs, given that mutual recognition of conformity assessment and WELMEC type approval agreement would normally allow one conformity assessment to be accepted all over the EU (Scenario 2A). In its effects Scenario 2A is the same as Scenario 1B.

The only case which could involve significant costs is where a Member State would try to impose a technology differing from international standards. This case, however, looks highly improbable in the light of WTO/TBT and the obligations of Member States under the principle of mutual recognition. (Scenario 2B). Scenario 2B is comparable to the situation under scenario 1C, which is currently not encountered, so it will be discarded

If a state chooses not to regulate (Scenario 2C) there would be no costs or protection. Scenario 2C is equal to Scenario 1D.

Foreign producers would not be unduly influenced by the repeal. Just like now they can continue to benefit from mutual recognition on the EU single market based on a national conformity assessment certificate.

### **6.1.3. Impacts of option 3 (repeal directives and inclusion in Measuring Instruments Directive)**

Option 3 would be to introduce the sectors into the New Approach directive for measuring instruments. The directive allows all instruments which comply with the essential requirements facilitating such compliance by recognising international standards which can easily be updated, i.e. without adapting the directive. The directive allows a Member State to prescribe legal metrological control as it thinks fit (opt-in that recognises subsidiarity) but on the condition that only instruments conforming to the directive may be used. This is the case of scenario 3A. As there are currently not barriers to trade, the impacts of scenario 3A would conceivably be equal to scenario 1B.

However, Article 2 of the same directive allows for optionality, so a Member State may choose not to introduce any legal metrological control. This is the case of Scenario 3B which in its impacts is equal to Scenario 1D.

Foreign producers would not be unduly influenced. European conformity assessment would replace national conformity assessment certificate without any difference from the current situation.

## **6.2. Specify uncertainties and how impact may be affected by changes in parameters (uncertainty and sensitivity analysis).**

Notwithstanding that the simplification exercise was kicked off nearly one and a half years ago by means of a meeting with national experts in April 2007, there is still some uncertainty about the existing situation in Member States. Authorities have until now not very clearly expressed themselves. According to the consultant's study, however, in general the market place does not seem to be overly hindered by regulation at the moment, which would dovetail with the apparent lack of complaints about barriers to trade being brought forward in the consultation. Nevertheless, sensitivity analysis will be provided below (Impacts of dynamics) of different possible responses of Member States to a change of their regulatory framework.

If the option of repeal would be chosen, it does not seem probable that Member States would suddenly increase national regulation, given that Member States could in the past already do

so and so there is no ground to assume that they will suddenly start legislating when obsolete directives are repealed.

As the current directives are virtually not used, there do not seem to be substantial economic, environmental or social impacts. In no way will repeal reduce the current possibilities of Member States to address the issue of measurement in these sectors. National rules may continue to exist and new rules may be formulated based on international standards with mutual recognition requiring Member States to give uninhibited access to their market of products giving similar protection and levels of performance.

### 6.3. What are the potential obstacles to compliance?

There do not seem to be obstacles to compliance in the case of repeal (option 2). In the case of inclusion under MID (option 3), there could be substantial opting out by a substantial number of Member States.

## 7. COMPARING THE OPTIONS

As monetisation of impacts is difficult, the analysis is of a qualitative nature.

### 7.1. Impacts of options

The options are the two possible outcomes of the simplification objective: repeal (option 2) or re-regulation (option 3). Both options would achieve the objective of simplification and therefore other criteria are added to compare them. Only where the criteria differ per option have they been made explicit.

It would appear that in this case where there are no reported barriers to trade and no other overriding policy needs, there only remain the issues of a high level of protection versus administrative costs which are the distinguishing impacts between options.

High level of protection is ensured either by national law based on international standards (scenario 1B and 2A) or by harmonisation (scenario 3A). When there are no laws, there is no guaranteed protection (scenarios 1D, 2C and 3B)

All costs are of an equal magnitude across the options, i.e. the low to medium administrative costs of scenario 1B are equal to those of 2A and 3B. Where there are no laws no administrative costs need be made (scenarios 1D, 2C and 3B).

Competitiveness is equally ensured under all scenarios given that there are no barriers to trade and that this is not going to change under any of the scenarios.

**Table 2: Impacts per option (scenario) (+ = benefit, - = cost)**

Scenario	1B	1D	2A	2C	3A	3B
High level protection	+	0	+	0	+	0
Administrative costs	-	0	-	0	-	0
Total	0	0	0	0	0	0

In the case of regulation (scenarios 1B, 2A and 3A) administration costs to manufacturers pay for the benefit of a high level of protection. Where there is no law there are no costs. No negative impacts on trade are expected in either case.

The trade-off between protection benefits and administrative costs may exist for weights as concerns honesty of transaction and tyre pressure gauges as concerns performance, although harmonisation is nowhere required in the light of an overriding policy need and national rules can be expected to be equally effective in ensuring such protection where needed

## 7.2. Present results of the weighing

As these administration costs concern the conformity assessment, which already exists in all Member States with additional national rules covering technological progress under scenario 1B, it would seem that these costs are discounted in the EU market. Also the benefits of a high level of protection are already being enjoyed under scenario 1B and these costs and benefits will not change either under repeal (option 2) or reregulation (option 3).

It is most likely that Member States will not wish to change from their current situation, whatever the outcome may be, e.g. a Member State now in scenario 1B will keep national rules unchanged under repeal (scenario 2A) and will opt-in under harmonisation (scenario 3A).

Comparison in Table 3 below of the options to the baseline shows zero impacts everywhere! Whatever change is made it is “impact free” and no negative impacts on trade are expected.

**Table 3: Impacts of options compared to the baseline option 1 (likely choice by Member States)**

Scenario	2A vs 1B	2C vs 1D	3A vs 1B	3B vs 1D
High level protection	0	0	0	0
Administrative costs	0	0	0	0
Total	0	0	0	0

### 7.3. Impacts of dynamics (uncertainty)

There may be reasons for Member States to cross-over either to deregulate by getting rid of current national rules or to increase protection by new rules, be they national or harmonised. It may seem less likely but should not be discarded in this analysis.

Introducing rules where there were none would give more protection at the price of an increase in administration costs (columns 2 and 4 of the Table 4 below). Deregulating would mean less guaranteed protection with a gain of no longer requiring administration costs (columns 3 and 5 of the Table 4 below).

**Table 4: Effects of crossing over compared to baseline option 1 (less likely choice by of Member States)**

Scenario	2A vs 1D	2C vs 1B	3A vs 1D	3B vs 1B
High level protection	+	-	+	-
Administrative costs	-	+	-	+
Total	0	0	0	0

Only in the case of shifts to more regulation will there be low to medium sized costs for conformity assessment compared to the case of no regulation (shift from 1D to 2A or 3A). Such shifts are under both options 2 and 3 a choice by each Member State in line with the principle of subsidiarity. It seems, however, quite unlikely that a Member State will decide to substantially change its current stance on regulations, because it can already do so in the current situation. In the case of option 2 there is no obligation to change from the current situation. Under Option 3 there could be minor ‘moral’ pressure because Member States must indicate in writing what the reasons are for their opt-out (Art. 2 of MI Dir 2004/22/EC)

### 7.4. Indicate if the analysis confirms whether EU action would have an added value.

The analysis confirms that mutual recognition based on international and industry standards is common in all sectors and repeal of the current directives (option 2) would have zero costs over the current situation (option 1). EU action consisting of repeal of the directives has added value in the context of the overall policy aim of simplification and better regulation.

As regards, the option of regulation under MID, value added of EU action is less evident due to the absence of any reported barriers to trade, which would point to a failure of mutual recognition. Next to that there could be associated policy benefits, but there is no reason to assume that these cannot be achieved just as well by national rules under mutual recognition. It is also to be expected that half or more of Member States would opt-out which would add an uncertainty that would compromise the aim of the re-regulation.

The simplification benefit is evident in the case of repeal (option 2) but less evident in the case of re-regulation under the MID, due to the apparent lack of barriers to trade.

### 7.5. If possible and appropriate, set out a preferred option.

On the basis of impact assessment as such, there is no preferred option. This is due to the lack of trade barriers and due to the Old Approach directives being less and less used.

The justification to repeal all 8 metrology directives (option 2) would be in line with the Commission’s approach in COM(2005)535 to simplify the *acquis* of European law by

repealing obsolete legislative acts, which have little or no practical impact and therefore have become irrelevant, It would also be fully in accordance with the principle of subsidiarity.

Option 3 does not appear to reach beyond the current situation of mutual recognition. This also given that a substantial number of Member States are expected to opt-out of harmonisation, as is possible under Art. 2 of the MID.

## **8. MONITORING AND EVALUATION**

### **8.1. What is the broad outline for possible monitoring and evaluation arrangements?**

Stakeholders could bring up new evidence which could lead the Commission services to consider, in the light of developments whether new policy needs would require harmonisation in the future. Such new evidence, together with the option of expanding the scope of the directive by means of additional MI-annexes, could be considered in the report by the Commission on the Measuring Instruments Directive which is foreseen before 30 April 2011 by Article 25 of Directive 2004/22/EC.

### **8.2. How has the opinion of the IA board of 24 September 2008 been taken into account**

The opinion of the IA board has been taken into account in this version of the report. The following changes have been made:.

(1) “Improve the presentation of the underlying framework”: Section 3.2 about the underlying drivers of the problem has been extended from the first sentence only to a full page as well and also have been added the last two sentences in the description of Option 3 in section 3.6. Table 1, which initially was in the annex, has been moved forward to section 3.2.

(2) “Clarify the current role of the directives”: This has been taken into account in section 3.2, notably the second and third sentences of the first paragraph as well as changes to section 3.4.

(3) “Clarify the impact on administrative burden”: In section 7.1 the first paragraph has been added, paragraphs 4 and 5 reworded and the last paragraph added whilst in section 7.3 the penultimate paragraph and in section 7.4 the last paragraph have been added. The comment on competitiveness has led to rephrasing the penultimate paragraph of section 7.1 and the third paragraph of section 7.2 as well as adaption of Tables 2, 3 and 4.

## ANNEX: Analysis of Sectors

### MARKET SIZE AND REGULATION

In its study RPA has estimated the size of the market currently covered by the directives and the additional sales of technologically more advanced alternatives. The largest sector under the current directives is weights at €30m, whilst, if technological progress is taken into account, additional sales for tyre pressure gauges amount to €70m. Most sectors are small, if not minute, compared to these two, already not large, sectors. Manufacturers have confirmed to the Commission services that annual turnover of the third largest sector, alcohol meters, amounts to only €8m, see table 1.

**Table 1: Estimates of the annual turnover per sector on the EU market, currently under a directive and additional due to technological innovation (million €)**

Sector	Annual turnover on the EU market including imports and excluding exports (million €)		
	Only existing directive	Additional due to technical innovation	Total: existing + new
Non-clean water meters	4	0	4
Alcohol meters	2	6	8
Weights	30	0	30
Tyre gauges	3	70	73
Mass of grain	0.6	4	4.6
Calibration ship tanks	0.75	0	0.75
<b>Total</b>	<b>40</b>	<b>80</b>	<b>120</b>

(Source: Study for the Commission of July 2008 by RPA Ltd.)

The study shows fairly exhaustive coverage by international standards, whereby technological progress is taken into account for alcohol and mass of grain by means of references in EU regulations. There are also alternative standards for ship tanks, see Table 1 in the main text..

### ISSUES PER SECTOR

**Non-clean water.** In non-clean water there are many uses, e.g. measuring waste water, irrigation water use as well as metering of large scale sales among utilities of clean water. However these fields are highly diverse and all outside of the current scope of the MID. EC harmonisation would appear to be technically complex, while there do not seem to be drivers in the area of EU environmental policy requiring such harmonisation. In its reaction to the public consultation, the EU water manufacturing industry has asked for the existing directive to be repealed and it does not require harmonised legislation for non-clean water meters.



**Alcohol meters** In their reactions to the public consultation two manufacturers of alcoholmeters and Scotch whiskey producers indicate that harmonisation should incorporate and not inhibit technological innovation. They do not mention any trade barriers. The use of alcohol meters that could be different and more technological advanced than those in the directive is already prescribed in the EU regulations on wine and spirits drinks (Regl. 2676/90 and 2870/2000). It would appear that these regulations go much further than OIML and the directive. The regulations are directly applicable and do not contain any conformity assessment criteria for the instruments used. It is unclear on which grounds a proposal for harmonisation could be justified for instruments, the use of which is currently already harmonised for all intents and purposes by means of these regulations for wine and spirit drinks. For beer on the other hand, there are no EU regulations.

**Alcohol tables** are covered by international OIML and ISO standards and are already harmonised in national law of all Member States, due to the fact that the current directive is mandatory. The above mentioned regulations for wine and spirit drinks also contain similar tables, but only for the alcohol ranges concerning wine and spirits. There does not seem any reason to change such laws. If there were no longer an EU directive, there would remain a legal base in the regulations. Lower percentage alcohol tables would need to remain covered by national law based on international standards. Alcohol tables do not concern a measuring instrument, but rather the way measurements by alcohol meters should be read in order to obtain a percentage, so it would not be possible to include them in the Measuring Instruments Directive.

**Medium and Above-Medium Accuracy Weights:** The two optional Directives have a link to the Directive on Non-automatic Weighing instruments (Directive 90/384/EEC) which is mandatory and includes manual weighing with weights. Experts of 17 Member States indicate that manual weighing still exists in shops and on markets and for precision weighing in pharmaceuticals. Practical use may be expected to decline but there may nonetheless remain a back-up function of material weighing. Given that there is no technological advance, international standards duplicate fully the directive.

**Tyre Pressure Gauges for Motor Vehicles,** Road safety and energy efficiency could be deemed policy needs to harmonise tyre pressure gauges. It could complement current Commission initiatives to improve road safety and energy efficiency by means of more accurate tyre pressure monitoring systems (TPMS) in new cars (COM(2008)316). The proposal is to let new cars be equipped with a system for continuous monitoring of tyre pressure. A driver would be warned about less than optimal tyre pressure. In the accompanying impact assessment, it is estimated that energy efficiency of cars can be improved by 2.5% if tyres are correctly inflated. At this stage, it is not evident that harmonisation of tyre pressure gauges is required as a precondition to obtain the benefits outlined due to TPMS. Directive 2004/22/EC on measuring instruments also allows Member States an opt-out, so possibly only half of Member States will apply it.

**Mass of grain** is only one of the elements used to determine the payments for grain under EU intervention (next to density, humidity) and therefore more advanced instruments than those in the directive are already prescribed by the AGRI regulation on cereals (Regl. 824/2000). This regulation references international/European ISO/EN standards, not those of OIML and the directive. The regulations are directly applicable and do not contain any conformity assessment criteria for the instruments used. It is unclear on which grounds a proposal for harmonisation could be justified for instruments, the use of which is currently already harmonised for all intents and purposes by means of the EU agricultural regulation.

**Calibration of ships tanks** is about marking the contents of tanks on inland and coastal shipping. The procedure is to fill them and place marks. The indications on the tanks are rarely the only ones used in transactions, because generally the transaction is based on the measurement when the cargo has been unloaded. It is not an element in the inland shipping safety directive (Dir 2006/87/EC). For petroleum transport there exist ISO standards and a widely used industry API/EI/ISO standard under the Phoenix agreement. As few Member States currently require legal metrological control there do not seem to be overriding EU policies that would require intensifying such control.

Due to these developments there are no apparent trade barriers in any of the sectors, neither for the instruments under the existing directive nor for more technologically advanced instruments and there is widespread use of alternatives to the directives, many of which are based on international standards.