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***II
RECOMMENDATION FOR SECOND READING

on the Council common position adopting a European Parliament and Council directive on measuring instruments
(9681/4/2003 – C5-0417/2003 – 2000/0233(COD))

Committee on Industry, External Trade, Research and Energy

Rapporteur: Giles Bryan Chichester

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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PROCEDURAL PAGE

At its sitting of 3 July 2001 Parliament adopted its position at first reading on the proposal for a European Parliament and Council directive on measuring instruments (COM(2000) 566 – 2000/0233(COD)).

At the sitting of 4 September 2003 the President of Parliament announced that the common position had been received and referred to the Committee on Industry, External Trade, Research and Energy (9681/4/2003 – C5-0478/2003).

The committee had appointed Giles Bryan Chichester rapporteur at its meeting of 11 September 2002.

For the first reading the committee had appointed Lisbeth Grönfeld Bergman at its meeting of 12 October 2000.

It considered the common position and the draft recommendation for second reading at its meetings of 1 October 2003, 4 November 2003, 26 November 2003 and 2 December 2003.

At the last meeting it adopted the draft legislative resolution unanimously.

The following were present for the vote) Jaime Valdivielso de Cué, (vice-chairman), Giles Bryan Chichester (rapporteur), Gordon J. Adam (for Massimo Carraro), Konstantinos Alyssandrakis, Sir Robert Atkins, Guido Bodrato, Nicholas Clegg, Willy C.E.H. De Clercq, Concepció Ferrer, Norbert Glante, Alfred Gomolka (for Angelika Niebler), Michel Hansenne, Roger Helmer (for W.G. van Velzen), Hans Karlsson, Rolf Linkohr, Eryl Margaret McNally, Erika Mann, Bill Newton Dunn (for Colette Flesch), Seán Ó Neachtain, Paolo Pastorelli, Samuli Pohjamo (for Elly Plooij-van Gorsel), Paul Rübig, Esko Olavi Seppänen, Claude Turmes, Alejo Vidal-Quadras Roca, Myrsini Zorba.

The recommendation for second reading was tabled on 3 December 2003 .

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position adopting a European Parliament and Council directive on measuring instruments
(9681/4/2003 – C5-0478/2003 – 2000/0233(COD))

(Codecision procedure: second reading),

The European Parliament,

– having regard to the Council common position (9681/4/2003 – C5-0417/2003),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2000) 566)[2],

– having regard to the amended proposal (COM (2002) 37))[3],

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on Industry, External Trade, Research and Energy (A5-0458/2003),

1. Amends the common position as follows;

2. Instructs its President to forward its position to the Council and Commission.

Council common position	Amendments by Parliament
Amendment 1 Recital 5	
(5) Member States should ***retain the option to*** prescribe legal metrological control. Where legal metrological control is prescribed, measuring instruments complying with common performance requirements should be used.	(5) Member States should***, as a general rule,*** prescribe legal metrological control. Where legal metrological control is prescribed, ***only*** measuring instruments complying with common performance requirements should be used.
Justification	
This amendment introduces "a general rule" while allowing exemptions to be introduced, under the principle of optionality. The latter implies that Member States may exercise their	

[1] OJ C 65, 14.3.2002, p. 34.
[2] OJ C 62, 27.2.2001, p. 1
[3] OJ C 126, 28.5.2002, p.368.

right to decide whether or not to regulate any of the instruments covered by this Directive. It seeks to meet in part the amendments on optionality of the 1st reading (n° 2, 8 and 9) which have not been taken over by the Common Position. Hence, this amendment is admissible and seeks to attain the objectives of the Internal Market, without compromising the principles underlying the Internal Market.

Amendment 2
Recital 5a (new)

(5a) The principle of optionality introduced by this directive, implying that Member States may exercise their right to decide whether or not to regulate any of the instruments covered by this Directive, will be applicable only to the extent that this clause will not cause unfair competition.

Justification

The amendments on optionality of the first reading (N° 2, 8 and 9) have <u>not</u> been taken over by the Common Position. Hence this amendment should be considered in conjunction with the amendment to Recital 5 and Article 1 a (new). It essentially states that a Member State will be free to decide on whether or not to regulate in this field. Member State's legislation should not act as a technical barrier to the completion of the internal market, nor cause unfair competition, and the conditions attached to optionality should be respected.

Amendment 3
Recital 6

(6) The responsibilities of the manufacturer for compliance with the requirements of this Directive should be specifically stated.	(6) The responsibilities of the manufacturer ***or the person placing it on the market (the trader)*** for compliance with the requirements of this Directive should be specifically stated.

Justification

This amendment is linked to one tabled to Article 3, point (da). It seeks to clarify that the manufacturer or the person placing it on the market (the trader), in the case of an imported instrument, are to be considered as the same person in terms of responsibility in this Directive. Given the modification of the definition of the manufacturer by the Common Position, this amendment is 'admissible', meeting the provisions of Rule 80 of the Rules of Procedure.

Amendement 4
Recital 12 a (new)

(12a) The conformity assessment of sub-assemblies will respect the provisions of this Directive. If sub-assemblies are traded separately and independently of an instrument, the exercise of conformity assessment will be undertaken independently of the instrument concerned.

Justification

It seeks to clarify the application of the exercise of conformity assessment when sub-assemblies are traded as separate components and independently of a measuring instrument. This amendment should be taken in conjunction with the one tabled to Article 4, and it is admissible because it amends a new text proposed by the Common Position.

Amendment 5
Recital 13

(13) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measurement there must be an appropriate procedure or a choice between different procedures of equivalent stringency. The procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the "CE" marking, which are intended to be used in the technical harmonisation Directives. However, derogations may have to be made for these modules in order to reflect specific aspects of metrological control. Provision should be made for the "CE" marking to be affixed during the fabrication process.	(13) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measurement ***and, where appropriate, sub-assemblies*** there must be an appropriate procedure or a choice between different procedures of equivalent stringency. The procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the "CE" marking, which are intended to be used in the technical harmonisation Directives. However, derogations may have to be made for these modules in order to reflect specific aspects of metrological control. Provision should be made for the "CE" marking to be affixed during the fabrication process.

Justification

It should be considered in conjunction with the relevant amendment to recital 12a (new) on the conformity assessment of sub-assemblies.

Amendment 6

Recital 13 a (new)

(13a) Continued development in

measurement technology as well as concerns expressed by stakeholders about certification stress the need for ensuring consistent conformity assessment procedures for industrial products, as requested by Council Resolution adopted on 10 November 2003.

Justification

This amendment should be considered in conjunction with the one tabled to Article 23. It stems from a recent Council Resolution on "Enhancing the Implementation of the New Approach Directives", which was adopted by the Competitiveness Council on 10 November 2003. In fact the said Resolution states that the Council invites the Commission "To propose appropriate initiatives in the fields of conformity assessment and of market surveillance".

Amendment 7
Recital 19a (new)

(19a) Council Decision 1999/468/EC on Comitology states that both Advisory and Regulatory committees will be "composed of the representatives of the Member States" yet it does not specify who the representatives should be; it is therefore desirable that the Measuring Instrument Committee be composed of representatives of all interested parties;

Justification

Council Decision 1999/468/EC on comitology (OJ L184, 17.07.99) states that both Advisory and Regulatory committees will be 'composed of the representatives of the Member States and chaired by the representative of the commission'. Yet the Common Position modified the initial MID proposal by deleting the reference to the composition of the Measuring Instruments Committee. Furthermore, the said Decision does not specify who the 'representatives of the Member States' would be. The absence of naming the 'representatives' is correct because representation may be varied and representative of all interested parties such as manufacturers, traders and consumers. Such participation is necessary so that all views and advice are presented to the said committee.

Amendment 8
Article 1 a (new)

Article 1a

1. Member States may prescribe the use of measuring instruments mentioned in Article 1 for measuring tasks for reasons of

	public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of consumers and fair trading, where they consider it justified.
	2. Where Member States do not prescribe such use they shall notify the reasons thereof to the Commission and the other Member States.

Justification

This amendment is to follow up the one introduced in the first reading on the subject of optionality. But the Common Position has rejected Parliament's amendment 2, 8 and 9 on optionality. The amendment simply clarifies the conditions under which the optionality clause (the right of a Member State to decide whether or not to regulate some or none of the devices or instruments covered by this proposal) will be applicable.

Amendment 9
Article 2, paragraph 1

This Directive establishes the requirements that the devices and systems referred to in Article 1 have to satisfy with a view to their being placed on the market and/or put into use for those tasks ***for which a Member State prescribes legal metrological control***.	This Directive establishes the requirements that the devices and systems referred to in Article 1 have to satisfy with a view to their being placed on the market and/or put into use for those tasks ***mentioned in the first paragraph of Article 1 a***.

Justification

This amendment is a follow-up to the one to Article 1a (new) on the conditions attached to the clause of optionality.

Amendment 10
Article 3, point (c)

(c) "legal metrological control" means the control of the measurement tasks for the field of application of a measuring instrument***, prescribed by the Member States*** for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;	(c) "legal metrological control" means the control of the measurement tasks ***intended*** for the field of application of a measuring instrument***,*** for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;

Justification

This amendment clarifies the field of application of this proposal on measuring instruments and the tasks associated with public interest and consumer protection.

Amendement 11
Article 3, point (da) (new)

(da) "trader" means a natural or legal person, other than a manufacturer, responsible for placing a measuring instrument, that is in conformity with this Directive, on the market;

Justification

It is purely definitional seeking to distinguish the manufacturer from the trader, two natural or legal persons that bear the same responsibility for placing a measuring instrument on the market.

Amendment 12
Article 3, point (i)

(i) "normative document" means a document containing technical specifications adopted by the Organisation Internationale de Métrologie Légale (OIML).	(i) "normative document" means a document containing technical specifications adopted by the Organisation Internationale de Métrologie Légale (OIML)***, which is subject to the procedure stipulated in Article 13(1).***

Justification

This amendment makes clearer that normative documents from intergovernmental bodies such as OIML recommendations should be discussed and agreed by the Advisory Committee, published in the official Journal provided that this committee is representative of all parties concerned.

Amendment 13
Article 4, subparagraph 1 a (new)

1a. Sub-assemblies and measuring instruments may be assessed independently and separately for purposes of establishing conformity.

Justification

It clarifies that all requirements applied to measuring instruments, would also apply to sub-

assemblies because the two might be traded separately and independently of one another. The amendment is admissible because sub-assemblies are now better integrated in the legislative text as a new Article.

Amendment 14
Article 7, paragraphs 2 to 4

2. Member States ***requiring legal metrological control*** shall take all appropriate measures to ensure that measuring instruments may be placed on the market and/or put into use only if they satisfy the requirements of this Directive.	2. Member States shall take all appropriate measures to ensure that measuring instruments may be placed on the market and/or put into use only if they satisfy the requirements of this Directive.
3. A Member State ***requiring legal metrological control*** may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I, and in addition may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.	3. A Member State may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I, and in addition may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.
4. When different accuracy classes are defined for a measuring instrument:	4. When different accuracy classes are defined for a measuring instrument:
(a) the instrument-specific annexes under the heading "Putting into use" may indicate the accuracy classes to be used for specific applications.	(a) the instrument-specific annexes under the heading "Putting into use" may indicate the accuracy classes to be used for specific applications.
(b) in all other cases a Member State ***requiring legal metrological control*** may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.	(b) in all other cases a Member State may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.
In either case under (a) or (b), measuring instruments of a better accuracy class may be used at the choice of the owner.	In either case under (a) or (b), measuring instruments of a better accuracy class may be used at the choice of the owner.

Justification

It simply deletes one phrase in order to be consistent with the previous amendments that deleted reference to legal metrological control.

Amendment 15
Article 8, subparagraph 1

Conformity assessment of a measuring instrument with the relevant essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the instrument-specific annex. The manufacturer shall provide, where appropriate, technical documentation for specific instruments or groups of instruments as set out in ***Annex III***.	Conformity assessment of a measuring instrument with the relevant essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the instrument-specific annex. The manufacturer shall provide, where appropriate, technical documentation for specific instruments or groups of instruments as set out in ***Article 8a.***

Justification

This amendment should be considered in conjunction with the amendment-introducing Article 8a (new). Both amendments are consistent with the relevant amendments of the first reading (N° 14 and 28,) and follow the logic of the 1st reading, namely it is undesirable to use Annexes to describe the necessary documentation, which is used not only for the assessment of conformity but also for harmonised standards. The Common Position has rejected amendments 14 and 28.

Amendment 16
Article 8 a (new)

	TECHNICAL DOCUMENTATION
	1) The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall enable assessment of its conformity with the appropriate requirements of this Directive.
	2) The technical documentation shall be detailed enough in order to ensure :
	– the definition of the metrological characteristics,
	– the reproducibility of the metrological performances of produced instruments when properly adjusted using appropriate intended means, and
	– the integrity of the instrument.
	3) The technical documentation shall include insofar as relevant for assessment and identifications of the type and/or

instrument:

3.1. a general description of the instrument;

3.2. conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc;

3.3. manufacturing procedures to ensure consistent production;

3.4. if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

3.5. descriptions and explanations necessary for the understanding of paragraphs 3.2, 3.3 and 3.4, including the operation of the instrument;

3.6. a list of the standards and/or normative documents referred to in Article 10, applied in full or in part;

3.7. descriptions of the solutions adopted to meet the essential requirements where the standards and/or normative documents referred to in Article 10 have not been applied;

3.8. results of design calculations, examinations, etc;

3.9. the appropriate test results where necessary to demonstrate that the type and/or instruments comply with:

(a) the requirements of the Directive under declared rated operating conditions and under specified environmental disturbances

(b) the durability specifications for gas-, water-, heat-meters as well as for liquids other than water.

3.10. the EC-type examination certificates or EC design examination certificates in respect of instruments containing parts identical to those in the design.

4) The manufacturer shall specify where seals and markings have been applied.

	5) The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

Justification

It reintroduces Amendment 14 of the first reading. Annex III of the Common Position as modified by the Council is shifted to the main body of legislation. This amendment should also be considered in conjunction with the ones tabled to Article 8(1) and to Annex III. This amendment follows the logic and practice of Directives on food safety and on controls on products of animal origin. This amendment shall apply mutatis mutandis to all parts of the proposal when reference to Annex III is made

Amendment 17
Article 9, paragraph 2

2. Member States shall apply the criteria set out in ***Annex II*** for the designation of such bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards, the references of which have been published in the Official Journal, shall be presumed to meet the corresponding criteria. Member States shall publish the references to these national standards.	2. Member States shall apply the criteria set out in ***Article 9 a*** for the designation of such bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards, the references of which have been published in the Official Journal, shall be presumed to meet the corresponding criteria. Member States shall publish the references to these national standards.
If a Member State has not introduced national legislation ***regulating a measuring instrument***, it retains the right to designate and notify a body for tasks relating to that instrument.	If a Member State has not introduced national legislation ***for tasks mentioned under Article 1 a***, it retains the right to designate and notify a body for tasks relating to that instrument.

Justification

This amendment is necessary for two reasons: first, a notified body might not exist in a Member State that allows a measuring instruments to be traded on its market; second, a host country may wish to designate a notified body for tasks related to a commercialised instrument.

Amendment 18
Article 9 (3), indent 1

– ensure that the body continues to meet the criteria set out in ***Annex II*****,**	– ensure that the body continues to meet the criteria set out in ***Article 9a***,

Justification

This amendment is a technical correction due to previous amendments to Article 9.

Amendment 19
Article 9 a (new)

CRITERIA TO BE SATISFIED BY BODIES DESIGNATED

Set out below are the criteria that Member States shall apply for the designation of bodies according to Article 9(1).
1. The body, its director and staff involved in conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or user of the measuring instruments that they inspect, nor the authorised representative of any of them. Also they may not be not directly involved in the design, manufacture, marketing or maintenance of the instruments, nor represent the parties engaged in these activities. The preceding criterion does not, however, preclude in any way the possibility of exchanges of technical information for purposes of conformity assessment, between the manufacturer and the body.

2. The body, its director and staff involved in conformity assessment tasks shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology.

Should the body subcontract specific tasks, it shall first ensure that the subcontractor meets the provisions of this Directive, and in particular of this Article. The body shall keep the relevant

documents assessing the subcontractor's qualifications and the work carried out by him under this Directive at the disposal of the notifying authority.

4. The body shall be able to carry out all the conformity assessment tasks for which it has been designated, whether these tasks are carried out by the body itself or on its behalf and under its responsibility. It shall have at its disposal the necessary staff and have access to the necessary facilities for carrying out the technical and administrative tasks entailed in conformity assessment in a proper manner.

5. The body's staff shall have:

– sound technical and vocational training, covering all conformity assessment tasks for which the body was designated;
– satisfactory knowledge of the rules in respect of the tasks which it carries out, and adequate experience of such tasks;
– the ability required to draw up the certificates, records and reports to demonstrate that the tasks were carried out.

6. The impartiality of the body, its director and staff shall be guaranteed. The remuneration of the body shall not depend on the results of the tasks it carries out. The remuneration of the body's director and staff shall not depend on the number of tasks carried out, nor on the results of such tasks.

7. The body shall take out civil liability insurance, if its civil liability is not covered by the Member State under national law.

8. The body's director and staff shall be bound to observe professional secrecy with regard to all information obtained in the course of exercising their duties pursuant to this Directive, except vis-à-vis the authority of the Member State which has designated it.

Justification

This amendment is the reintroduction of amendment 16 of the first reading, which was not accepted by the Common Position. It seeks to reproduce the main elements of Annex II in the main body of legislation. There are two main reasons for supporting such an amendment. First, it follows faithfully the legal provisions on mission tests, responsibility, independence, confidentiality and transparency, which have been adopted in Regulation (EC) N°178/2002 laying down the general principles and requirements of food law and European Food Safety Authority. Second, Annex II is purely institutional in nature, not technical. In all EC legislation, independence and impartiality, accountability and transparency are stated in an article, not in an Annex. This amendment should be considered in conjunction with the amendment-deleting Annex II. This amendment shall apply mutatis mutandis to all parts of the proposal in which reference to Annex II is made.

Amendment 20
Article 10, paragraph 2, subparagraph 1

2. Member States shall presume conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes in respect of a measuring instrument that complies with the normative document referred to in Article 13(1)(a), whose references have been published in the Official Journal of the European Union, C series.	2. Member States shall presume conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes in respect of a measuring instrument that complies with the ***corresponding parts of the*** normative ***documents and lists*** referred to in Article 13(1)(a), whose references have been published in the Official Journal of the European Union, C series.

Justification

This amendment clarifies the use and application of normative documents employed for the purpose of presumption of conformity with the essential requirements.

Amendment 21
Article 10, paragraph 3

3. A manufacturer may choose to use any technical solution that complies with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes. However, ***only by*** applying ***those methods*** mentioned in the relevant standards ***and*** documents referred to in paragraph***s 1 and*** 2 is the presumption of conformity ensured.	3. A manufacturer may choose to use any technical solution that complies with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes ***(MI-001 to MI-010). In addition, to benefit from*** the presumption of conformity, ***he has to correctly apply solutions*** mentioned ***either*** in the relevant ***European harmonised*** standards, ***or in the corresponding parts of the normative documents and lists,*** referred to in

paragraphs 1 and 2.

Justification

This amendment explicitly states the three routes to the presumption of conformity. The first route is to demonstrate conformity with the essential requirements as stated in Annex I and the relevant instrument-specific Annexes (MI-001 to MI-010). The second route is when the manufacturer uses a technical solution by applying the relevant European harmonised standard. The third route is compliance with the list of the parts of the normative documents as approved by the Advisory Committee under the comitology procedure.

Amendment 22
Article 13, paragraph 1, point (a)

(a) identify normative documents drawn up by OIML and indicate parts thereof compliance with which gives rise to a presumption of conformity with the corresponding essential requirements of this Directive;	(a) identify normative documents drawn up by OIML and***, in a list***, indicate ***the*** parts thereof compliance with which gives rise to a presumption of conformity with the corresponding essential requirements of this Directive;

Justification

This amendment is a simple rephrasing to stress that the normative documents as drawn up by OIML need not be used in whole but only in part. Under these circumstances the Advisory Committee will adopt a list indicating the relevant specific parts of normative documents.

Amendment 23
Article 13, paragraph 1, point (b)

(b) publish the references of the document referred to in point (a) in the Official Journal of the European Union, C series.	(b) publish the references of the ***normative documents and the list*** referred to in point (a) in the Official Journal of the European Union, C series.

Justification

This follows up from the previous amendment to Article 13, paragraph 1, point (a).

Amendment 24
Article 13 (2)

2. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 12(3), may take any appropriate measure to amend instrument-specific	2. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 12(3), may take any appropriate measure to amend instrument-specific

annexes in respect of:	annexes ***(Annexes MI-001 to MI-010)*** in respect of:
– ***the inclusion of sub-assemblies,***	
– the maximum permissible errors (MPEs) and accuracy classes,	– the maximum permissible errors (MPEs) and accuracy classes,
– the rated operating conditions,	– the rated operating conditions,
– the critical change values,	– the critical change values,
– disturbances,	– disturbances,
– ***the list of conformity assessment procedures,***	

Justification

This amendment seeks to establish the institutional balance that one finds in Council Decision 1999/468/EC on the implementing powers conferred on the Commission (OJ L 184, 17/07//1999), and, in particular, Article 3 on 'what an advisory procedure committee can do' and Article 8 on 'why the EP should exercise control of the Commission' under the co-decision procedure. The amendment is admissible because the entire text on comitology has been changed by the Common Position. The initial proposal had proposed the 'advisory procedure'. The Common Position has introduced an innovation: the 'advisory procedure' for insignificant matters but the regulatory procedure for important issues, such as 'instrument-specific annexes' and by implication the 'conformity assessment procedure'. Amendment 17 of the first reading was not accepted by the Common Position.

Amendment 25
Article 19

Member States may require measuring instruments subject to legal metrological control to continue to meet appropriate in-service requirements.	***deleted***

Justification

Article 19 is added by the Common Position, but makes no legal sense unless it is linked to specific 'in-services requirements' and is obligatory. As drafted, its clarity is doubtful. And as proposed, it complicates the monitoring of this directive. These two reasons make the case for its deletion.

Amendment 26
Article 23

The European Parliament and the Council invite the Commission to report, before *, on the implementation of this Directive, ***and in particular on the application of Articles 1***	The European Parliament and the Council invite the Commission to report, before *, on the implementation of this Directive, *inter alia* on the basis of reports provided by the

and 2 thereof, *inter alia* on the basis of reports provided by the Member States, and, where appropriate, to submit a proposal for amendments.	Member States, and, where appropriate, to submit a proposal for amendments.
* 7 years after the date of entry into force of this Directive.	* 7 years after the date of entry into force of this Directive.

Justification

This amendment is a follow-up to the ones concerned with Article 1 a (new).

Amendment 27
Article 23, paragraph 1a (new)

	1a. The European Parliament and Council invite the Commission to evaluate if conformity assessment procedures for industrial products are properly applied and, where appropriate, to propose amendments in order to ensure consistent certification.

Justification

The Council resolution referred to in Amendment to Recital (13a) also states in paragraph 2, section c) that the Council invites the Commission "To ensure, in co-operation with Member States, consistent application of conformity assessment procedures to products covered by more than one Directive, by considering whether a more consistent range of modules can be made available in the individual Directives and ensuring that only then standard modules are used. The suppliers' declaration of conformity should be used whenever feasible."

Amendment 28
Annex -I
JOINT DECLARATION
OF THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE COMMISSION

	The Council and the Parliament undertake to act expeditiously in accordance with their respective rules of procedure, on a proposal from the Commission, concerning the conformity assessment procedures (Council Decision 93/465/EC), as indicated in the Competitiveness Council Resolution adopted on 10 November 2003. The Commission has the intention to submit the necessary proposals as foreseen in its 2004 legislative programme, after consulting the

interested parties.

Justification

This joint declaration is not legally binding on any of the three community institutions engaged in EC legislation. It should be considered as a political objective and commitment to revising horizontal as well as specific legislation in the field of the New Approach to technical harmonisation and standards and the Global Approach to conformity assessment.

EXPLANATORY STATEMENT

Introduction

National legislation on measurements and measuring instruments has been with us a long time. It precedes European legislation and reflects the importance of accuracy of measurement on the daily life of citizens. All EU and developed countries have metrological institutes charged with the task of establishing traceability of measurement results.

The first question to ask is: *Why the interest in measuring instruments?* The answer is because all developed countries have complex economies, which need *a minimum level of measurement accuracy for fair trading in the public interest*. Thus all legislation is based on the premise that the public interest is served if measuring instruments are subjected to legislative requirements that guarantee this minimum level of accuracy.

As long as national legislation in this field is compatible with the principles of the EC Treaty (in particular Article 30 of the Customs Union on prohibitions or restrictions of imports), its justification must be based on grounds of **public interest**. However, if intra-Community trade considerations are taken into account, then national legislation should **not** be incompatible with each other, nor with EC legislation. Otherwise, it will lead to barriers to trade. This is the basic premise underlying the Single European Act. Yet in the case of instruments covered by this proposal, national legislation is not compatible. Hence the Internal Market for measuring instruments needs to be strengthened through harmonisation of national legislation.

EC legislation

Harmonisation commenced in 1971[1]. As far as the need for a Measuring Instruments Directive (MID proposal) is concerned, the Commission makes three claims, which are relevant to the Common Position of the Council and the second reading of the EP. First, "The existing Community legislation is deficient in many ways, and the current proposal will replace the legislation in as far as necessary" (COM (2000) 466, pg. 6). Second, it is claimed that this Measuring Instruments proposal for a Directive follows the guidelines of the New Approach to harmonisation, aiming at creating an 'internal market for measuring instruments that are subject to legal metrological control' (pg.7). Third, it is also claimed that the MID proposal 'follows the Global Approach to testing and certification' (pg.8).

These three claims are interdependent and should be seen in their context. An easy answer to the question of the need to revise old legislation is that new technology has made existing regulation obsolete and inapplicable. But technology in the eleven instruments covered by MID (ten under the Common Position) changes, according to the experts the rapporteur has consulted, within a period of *five* years. Your rapporteur, therefore, wonders whether or not the proposal has foreseen this rate of technological advance.

[1] According to the Commission document (COM (2000) 566), "The legislation on measuring instruments consists of a framework Directive 71/316/EEC plus 23 specific Directives (16 base Directives plus 7 amending Directives). Of these, 17 Directives (11 base Directives plus 6 amending Directives) will be repealed and replaced by the proposed Directive" (pg. 7).

There is another important question to raise: If in the EU, we have some measuring instruments that are *not* subject to legal metrological control in some Member States, will they be able to be traded in the others which do regulate? Who is to monitor whether fair trading practices are ensured if instruments regulated to comply with the provisions of this proposal compete with instruments that are not regulated and there is an open market for the latter without any metrological control?

This brings us back to the substance of the MID proposal, and to this effect, your rapporteur has tabled amendments to remedy the situation which essentially deal with the **optional nature** of the MID proposal. It allows regulated and unregulated measuring instruments to co exist and even be traded in the same market. This was a feature of the Old Approach to harmonisation and remains a feature of the MID proposal.

Irrespective of the claims made by the Commission, the Common Position of the Council should be considered in the context of the stated objectives and the Amendments of the EP of the first reading.

Objective of the MID legislative proposal

There is not a single article in the Common Position on the aims of this legislation. The Council may feel that it has fulfilled its duty in the the Common Position by accepting EP amendment No. 1 to recital (2) of the EP first reading, which states the reasons of public interest[1]. However, the Common Position has failed to be consistent with the consequences of regulating a public good, like a measuring instrument, by not stating this aim in an appropriate article.

Optionality

The first consequence of the Council's omission is the retention of the *optional nature* of the MID proposal. In the language of this proposal, it is called **optionality.** What does optionality, in essence, mean to the MID? The legal aspect of optionality implies that Member States themselves would decide which instruments to regulate. This in turn would result in a **two-tier** system comprising:

a) an open system regulated by the requirements of the MID; and
b) an open system with no regulation.

According to a written submission by an official body, "In the unregulated areas, where the market is without metrological regulation, manufacturers of all shades (from the bona fide to the less scrupulous) will be able to market their instruments without any regulatory intervention".

EP amendments (Nos. 2, 8, 9, and 21) from first reading attached conditions to the two-tier

[1] It is not clear in the Common Position, for example, whether consumer protection or public protection is the main objective. Yet both are meant as objectives of the MID *by implication,* because water meters (MI-001), gas meters (MI-002), electricity meters (MI-003) and petrol pumps (MI-005) are instruments which are covered by the field of *consumer protection.* Similarly, measuring instruments such as evidential breath analysers (MI-010) and exhaust gas analysers (MI-011) are typical examples of public protection.

system: a) optionality should not act as a barrier to completing the internal market; b) optionality is not a de facto system but only an exemption to the rules of the single market; c) there should be a transitional period of five years after the entry into force of the MID for the phase out of optionality.

The Common Position of the Council has confused the issue of optionality by the following means: i) it accepts EP Am 2 in part as a new recital 5 but the wording has been modified and has distorted the essence of Am 2; ii) it adds a new paragraph 2 on notifications to Article 9 without attaching any conditions to optionality; iii) it adds a revision clause in Article 23, which is partly a response to EP Am 21, but with a transitional period of 7 years.

Your rapporteur's draft recommendation remedies this anomalous situation in a number of respects, by proposing suitably modified amendments, which were accepted by the Industry committee in its final vote. The justifications supporting the said amendments are detailed and merit the close attention of Members of the EP[1].

Harmonised Standards or Normative Documents

In addition to the one created by optionality, we have a second incidence of a **two-tier system** associated with the *presumption of conformity by the manufacturer with the essential requirements.*

Under the MID proposal, presumption of conformity by the manufacturer with the essential requirements may be based on:

a) Either compliance with the national standards conceived to implement *EU harmonised standards* (i.e. through the national transposition of the MID, see Article 10 paragraph 1 and 2 of the Common Position);
b) Or compliance by the manufacturers with the *Normative Documents* produced by the Organisation Internationale de Métrologie Légale (OIML - an inter-governmental international body).

The conditions under which the *two methods* lead to presumption of conformity need EP scrutiny. And your rapporteur has introduced a hierarchy of conditions to determine when the normative documents can be deemed an option for the presumption of conformity, for example, in situations where EU standards do not exist. However, in the final vote by the Industry committee, this hierarchy was deleted.

Advisory or Regulatory Committee?

A third instance of a **two-tier** system is introduced in the Common Position by its treatment of **Comitology.**

[1] It is of interest to note a claim made by official bodies in a written submission to the rapporteur : "manufacturers who make instruments for the regulated market and also wish to sell into the unregulated market may have to manufacture separate lower cost versions of their products in order to compete on an equal basis".

It should be recalled that in its first reading, the EP proposed Amendment N° 17 limiting the role of the Advisory Committee. EP Am. 17 deleted ex-Article 12, paragraph 1, point (a) of the initial proposal because it wanted to retain the EP's power to share responsibility for any amendments to instrument specific annexes. The first reading deleted three types of cases: 'maximum permissible errors'; 'critical change values'; and 'list of conformity assessment procedures'. The EP did accept the **Advisory procedure** in principle.

However, both the Commission and Council rejected the amendment, and they agreed to introduce a two-tier system in power sharing.

The Common Position, with the support of the Commission as stated in its amended proposal, has introduced both an **advisory procedure** for the Commission and a **regulatory procedure** for the Council. This is a political inter-institutional issue, not a technical matter.

Your rapporteur has introduced appropriate amendments, which the Industry committee accepted. They seek to remedy, in part, the situation by insisting on a wider representation of the Measuring Instruments Committee, and by limiting the role of the **Regulatory committee**.

Other Issues of Interest

Notified Bodies

Two EP amendments from the first reading (Am 16 and 28) were conceived in the logic and spirit of the then discussion on the Food Safety Authority and its relevant Regulation. Consequently, these amendments shifted the criteria for the designation of national bodies from ex-Annex III (now Annex II) to the body of the text of the proposal.

Both the Commission and Council rejected the two amendments, thus retaining the criteria in Annex II of the Common Position. Their justification for doing so is woolly-minded.

Your rapporteur insists on the said amendments by arguing that this is an institutional matter, very important and equivalent to the role assigned to the Food Safety Authority. The MID, with its two-tier system, would work only if the criteria for designated national bodies were carefully worked out. And this is not a technical matter, but solely an **institutional** one.

Technical Documentation

Another contentious issue has been the choice of the Common Position to retain the **Technical Documentation** as an Annex to the proposal. In the first reading, EP amendment 14 shifted Annex IV (now Annex III) on technical documentation to the main legislative text as Article 7a (new). Both the Commission in its amended proposal and the Council in its Common Position rejected the EP relevant amendments (Nos. 14 and 29), thus preferring the initial proposal. Hence Annex III of the Common Position is now seriously modified but is left as an annex. Your rapporteur is of the view that, as in the field of Food Safety regulations, technical documentation belongs to the main body of the text, not in an annex.

Your rapporteur's choice is guided by three concerns. First, it is not clear under which procedure (regulatory or advisory) the new Annex III would be amended, if there were a need for change. The new Articles on comitology (N 12 and 13) are not precise, they rather confuse the issue. Second, technical documentation for measuring instruments is important because without it - or if mis-used - it may prejudice the procedure for conformity assessment. Third, the documentation helps notified bodies ensure proper monitoring and surveillance.

Annex MI-10 on Evidential Breath Analysers

Annex MI-10 has been deleted by the Common Position on the following grounds. First, the results of any test using this MI are used in several Member States' courts as legal evidence. Hence national authorities seem eager to keep control of the test performance. Such control, however, rules out conformity assessment by notified bodies as laid down in Annex II (ex-Annex III). Second, if national courts dispute the results produced by 'an' instrument, national authorities need to react speedily to adapt specifications in conformity to national courts' ruling.

The rapporteur considers these justifications acceptable on the proviso that when revision of the MID is due (see new Article 23), the re-inclusion of MI-10 will be re-considered.

Essential requirements (Annexes I and II)

Annex I on essential requirements and former Annex II on test programmes have been merged by the Council in its Common Position. The fusion was not the result of EP first reading, but the consequence of your rapporteur's numerous contacts with the Commission and Council Presidencies. Whereas essential requirements of this proposal have been the core discussion under the "New Approach" in the Council, the test programmes as foreseen by the New Approach have not been conducted according to harmonised criteria. Furthermore, test programmes of existing legislation on measuring instruments have been non-mandatory and usually treated by means of national standards. However, the revised Annex I has taken over a number of elements from the test programmes and therefore needs careful consideration by the EP.

Modules Annexes (A to H1)

The conformity assessment procedures range from module A to H1 and are described in detail in Council Decision 93/465/EEC (OJ L220, 30.08.93). The annex of this decision has been reproduced, with some modifications, in its entirety in annexes A to H1 of the MID proposal. Some 30 pages in the initial proposal are a pure case of repetition of technical detail.

Interestingly, Council Decision 93/465/EEC has the **same legal status** as Council Decision 1999/468/EEC of 28.06.99 on Comitology. Yet the latter is not repeated in the MID.

In essence, the conformity assessment procedures use different modules, such as, for example, module B for the design phase of a product but module A or G or H for both the design and production phases, in order to lead the manufacturer to conform to the essential requirements,

demonstrate product conformity and thus obtain the CE marking.

According to the *Blue Guide to the implementation of Directives based on the new approach and the global approach, "*the modules give the legislator, in relation to the type of products and hazards involved, the means to set up the appropriate procedures for manufacturers to demonstrate product conformity against the provisions of the directive" (pg. 31)[1].

Hence, given the fact that there is a Council Decision on the subject and that the national authorities have in the main transposed this Decision into national legislation, your rapporteur is puzzled by the desire of the Commission and Council to include unnecessary annexes. They neither conform to the New Approach, nor increase the clarity and simplification principles of Community legislation.
For these reasons, your rapporteur has introduced important amendments, which seek to re-establish simplification, clarity and conciseness into the MID proposal. The three amendments on conformity assessment procedures are compromise amendments, which were adopted by the Industry committee.

[1] See European Commission document, published by the Office for European publications of the EC, Luxembourg 2000.