

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 10 February 1989

Proposal for a
COUNCIL DIRECTIVE

on the harmonization of the laws of the Member States
relating to non-automatic weighing instruments

(presented by the Commission)

EXPLANATORY MEMORANDUM

concerning the proposal for a Council directive
on the approximation of the laws of the Member States
relating to non-automatic weighing instruments

I. GENERAL

1. Introduction

The proposed directive is a harmonization directive, drawn up according to the principles of the new approach to technical harmonization as presented by the Council in its Resolution of 7 May 1985. It is recalled that the principles of this new approach are

- the elaboration by the directive of essential requirements that the product(s) covered shall meet
- the mandating of the European standardizing bodies to prepare harmonized standards that meet the essential requirements of the directive
- the presumption of conformity that these standards give regarding the essential requirements of the directive
- the voluntary character of the harmonized standards.

Furthermore new approach directives on technical harmonization are as a general rule of total character. The need for the total character follows on the one hand from the fact that the product requirements specified are regarded as essential and must therefore be met by all products on the

market, and on the other hand from the Commission's objective to use technical harmonization as a means for establishing a global level of safety or consumer/user protection that should exist throughout the Community and free circulation.

The directive applies to all non-automatic weighing instruments that are used in application fields that are traditionally subject to legal control by the Member States.

2. Justification

1. Member States base their rules in the domain of legal metrology in general on International Recommendations, prepared for this purpose by the Organisation Internationale de Métrologie Légale (OIML), of which they are all members. The existing International Recommendation on non-automatic weighing instruments has been overtaken by the rapid technological developments, mainly in the field of electronics. Consequently, OIML has been preparing a new International Recommendation, including electronic weighing instruments. This document is close to being accepted.

The Commission's policy has always been to base its harmonization directives in the field of legal metrology too on OIML International Recommendation, whenever possible. This is true for the one existing directive on non-automatic weighing instruments (73/360/EEC) which provides for optional harmonization. This directive does not cover electronic instruments and modification to deal with the progress in technology has become necessary.

2. A directive according to the new approach requires that the products that are covered by it form a homogeneous category of products, as it is otherwise not possible to establish essential requirements that are sufficiently precise to enable conformity assessment, to serve as the basis for the elaboration of harmonized standards and to form a basis for legal action, if necessary, all of which are demanded by the Resolution.
 3. In line with the preceding the proposed directive is drawn up according to the new approach, is of total character and covers all non-automatic weighing instruments, including in particular electronic instruments.
3. Relation with the Resolution on the new approach to technical harmonization and horizontal documents

The proposed directive applies the principles of the Resolution strictly and follows the structure that is presented in annex II of the Resolution.

Since the publication of the Resolution the Commission is developing a policy on conformity assessment to complement and clarify the Resolution in that respect. A horizontal document has been elaborated that is currently being discussed with the Member States.

The document contains an annex with modules for the conformity assessment procedures that are foreseen for technical harmonization directives. The present proposal for a directive uses the relevant modules in its annex on conformity assessment procedures (annex 2).

II. THE PROPOSAL

1. The field of application

It is a particular characteristic of legal metrology that it depends upon an instrument's application whether or not technical regulations apply. In line with this characteristic the directive makes distinction between:

a) those categories of application for which only instruments may be used that

- satisfy the essential requirements specified by the directive and

- have been subject to EC conformity assessment.

These instruments shall carry the CE mark of conformity.

b) all categories of application other than those under a). Instruments to be used for any of these other applications shall be manufactured in accordance with sound engineering practice and shall not carry the CE mark of conformity.

All instruments that satisfy the provisions of the directive that apply to them, whether used for applications of category a) or category b), circulate freely.

The categories of application falling under a) are:

1. usage for an application whereby a payment is to be made the value of which depends upon the result of the weighing operation.

2. usage for law enforcement purposes and expert opinion.

3. usage in the medical practice for weighing patients for reasons of health monitoring, diagnosis and treatment.

2. Conformity assessment

2.1 General considerations

The policy on conformity assessment to complement the new approach to technical harmonization contains the following main elements:

1. Limitation of third party intervention by allowing production control by the manufacturer on the basis of an approved quality assurance system as an alternative to product control by a third party.
2. Limitation of intervention by public authorities by permitting the execution of third party tasks by notified private bodies.
3. The provision in the directives of alternative conformity assessment procedures that are considered equivalent, and the free choice by the manufacturer of the procedure to be used.
4. The introduction of one, single Community mark of conformity which indicates conformity with the essential requirements of the directive.

2.2 The proposed directive on non-automatic weighing instruments

1. Conformity assessment is required for the instruments that are used for any of the applications of category a), which are the instruments that shall satisfy the essential requirements. In line with the Commission's current

thoughts on conformity assessment as presented in paragraph 2.1 two conformity assessment procedures are foreseen:

- I) Type examination, followed by verification
- II) Type examination, followed by a declaration of production conformity of type 2.

Of these, type examination followed by verification is the traditional procedure in the domain of legal metrology. The declaration of production conformity of type 2 is an alternative to verification.

2. Type examination

Both procedures that are foreseen have the type examination in common.

The EC type examination is the procedure whereby a third party (a notified body) ascertains that a type of the instrument (i.e. an instrument that is representative of the production envisaged) meets the provisions of the directive and issues a type approval certificate.

3. Verification

Verification, in combination with type examination, constitutes the classical conformity assessment procedure in legal metrology. In the verification step a third party (a notified body) checks and attests that each individual instrument concerned is in conformity with the approved type and satisfies the requirements of the directive that apply to it. The notified body affixes the CE mark of conformity to each instrument and draws up a written certificate of conformity.

4. Declaration of production conformity, type 2

The declaration of production conformity of type 2 is provided as an alternative to the verification. Under this procedure the manufacturer is obliged to have implemented an approved (by a notified body) quality assurance system that satisfies the requirements of the European standard EN 29002 or equivalent requirements, supplemented by all necessary product-specific requirements. This type of quality assurance system enables the assessment, at the level of the individual instruments, of the conformity with the approved type.

Under this procedure the manufacturer declares that the instruments concerned are in conformity with the type as described in the type approval certificate and satisfy the requirements of the directive that apply to them. The manufacturer affixes the CE mark to each instrument and draws up a written declaration of conformity for each instrument.

**Proposal for a Council Directive
on the harmonization of the laws of the Member States
relating to non-automatic weighing instruments**

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100.a thereof,

Having regard to the proposal from the Commission¹,

In cooperation with the European Parliament²,

Having regard to the opinion of the Economic and Social Committee³,

Whereas Member States have the responsibility of protecting the public against incorrect results of weighing operations by means of non-automatic weighing instruments when used for certain categories of applications;

Whereas, in each Member State, mandatory provisions fix in particular the necessary performance requirements of non-automatic weighing instruments by specifying metrological and technical requirements, together with inspection procedures before and after taking into service; whereas these mandatory provisions do not necessarily lead to different levels of protection from one Member State to another but do, by their disparity, hinder trade within the Community;

1 OJ No C

2 OJ No C

3 OJ No C

Whereas the national provisions ensuring such protection must be harmonized in order to guarantee the free movement of non-automatic weighing instruments while ensuring a justified level of protection in the Community;

Whereas Community legislation as it stands at present provides that, notwithstanding one of the fundamental rules of the Community, namely the free movement of goods, barriers to intra-Community movement resulting from disparities in national laws on the use of products have to be accepted in so far as the provisions from those national laws are recognized as necessary to ensure that the products concerned meet essential requirements; whereas the harmonization of laws in the present case must therefore be confined to those provisions needed to ensure that non-automatic weighing instruments satisfy the essential metrological and performance requirements; whereas, because they are essential, these requirements must replace the corresponding national provisions;

Whereas this Directive should therefore contain only mandatory and essential requirements; whereas, to facilitate proof of conformity with the essential requirements, it is necessary to have harmonized standards at European level, in particular as to the metrological, design and construction characteristics, so that instruments complying with those harmonized standards may be assumed to conform to the essential requirements; whereas these standards, harmonized at European level, are drawn up by private bodies and must remain non-mandatory texts;

whereas for that purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European Standard or Harmonized Document) adopted by one or both of those bodies upon a remit from the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations⁴ and the above mentioned general guidelines;

Whereas assessment of conformity with the relevant metrological and technical requirements is necessary to provide effective protection for users and third parties; whereas the existing conformity-assessment procedures differ from one Member State to another; whereas, to avoid multiple assessments of conformity, which are in effect barriers to the free movement of the instruments, arrangements should be made for the mutual recognition of conformity-assessment procedures by the Member States; whereas, to facilitate the mutual recognition of conformity-assessment procedures, harmonized Community procedures should be set up, together with harmonized criteria for the designation of the bodies responsible for carrying out tasks pertaining to the conformity assessment procedures;

Whereas the presence on a non-automatic weighing instrument of the CE mark of conformity indicates that it satisfies the provisions of this Directive and therefore makes it unnecessary to repeat the assessments of conformity already carried out;

⁴ OJ No L 109, 26.04.1983, p. 8.

Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers within which the free movement of goods, persons, services and capital is guaranteed,

HAS ADOPTED THIS DIRECTIVE:

Chapter I - Field of application; placing on the market; free movement.

Article 1

1. A weighing instrument is defined as a self-contained instrument or a system for the determination of the mass of a body by using the action of gravity on that body. The value of the mass of the body must be indicated.

A system is a set of interconnected devices assembled to carry out a weighing task. A self-contained instrument may be part of a larger system.

A non-automatic weighing instrument is defined as a weighing instrument that requires the intervention of an operator to perform a mass determination.

A non-automatic weighing instrument may additionally indicate and/or print values of quantities, directly derived from the mass value of the body.

A non-automatic measuring instrument for the measurement of mass-related quantities or from mass-derived values is a non-automatic weighing instrument as defined above if it uses the action of gravity and if, and only in so far as, it indicates mass values.

This Directive applies to all non-automatic weighing instruments, hereafter referred to as 'instruments'.

2. For the purposes of this Directive the following categories of application apply:

(a) (1) commercial transactions;

(2) the determination of a toll, tariff, tax, bonus, penalty, indemnity or similar type of payment;

(3) law enforcement and expert opinion;

(4) health monitoring, diagnosis and treatment of illness and disorders in the medical (human and veterinary) practice.

(b) All applications other than those set out at (a).

Article 2

Member States shall take all necessary steps to ensure that instruments may be placed on the market and taken into service only if, when properly installed and used for the purposes for which they are intended, they meet the provisions of this Directive that apply to them.

Article 3

1. Instruments to be used for any of the applications referred to in Article 1(2)(a) shall satisfy the essential requirements set out in Annex 1. Where the instrument is constructed as a system, all devices of the system that are not involved in any of the applications referred to in Article 1(2)(a) are excluded from this requirement.

2. Instruments not to be used for any of the applications referred to in Article 1(2)(a) need not satisfy the essential requirements set out in Annex 1 but may do so, if the manufacturer so wishes.

If they do not satisfy the essential requirements they shall be manufactured in accordance with sound engineering practice of one of the Member States. If, however, they do satisfy the essential requirements set out in Annex 1 they may, if the manufacturer so wishes, be subject to the conformity assessment as specified in Article 8.

Article 4

Member States shall not impede the placing on the market and the taking into service of instruments that meet the provisions of this Directive.

Article 5

1. Member States shall presume conformity with the essential requirements referred to in Article 3 in respect of instruments complying with the relevant national standards implementing the harmonized standards that meet the essential requirements referred to in Article 3.
2. The Commission shall publish the references of the harmonized standards, referred to in paragraph 1, in the Official Journal of the European Communities.

Member States shall publish the references of the national standards, referred to in paragraph 1.

Article 6

Where a Member State or the Commission considers that the harmonized standards referred to in Article 5(1) do not fully meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, hereinafter referred to as "the Committee", giving the reasons therefor. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 5(2).

Article 7

1. Where a Member State considers that instruments bearing the CE mark of conformity referred to in Annex 2 (2), (3) and (4), do not meet the provisions of this Directive when properly installed and used for the purposes for which they are intended, it shall take all appropriate measures to withdraw those products from the market or to prohibit or restrict their being placed on the market.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether non-compliance is due to :

- (a) failure to meet the essential requirements referred to in Article 3, where the instrument does not meet the standards referred to in Article 5(1);
- (b) incorrect application of the standards referred to in Article 5(1);
- (c) shortcomings in the standards referred to in Article 5(1) themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible.

The Commission shall immediately inform the Member State concerned of the result of such consultation. If the Commission finds that the measure is justified it shall immediately inform the other Member States.

If the measure was taken by the Member State on the grounds of assumed shortcomings in the standards the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State concerned intends to maintain the measures, and shall initiate the procedures referred to in Article 6.

3. Where an instrument which does not comply bears the CE mark of conformity, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.
4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Chapter II - Conformity assessment

Article 8

1. For the purposes of this Directive a distinction is made between manufacture of standard instruments and manufacture of non-standard instruments, manufacture of non-standard instruments being unit or limited series manufacture involving typically, but not necessarily, custom-designed instruments, special-purpose instruments, and the like.

Manufacture of standard instruments

2. Instruments to be used for any of the applications referred to in Article 1(2)(a) shall be subject to the EC type examination referred to in Annex 2(1).
3. Instruments not to be used for any of the applications referred to in Article 1(2)(a) that satisfy the essential requirements set out in Annex 1 may, at the choice of the manufacturer, be subject to the EC type examination referred to in Annex 2(1).
4. In either of the cases referred to in paragraphs 2 and 3, instruments not using any electronic device and of which the load measuring device does not use any spring to balance the load need not be subject to said EC type examination but may, at the choice of the manufacturer, be subject to it.
5. Instruments as referred to in paragraph 2, including those that have been exempt from the EC type examination on the grounds of the provisions of paragraph 4, shall prior to their being taken into service be subject, at the choice of the manufacturer:
 - either to the EC declaration of production conformity (type 2) referred to in Annex 2(2),
 - or to the EC verification (type 1) referred to in Annex 2(3).
6. Instruments as referred to in paragraph 3 that have been subject to the EC type examination or that have been exempted from it on the grounds of the provisions of paragraph 4 may, at the choice of the manufacturer, be subject, prior to their being taken into service, to any of the two procedures referred to in paragraph 5.

Manufacture of non-standard instruments

7. Instruments to be used for any of the applications referred to in Article 1(2)(a) shall each be subject to the EC verification (type 2), referred to in Annex 2(4).
8. Instruments not to be used for any of the applications referred to in Article 1(2)(a) that satisfy the essential requirements set out in Annex 1 may, at the choice of the manufacturer, be subject to the EC verification (type 2), referred to in Annex 2(4).

Common provisions

9. The records and correspondence relating to the procedures referred to in paragraphs 2 to 8 shall be drafted in an official language of the Member State where said procedures will be carried out, or in a language accepted by the responsible body.

Article 9

1. Member States shall notify to the other Member States and the Commission the bodies which they have designated for carrying out tasks pertaining to the procedures referred to in Article 8, the specific tasks for which each body has been designated and the identification codes of the designated bodies.

The Commission shall publish the list of those notified bodies, together with the tasks for which they have been designated, in the Official Journal of the European Communities and shall ensure that the list is kept up to date.

2. Member States shall apply the minimum criteria, set out in Annex 5, for the designation of bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards are presumed to satisfy the criteria set out in Annex 5.

3. A Member State that has designated a body shall withdraw the designation if the body no longer meets the criteria for designation referred to in paragraph 2. It shall immediately inform the other Member States and the Commission accordingly.

Chapter III - CE mark of conformity and inscriptions

Article 10

1. The CE mark of conformity and the required supplementary data, as described in Annex 4, shall be affixed to the instruments concerned in a clearly visible, easily legible and indelible form.
2. The affixing to instruments of marks which are likely to be confused with the CE mark of conformity shall be prohibited.

Article 11

Where it is established that the CE mark of conformity has been wrongly affixed to instruments because:

- they do not conform to the relevant standards referred to in Article 5(1);
- they do not conform to an approved type;
- they conform to an approved type which does not meet the essential requirements applicable to it, or
- the manufacturer has failed to fulfil his obligations under the EC declaration of conformity (type 2),

the EC type approval certificate and/or the approval of the quality system, as the case may be, shall be withdrawn by the competent notified body.

Article 12

Where an instrument that is to be used for any of the applications referred to in Article 1(2)(a) is constructed as a system and where that system contains devices that have not been subject to conformity assessment as referred to in Article 8, each of those devices shall carry the inscription "not permitted for trade purposes" in the official languages of the Member State where the instrument is taken into service. That inscription shall be affixed to the devices in a clearly visible, easily legible and indelible form.

Chapter IV - Control of instruments in service

Article 13

1. Instruments that carry the CE mark of conformity and are used for any of the applications referred to in Article 1(2)(a) shall be subject to in-service inspection by a notified body to ensure that they are still in conformity with the type as described in the type approval certificate (if applicable) and satisfy the requirements of this Directive that apply to them.
2. They shall be re-verified:
 - (a) after repair, modification, or re-assembly;
 - (b) after relocation in a geographical area with a gravity value that is sufficiently different to justify the re-verification, in particular of the error of indication.

3. When carrying out these inspections the notified body shall carry out the appropriate tests as set out in the relevant standards referred to in Article 5, or equivalent tests. In the cases referred to in paragraph 2 it shall apply the maximum permissible error limits as specified in Annex 1(4)(1). In all other cases it shall apply the maximum permissible error limits as specified in Annex 1(4)(2).

Chapter V - Transition period

Article 14

1. EEC type approvals pursuant to Council Directive 73/360/EEC⁵ and national type approvals, that are valid on 1 July 1992, shall remain valid until the date of their expiration or until 1 July 2002, whichever date is the earlier. After that date they shall nevertheless remain in force for the instruments referred to in paragraph 2.
2. Member States shall allow the further use, as from 1 July 1992, of instruments that are legally in service at that date and for as long as they satisfy the requirements that are applicable to them on the basis of their type approval or their initial verification.

⁵ OJ No L 335, 5.12.1973, p.1.

Chapter VI - Final provisions

Article 15

Any decision taken pursuant to this Directive and resulting in restrictions on the taking into service of an instrument shall state the exact grounds on which it is based. Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the judicial remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.

Article 16

1. Before 1 January 1992 Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply such provisions from 1 July 1992.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.
3. Directive 73/360/EEC shall be repealed as from 1 July 1992.

Article 17

This Directive is addressed to the Member States.

Done at.....

For the Council
The President

The essential requirements that must be met by the instruments, referred to in article 1.2(a), are set out below. The terminology used is of the Organization Internationale de Métrologie Légale.

METROLOGICAL REQUIREMENTS

1. Units of mass

The units of mass used shall be legal in the sense of directive 80/181/EEC¹.

Subject to this condition, the following units are permitted:

- of the SI units: kilogramme, microgramme, milligramme, gramme, tonne
- of the Imperial units: pound, ounce (avoirdupois), troy ounce
- of the other units: metric carat, if weighing precious stones

For instruments that make use of the Imperial units of mass referred to above, the relevant essential requirements specified hereafter shall be converted to said Imperial units, using simple interpolation.

1 OJ n° L 39 of 15.02.1980, p. 39.

2. Accuracy classes

2.1. The following accuracy classes have been defined:

- I special
- II high
- III medium
- IIII ordinary

The specifications of these classes are given in table 1.

TABLE 1 : Accuracy classes

Class	Verification scale Interval (e)	Minimum capacity (Min)	Maximum capacity (Max)	
		minimum value	minimum value	maximum value
I	$0.001 \text{ g} \leq e$	100 e	50 000 e	-
II	$0.001 \text{ g} \leq e \leq 0.05 \text{ g}$	20 e	100 e	100 000 e
	$0.1 \text{ g} \leq e$	50 e	5 000 e	100 000 e
III	$0.1 \text{ g} \leq e \leq 2 \text{ g}$	20 e	100 e	10 000 e
	$5 \text{ g} \leq e$	20 e	500 e	10 000 e
IIII	$5 \text{ g} \leq e$	10 e	100 e	1 000 e

2.2. Scale Intervals

1. The actual scale interval (d) and the verification scale interval (e) shall be in the form

1×10^k , 2×10^k , or 5×10^k mass units,

k being any integer or zero.

2. For all instruments other than those with auxiliary indicating devices, d is equal to e.
3. For instruments with auxiliary indicating devices the following conditions apply:

$$e = 1 \times 10^k \text{ g}$$

$$d < e \leq 10 d$$

except for instruments of class I with $d < 10^{-4}$ g, for which $e = 10^{-3}$ g.

3. Classification

3.1. Instruments with one weighing range

3.1.1. Instruments without an auxiliary indicating device may belong to any of the four accuracy classes defined.

3.1.2. Instruments equipped with an auxiliary indicating device shall belong to class I or class II. For these instruments the minimum capacity lower limits for these two classes are obtained from table I by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If $d < 10^{-4}$ g, the maximum capacity of class I may be less than 50 000 e.

3.1.3. In case an instrument meets the specifications of more than one accuracy class, the choice of class is left to the manufacturer. The instrument shall meet all requirements of this directive for the class chosen.

3.2. Instruments with multiple weighing ranges

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to 3.1. If the weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

3.3. Multi-Interval Instruments

3.3.1. Instruments with one weighing range may have several partial weighing ranges (multi-interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range l of multi-interval instruments is defined by

- its verification scale interval e_l , with $e_{l+1} > e_l$
- its maximum capacity Max_l , with $Max_r = Max$
- its minimum capacity Min_l , with $Min_l = Max_{l-1}$
and $Min_1 = Min$

where $l = 1, 2, \dots, r$

l = partial weighing range number

r = the total number of partial weighing ranges.

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3 The partial weighing ranges are classified according to table 2. All partial weighing ranges shall fall into the same accuracy class, this class being the instrument's accuracy class.

TABLE 2 : Multi-Interval Instruments

$i = 1, 2, \dots, r$

i = partial weighing range number

r = total number of partial weighing ranges

Class	Verification scale Interval (e)	Minimum capacity	Maximum capacity (Max _i)	
		(Min)		
		minimum value	minimum* value	maximum value
I	$0.001 \text{ g} \leq e_i$	$100 e_i$	$50\,000 e_{i+1}$	-
II	$0.001 \text{ g} \leq e_i \leq 0.05 \text{ g}$	$20 e_i$	$5\,000 e_{i+1}$	$100\,000 e_i$
	$0.1 \text{ g} \leq e_i$	$50 e_i$	$5\,000 e_{i+1}$	$100\,000 e_i$
III	$0.1 \text{ g} \leq e_i$	$20 e_i$	$500 e_{i+1}$	$10\,000 e_i$
IIII	$5 \text{ g} \leq e_i$	$10 e_i$	$50 e_{i+1}$	$1\,000 e_i$

* for $i=r$ the corresponding column of table 1 applies, with e replaced by e_r

4. Accuracy

4.1 On EC Initial conformity assessment the error of indication shall not exceed the maximum permissible error of indication as shown in table 3. In case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net and tare value for all possible loads, excluded preset tare values.

TABLE 3 : Maximum permissible errors

Load				Maximum permissible error on EC initial conformity assessment
Class I	Class II	Class III	Class IIII	
$0 \leq m \leq 50\,000 \text{ e}$	$0 \leq m \leq 5\,000 \text{ e}$	$0 \leq m \leq 500 \text{ e}$	$0 \leq m \leq 50 \text{ e}$	$\pm 0.5 \text{ e}$
$50\,000 \text{ e} < m \leq 200\,000 \text{ e}$	$5\,000 \text{ e} < m \leq 20\,000 \text{ e}$	$500 \text{ e} < m \leq 2\,000 \text{ e}$	$50 \text{ e} < m \leq 200 \text{ e}$	$\pm 1.0 \text{ e}$
$200\,000 \text{ e} < m$	$20\,000 \text{ e} < m \leq 100\,000 \text{ e}$	$2\,000 \text{ e} < m \leq 10\,000 \text{ e}$	$200 \text{ e} < m \leq 1\,000 \text{ e}$	$\pm 1.5 \text{ e}$

4.2 The maximum permissible errors in service are twice the maximum permissible errors on EC initial conformity assessment.

5. Weighing results of an instrument shall be repeatable, and shall be reproducible among indicating devices used and methods of balancing used.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

6. The instrument shall react to small variations of the load.

7. Influence quantities and time

7.1 Instruments of classes II, III and IIII, liable to be used in tilted position, shall be sufficiently insensitive to the degree of tilting that can exist in normal installed condition.

7.2 The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to:

- 5 °C for an instrument of class I,
- 15 °C for an instrument of class II,
- 30 °C for an instrument of class III or IIII.

In the absence of a manufacturer's specification, the temperature range of -10°C to +40°C applies.

7.3 Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

7.4 Electronic instruments, except those of class I and of class II if e is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.

7.5 Loading an instrument of class II, III or IIII for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.

7.6 Under other conditions the instruments shall either continue to function correctly or be automatically put out of service.

DESIGN AND CONSTRUCTION

8. General requirements

8.1 Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed, and when used in an environment for which they are intended.

8.2 When exposed to disturbances electronic instruments shall not display significant faults, or shall automatically detect and act upon significant faults.

Upon automatic detection of a significant fault electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

8.3 The requirements of 8.1 and 8.2 shall be met on a lasting basis. Electronic instruments shall therefore not display significant durability errors during a period of time that is normal in view of the intended use of the instruments, or shall automatically detect and act upon significant durability errors.

Digital electronic devices shall always exercise adequate control of the operation of the measuring process, of the indicating facility, and of all data storage and data transfer.

Upon automatic detection of a significant durability error electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

8.4 When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

8.5 The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.

8.6 Instruments shall be designed to permit ready execution of the statutory controls foreseen by this directive.

9. Indication of weighing results and other weight values

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in point 1 of this annex shall be according to the dispositions of directive 80/181/EEC¹, with the addition of the symbol for the metric carat which shall be the symbol 'ct'.

Indication shall be impossible above the maximum capacity (Max), increased by 9 e.

1 OJ n° L 39 of 15.02.1980, p. 39.

An auxiliary indicating device is permitted only behind the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, if identified such that they can not be mistaken for primary indications.

10. Printing of weighing results and other weight values

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

11. Levelling

When appropriate instruments shall be fitted with a levelling device and a level indicator, sufficiently sensitive to allow proper installation.

12. Zeroing

The instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

13. Tare devices and preset tare devices

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurately setting the indication to zero and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

14. Instruments for direct selling to the public with a maximum capacity not greater than 100 kg: additional requirements

Instruments for direct selling to the public shall show all essential information about the weighing operation and, in the case of price indicating instruments, of the price calculation of the product to be purchased, clearly to the customer.

The price to pay, if indicated, shall be accurate.

Price computing instruments shall show the essential indications for long enough to enable the customer to read them properly.

Price computing instruments may perform functions other than per article weighing and price computation only if all indications related to all transactions shall be printed clearly, unambiguously and conveniently arranged on a ticket or label for the customer.

The instruments shall bear no characteristics that can cause, directly or indirectly, indications whose interpretation is not easy or straightforward.

The instruments shall safeguard the customers against incorrect sales transactions due to malfunctioning of the instruments.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are only permitted if and such that they do not enable fraudulent use by the vendor, unbeknown to the customer.

Instruments with the characteristics of those used for direct selling to the public, which however do not meet the requirements described in this paragraph shall carry the indelible marking 'Not to be used for direct selling to the public'. This marking shall be clearly visible on the side of the instrument normally facing the customer if it were to be used for direct selling to the public.

15. Price labelling instruments

Price labelling instruments shall meet the requirements of price indicating instruments for direct selling to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below minimum capacity.

1. EC type examination

Annex 2

- 1.1. The EC type examination is the procedure by means of which a notified body ascertains and certifies that an instrument, representative of the production envisaged, meets the provisions of this directive that apply to it.
- 1.2. The application for the type examination shall be lodged by the manufacturer or his authorized representative established within the Community with a single notified body.

The application shall include

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition
- a written declaration that the application has not been lodged with any other notified body
- the design documentation, as described in annex 3.

The applicant shall place at the disposal of the notified body an instrument, representative of the production envisaged and hereafter called 'type'.

1.3. The notified body shall

1. examine the design documentation, verify that the type has been manufactured in conformity with this design documentation, and identify the elements that have been designed in accordance with the relevant provisions of the standards and essential requirements referred to in this directive

2. perform or have performed the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the standards referred to in article 5 have not been applied
3. perform or have performed the appropriate examinations and/or tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have been applied effectively, thereby assuring conformity with the essential requirements
4. agree with the applicant the location where the examinations and/or tests shall be carried out.

1.4. Where the type meets the provisions of this directive the notified body shall issue an EC type approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, the necessary data for identification of the approved instrument and, if relevant, a description of its functioning. The relevant technical elements such as drawings and schemes shall be annexed to the certificate.

The certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

1.5. The other notified bodies shall be informed forthwith of the issuing of the EC type approval certificate for the said type and its additions referred to in paragraph 1.7. They may obtain a copy of the EC type approval certificate and, on a reasoned request, may obtain a copy of the annexes to the certificate and the reports on the examinations and tests carried out.

- 1.6. A notified body that refuses to issue or withdraws an EC type approval certificate or any of its additions referred to in paragraph 1.7 shall so inform the Member State which notified this body and the other notified bodies, giving the reasons for the decision.
- 1.7. The applicant shall keep the notified body that has issued the EC type approval certificate informed of any modification to the approved type.

Modifications to the approved type must receive additional approval from the notified body that issued the EC type approval certificate where such changes influence the conformity with the essential requirements of this directive or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original EC type approval certificate.

2. EC declaration of production conformity (type 2)

- 2.1. The EC declaration of production conformity (type 2) is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2.2 declares that the instruments concerned are in conformity with the type as described in the EC type approval certificate and satisfy the requirements of this directive that apply to them.

The manufacturer shall affix the CE mark to each instrument and shall draw up a written declaration of conformity for each instrument.

The CE mark shall be accompanied by the identification symbol of the notified body responsible for the EC surveillance referred to in paragraph 2.2. The certificate of conformity shall accompany the instrument covered.

- 2.2. The manufacturer shall have adequately implemented a quality system as specified in paragraph 2.3 and shall be subject to EC surveillance as specified in paragraph 2.4.

2.3. Quality system

1. The manufacturer shall lodge an application for approval of his quality system with a notified body.

The application shall include:

- all relevant information, in particular the quality system's documentation and the design documentation of the approved type
 - an undertaking to carry out the obligations arising from the quality system as approved
 - an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.
2. The quality system shall ensure compliance of the instruments with the type as described in the EC type approval certificate and with the requirement(s) of this directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality programmes, plans, manuals, and records.

It shall contain in particular an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality

- the manufacturing process, and the quality control and quality assurance techniques and systematic actions that will be used
- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 2.3.2. It shall presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.

It shall notify its decision to the manufacturer and inform the other notified bodies thereof.

The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any updating of the quality system in relation to changes brought about by, e.g., new technologies and quality concepts.

5. A notified body that withdraws approval of a quality system shall so inform the other notified bodies, giving the reasons for the decision.

2.4. EC surveillance

1. The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular
 - the quality system documentation
 - the design documentation
 - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
3. The notified body shall make sure that the manufacturer maintains and applies the quality system and shall provide a surveillance report to the manufacturer.

3. EC verification (type 1)

1. The EC verification (type 1) is the procedure whereby a notified body checks and attests that instruments concerned are in conformity with the type as described in the EC type approval certificate and satisfy the requirements of this directive that apply to them. The notified body shall affix the CE mark to each instrument and draw up a written certificate of conformity for each instrument. The certificate of conformity shall accompany the instrument covered.
2. Each instrument shall be examined and appropriate tests as set out in the relevant standards referred to in article 5, or equivalent tests, shall be carried out to ensure their conformity with the relevant requirements of this directive.

3. The CE mark referred to in paragraph 1 above shall be accompanied by the identification symbol of the notified body.

4. EC verification (type 2)

1. The EC verification (type 2) is the procedure whereby a notified body checks and attests that the instruments concerned satisfy the requirements of this directive that apply to them. The notified body shall affix the CE mark to each instrument and shall draw up a written certificate of conformity for each instrument.

The certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each. It shall accompany the instrument covered.

2. Each instrument shall be examined and appropriate tests as set out in the relevant standards referred to in article 5, or equivalent tests, shall be carried out to ensure their compliance with the relevant requirements of this directive.

3. The CE mark referred to in paragraph 1 above shall be accompanied by the identification symbol of the notified body.

4. The design documentation of the instrument as specified in annex 3 shall be made available to the notified body.

5. Common provisions

1. The EC declaration of production conformity (type 2), the EC verification (type 1), and the EC verification (type 2) may be carried out at the manufacturer's works or any other location if the transport to the place of use does not require dismantling of the instrument, if the taking into

service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the instrument's performance is insensitive to gravity variations. In all other cases they shall be carried out at the place of use of the instrument.

2. If the instrument's performance is sensitive to gravity variations the procedures referred to in paragraph 5.1 may be carried out in two stages, where the second stage shall comprise all examinations and tests of which the outcome is gravity dependant, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. In case a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.
- 3.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in paragraph 5.1, and where these two stages will be carried out by different parties, an instrument that has undergone the first stage of the procedure concerned shall carry the identification symbol of the notified body involved in that stage.
2. The party that has carried out the first stage of the procedure shall issue for each of the instruments a certificate, containing the necessary data for identification of the instrument and specifying the examinations and tests that have been carried out.

The party that carries out stage two of the procedure shall carry out those examinations and tests that have not yet been carried out.
3. The manufacturer who has opted for the EC declaration of production conformity (type 2) in stage one may either use this same procedure in stage two or decide to continue in stage two with the EC verification (type 1).
4. The CE mark shall be affixed to the instrument after completion of stage two, together with the identification symbol of the notified body involved in stage two.

Design documentation

The design documentation shall contain in so far as relevant for assessment:

- a general description of the type
- conceptual designs and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of the above, including the operation of the product
- a list of the standards referred to in article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in article 5 have not been applied
- results of design calculations made and of examinations etc
- test reports

1. Instruments to be used for the applications referred to in article 1.2(a), and instruments to be used for the applications referred to in article 1.2(b) that have been subjected to the relevant EC conformity assessment procedure, shall carry

- a) - the CE mark of conformity as described in paragraph 3
- the identification symbol(s) of the notified body(ies) that has/have carried out the EC surveillance or the EC verification

The above mentioned mark and inscriptions shall be affixed to the instrument, distinctly grouped together.

b) the following inscriptions:

- manufacturer's mark or name
- the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles
- maximum capacity in the form Max ...
- minimum capacity in the form Min ...
- verification scale interval in the form e = ...

plus, when applicable

- serial number
- for instruments consisting of separate but associated units: identification mark on each unit
- scale interval in the form d = ...
- maximum additive tare effect " " " T = + ...
- maximum subtractive tare effect " " " T = - ...
- tare interval " " " d_T = ...
- maximum safe load " " " Lim ...
- the special temperature limits " " " ...°C / ...°C

2. Instruments to be used for the applications referred to in article 1.2(b) that have not been subjected to the relevant EC conformity assessment procedure shall carry
 - the manufacturer's mark or name
 - the maximum capacity in the form Max ...
3. The CE mark of conformity shall consist of the symbol CE as shown in annex 6, followed by the last two digits of the year in which it was affixed.
4. The instruments shall have adequate facilities for the affixing of the CE mark of conformity and/or inscriptions. These shall be such that it shall be impossible to remove the mark and inscriptions without damaging them, and that the mark and inscriptions shall be visible when the instrument is in its regular operating position.
5. Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.
6. The inscriptions Max, Min, e, d, shall also be shown near the display of the result if they are not already located there.
7. Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to said load receptors.

Set out below are the minimum criteria to be applied by Member States when designating bodies for the carrying out of tasks pertaining to the procedures referred to in article 8.

1. The bodies shall dispose of the necessary personnel, means and equipment.
2. The personnel shall have technical competence and professional integrity.
3. The staff and personnel shall be independent of all circles, groups or persons having direct or indirect interest in non-automatic weighing instruments regarding the carrying out of the tests, the preparation of the reports, the issuing of the certificates and the surveillance requested by this directive.
4. The personnel shall respect the professional secret.
5. The bodies shall have taken out a civil liability insurance if their civil liability is not covered by the State under national law.

The fulfilment of the conditions under 1. and 2. shall be periodically verified by the Member States.

CE

FINANCIAL NOTE

concerning the proposal for a Council directive on the approximation of the laws of the Member States relating to non-automatic weighing instruments

Introduction

The proposal for a directive relating to non-automatic weighing instruments lays down the essential requirements that must be satisfied by the instruments in question. Article 5 of the proposal makes a general reference to European standards. Instruments manufactured in compliance with such standards are presumed to be in conformity with the essential requirements of the directive.

Given the absence of European standards in the non-automatic weighing instruments sector, the Commission must request the CEN to fill that gap.

The Commission intends to contribute to the development of European standardization by entrusting the CEN with the task of drawing up the necessary standards in the non-automatic weighing instruments sector in accordance with the general guidelines for cooperation between the Commission, the CEN and CENELEC, which were approved on 13 November 1984. The work will be carried out on the basis of standardization requests transmitted to the CEN in pursuance of the framework contracts signed on 10 October 1985, which provide for financial support by the Commission.

The standardization work described above, which will be of limited duration, must be placed against the general background of the administration of the directive, which is a long-term activity.

Financial statement

1. Budget headings

Article 775 : Community projects concerning the internal market.

1.1 Item 7750 : Harmonization of industrial laws.

1.2 Item 7752 : Multiannual measures to strengthen European standardizing bodies.

2. Legal basis

2.1 Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards¹.

2.2 Directive to be adopted by the Council on the approximation of the laws of the Member States relating to non-automatic weighing instruments.

3. Proposed classification

Non compulsory expenditure.

4. Description and justification of the project

4.1 Objectives

The aim is to assist with the drafting of European standards that will meet the basic requirements of the directive on non-automatic weighing instruments, with a view to ensuring that the directive is properly implemented. The European standards will help to make European industry more competitive.

1 O.J. n° C 136, 4.6.1985

4.2 Staff

Apart from management of the directive, the proposed activities are short-term and highly technical. The Commission does not have staff qualified to deal with the technical aspects of the project.

5. Nature of the outlay and method of calculation

5.1 Nature

The project will take the form of standardization mandates, given on the basis of the existing framework contract of 10 October 1985 between the Commission and CEN/CENELEC.

5.2 Calculation

The level of financing will be determined for each mandate taking into account the work to be carried out by contractors.

Estimate of the appropriations (cost per unit x number of units)

European standards

50 000 x 4

6. Financial implications for intervention appropriations

6.1 Table of commitments and payments:

European standards (Item 7752)

	CE (Ecu)	CP (Ecu)
1989	100 000	50 000
1990	100 000	100 000
1991		50 000
Total	200 000	200 000

6.2 Community share of the financing

The Community share of the financing will cover 100% of the required expenses.

7. Comments

Nil.

8. Financial implications for staff and administrative appropriations

8.1 Staff required exclusively for the execution of the project

This project involves management of the directive on non-automatic weighing instruments, which will call for the participation of the Commission staff over a period of several years.

As from 1989 one A grade official will be required to work on the project for three months a year and one B grade official to work half time.

8.2 & 8.3 Staff and administrative appropriations

It is estimated that appropriations of 75 000 ECU per year will be necessary.

IMPACT ON COMPETITIVENESS AND EMPLOYMENT

concerning the proposal for a Council directive
on the approximation of the laws of the Member States
relating to non-automatic weighing instruments

1. Principal Justification of the proposed directive

Non-automatic weighing instruments, like many other measuring instruments that find large-scale, non-specialist application in society (usually, but not exclusively, in commercial transactions) are subject to legal control by Member States for reasons of fair trading or for otherwise protecting the parties that are involved in a weighing operation.

The national regulations for electronic non-automatic weighing instruments differ from one Member State to another and approvals are not mutually recognized. Consequently, a manufacturer who wishes to place an instrument on the market in all of the Member States of the Community must seek approval in each Member State and, as the case may be, manufacture different versions of his product in order to cope with the differences in the national regulations.

For mechanical non-automatic weighing instruments a directive (73/360) was adopted in 1973.

The proposed directive will harmonize the national regulations for all non-automatic weighing instruments (i.e. mechanical and electronic) and hence ensure the free movement of products that are covered by it and that meet the requirements that apply to them.

2. Characteristics of the sector

The European weighing machine industry employs over 22,000 people in more than 400 firms. Of these the vast majority are small or medium sized enterprises.

The sector which was by and large mechanical in the past has come to depend more and more on electronic techniques and products. Competition is stiff. Exports have been declining over the last years, with imports increasing at an average rate of 10% per year.

3. Obligations

The present directive requires that non-automatic weighing instruments used for defined applications meet the essential requirements and are subject to conformity assessment according to procedures given by it. These applications and procedures are similar to those laid down in directive 73/360, and therefore this proposal will entail very little extra administrative or financial cost.

No obligations by the Member States, other than those following from the transposition into national law of the directive, are foreseen.

4. Competitiveness and employment

The harmonization of the national regulations is expected to lead to a reduction in cost and to an increase in efficiency. Although third country manufacturers will share the same benefits, the European manufacturers have the opportunity to increase their competitiveness from which a positive effect on employment could be expected.

As a matter of fact, in order to ensure free movement for their products manufacturers now need to submit their products to a conformity assessment procedure in one of the Member States only. This is expected to lead to a reduction of the costs, as well as of the time delay involved in obtaining approval and will hence give the manufacturer the opportunity to place his products on the market faster and cheaper.

A new, alternative conformity assessment procedure permits the manufacturer to declare the conformity of his product with the approved type himself and to affix the CE mark of conformity to the product himself.

5. Parties consulted

The European federation of weighing instrument manufacturers CECIP (Comité européen des Constructeurs d'instruments de Pesage) has been a most active participant in the meetings of the Working Group that have resulted in the current proposal and are in agreement with the essential elements of the proposal.