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(Acts whose publication is not obligatory)

COUNCIL**COUNCIL DIRECTIVE**

of 19 December 1974

on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids

(75/106/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament ⁽¹⁾;

Having regard to the Opinion of the Economic and Social Committee ⁽²⁾;

Whereas in most of the Member States the conditions of presentation for sale of liquids in prepackages are the subject of mandatory regulations which differ from one Member State to another, thereby hindering trade in such prepackages; whereas such provisions must therefore be approximated;

Whereas in order to enable consumers to be correctly informed, the method of marking on the prepackage the nominal volume of the liquid contained in the prepackage should be prescribed;

Whereas it is also necessary to specify the maximum permissible errors in the contents of prepackages and whereas a reference method for such control should be defined in order to provide a simple method of ensuring that prepackages conform with the provisions laid down;

Whereas it is necessary to reduce as far as possible the number of volumes of contents that are too close to others of the same product and which consequently are liable to mislead the consumer; whereas, however, in view of the extremely high stocks of prepackages in the Community such a reduction can only be undertaken gradually;

Whereas Council Directive No 71/316/EEC ⁽³⁾ of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control, as last amended by the Act of Accession ⁽⁴⁾, provides, in Article 16, that the harmonization of the requirements for marketing certain products, in particular as regards the prescription, measurement and marking of prepacked quantities, may be covered by separate Directives;

⁽¹⁾ OJ No C 56, 2. 6. 1972, p. 35.

⁽²⁾ OJ No C 123, 27. 11. 1972, p. 9.

⁽³⁾ OJ No L 202, 6. 9. 1971, p. 1.

⁽⁴⁾ OJ No L 73, 27. 3. 1972, p. 14.

Whereas since too quick a change in the means of determining quantity laid down by their national legislation and the organization of new systems of control as well as the adoption of a new measurement system would present difficulties for certain Member States, a transitional period should be provided for these Member States; whereas such provision should not, however, further inhibit intra-Community trade in the products concerned and should not prejudice implementation of the Directive in the other Member States,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive relates to prepackages containing the liquid products listed in Annex III measured by volume for the purpose of sale in individual quantities of between 0.05 litre and five litres inclusive.

Article 2

1. A prepackage within the meaning of this Directive is the combination of a product and the individual package in which it is prepacked.

2. A product is prepacked when it is placed in a package of whatever nature, without the purchaser being present, and the quantity of product contained in the package has a predetermined value and cannot be altered without modifying the package.

Article 3

1. The prepackages which may be marked with the EEC mark listed in subsection 3.3 of Annex I are those which comply with Annexes I and III.

2. They shall be subject to metrological control under the conditions defined in Annex I, Section 5, and in Annex II.

Article 4

1. All prepackages referred to in Article 3 must in accordance with Annex I bear an indication of the volume of liquid, called the 'nominal volume of the contents', which they are required to contain.

2. For such prepackages only the nominal volumes of the contents indicated in Annex III shall be permitted.

3. Until the expiry of the transitional period during which the use of the imperial units of measurement appearing in Annex II to Council Directive No 71/354/EEC⁽¹⁾ of 18 October 1971 on the approximation of the laws of the Member States relating to units of measurement, as last amended by the Act of Accession, is authorized in the Community, the indication of the nominal volume of the contents expressed in SI units of measurement in accordance with subsection 3.1 of Annex I to this Directive shall, if the United Kingdom or Ireland so desire and on their national territories, be accompanied by an indication of the nominal volume of the contents expressed in the equivalent imperial units of measurement, if they are given in Annex I to this Directive.

Article 5

Member States may not refuse, prohibit or restrict the placing on the market of prepackages which satisfy the requirements and tests laid down in this Directive for reasons concerning the volume of the contents, the determination of such volume or the methods by which they have been checked.

Article 6

The amendments necessary to adjust the provisions of Annexes I and II to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Articles 18 and 19 of Council Directive No 71/316/EEC.

Article 7

1. Member States shall put into force the laws, regulations and administrative provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

2. By way of derogation from paragraph 1, Belgium, Ireland, the Netherlands and the United Kingdom may defer implementation of this Directive and the Annexes thereto until 31 December 1979 at the latest.

3. During the period in which the Directive is not operative in a Member State, that Member State shall not introduce stricter control measures regarding the quantity contained in prepackages covered by this Directive and coming from other Member States than those in force when the Directive was adopted.

⁽¹⁾ OJ No L 243, 29. 10. 1971, p. 29.

4. During the same period the Member States which have introduced the Directive shall accept those prepackages coming from Member States benefiting from the derogation provided for in paragraph 2 of this Article which comply with the provisions of Annex I.1 and Annex III to the Directive, even if they do not bear the EEC mark referred to in subsection 3.3 of Annex I, on the same basis and under the same conditions as those prepackages which comply with all the provisions of the Directive.

5. Member States shall ensure that the text of the main provisions of national law which they adopt

in the field covered by this Directive are communicated to the Commission.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 19 December 1974.

For the Council

The President

J. P. FOURCADE

ANNEX I

1. OBJECTIVES

Prepackages covered by this Directive shall be made up in such a way that the completed prepackages satisfy the following requirements:

- 1.1. the actual volume of the contents shall not be less, on average, than the nominal volume of the contents;
- 1.2. the proportion of prepackages having a negative error greater than the tolerable negative error laid down in subsection 2.4 shall be sufficiently small for batches of prepackages to satisfy the requirements of the tests specified in Annex II;
- 1.3. no prepackage having a negative error greater than twice the tolerable negative error given in the table of subsection 2.4 may be marked with the EEC mark provided for in subsection 3.3.

2. DEFINITIONS AND BASIC PROVISIONS

- 2.1. The nominal volume of the contents of a prepackage is the volume indicated on the prepackage, i.e., the volume of liquid which the prepackage is deemed to contain.
- 2.2. The actual volume of the contents of a prepackage is the volume of liquid it in fact contains. In all checking operations the value employed for actual volume of the contents shall be measured at or corrected to a temperature of 20° C.
- 2.3. The negative error is the quantity by which the actual volume of the contents is less than the nominal volume of the contents of the prepackage.
- 2.4. The tolerable negative error shall be fixed in accordance with the following table:

Nominal volume of the contents V_n in millilitres	Tolerable negative error	
	in % of V_n	in millilitres
from 50 to 100	—	4.5
from 100 to 200	4.5	—
from 200 to 300	—	9
from 300 to 500	3	—
from 500 to 1 000	—	15
from 1 000 to 5 000	1.5	—

3. INSCRIPTIONS AND MARKINGS

All prepackages made up in accordance with this Directive shall bear on the package the following markings affixed in such a manner as to be indelible, easily legible and visible on the prepackage in normal conditions of presentation:

- 3.1. the nominal volume of the contents expressed in litres, centilitres or millilitres and marked in figures at least 6 mm high if the nominal volume of the contents is greater than 100 cl, 4 mm high if it is from 100 cl down to but not including 20 cl and 3 mm high if it is not more than 20 cl, followed by the symbol for the unit of measurement used

or where appropriate by the name of the unit, in accordance with Council Directive No 71/354/EEC;

until the expiry of the transitional period, during which the use of the imperial units of measurement appearing in Annex II to Council Directive No 71/354/EEC is authorized in the Community, the indication of the nominal volume of the contents expressed in SI units in accordance with the preceding paragraph may be accompanied by that of the equivalent value in imperial (UK) units of measurement, calculated on the basis of the following conversion factors:

one millilitre = 0.0352 fluid ounce

one litre = 1.760 pints or 0.220 gallon

Member States may, where they think it necessary, insist on this second indication for products put up for sale on their national territories;

- 3.2. a mark or inscription enabling the department concerned to identify the packer or the person responsible for the packing or the importer established in the Community;
- 3.3. a small 'e' at least 3 mm high, placed in the same field of vision as the indication of the nominal volume of the contents, certifying that the prepackage meets the requirements of this Directive.

This letter shall have the form shown in the drawing contained in Annex II, Section 3, to Council Directive No 71/316/EEC.

Article 12 of this latter Directive shall apply *mutatis mutandis*.

However, if the package is a measuring container which complies with the relevant Directive and if the indication of its nominal capacity is visible under normal conditions of presentation of the prepackage, it is not necessary for the purposes of this Directive to indicate the nominal volume of the contents of the prepackage as required by point 3.1 above.

This shall not, however, be applicable when such nominal volume of the prepackage differs by an amount of up to and including 0.05 litre from another nominal volume provided for in Annex III for the same category of products.

4. RESPONSIBILITY OF THE PACKER OR IMPORTER

The quantity of liquid contained in a prepackage, known as the 'actual volume of the contents', shall be measured or checked on the responsibility of the packer. The measurement or check shall be carried out by means of a legal measuring instrument suitable for effecting the necessary operations.

The check may be carried out by sampling.

Where the actual volume of the contents is not measured, the check carried out by the packer shall be so organized that the nominal volume of the said contents is effectively ensured.

This condition is fulfilled if the packer carries out production checks in accordance with procedures recognized by the competent departments in the Member State and if he holds at the disposal of these authorities the documents containing the results of such checks, in order to certify that these checks, together with the corrections and adjustments which they have shown to be necessary, have been properly and accurately carried out.

One of the several methods of meeting the measuring and checking requirement is to use when making up the prepackage a measuring container of the type defined in the Directive relating thereto and filled under the conditions prescribed in this Directive and that on measuring container bottles.

5. CHECKS TO BE CARRIED OUT BY THE COMPETENT DEPARTMENTS ON THE PREMISES OF THE PACKER OR IMPORTER

Checks to ensure that the prepackages comply with the provisions of this Directive, shall be carried out by the competent departments of the Member States by sampling on the packers' premises or, if this is not practicable, on the premises of the importer or his agent established in the Community.

This statistical sampling check shall be carried out in accordance with the accepted methods of quality acceptance inspection. Its effectiveness shall be comparable to that of the reference method specified in Annex II.

6. OTHER CHECKS CARRIED OUT BY THE COMPETENT DEPARTMENTS

This Directive shall not preclude any checks that may be carried out by the competent departments of the Member States in the course of trade, in particular for the purpose of verifying that prepackages meet the requirements of the Directive.

ANNEX II

This Annex lays down the procedures of the reference method for statistical checking of batches of prepackages in order to meet the requirements of Article 3, and Section 5, Annex 1, of the Directive.

This check is based upon ISO standard No 2859 relating to methods of testing by attributes, taking an acceptable quality level of 2.5%. The sampling level corresponds to level II of that standard in respect of non-destructive tests, and to level S 3 in respect of destructive tests.

1. REQUIREMENTS FOR MEASURING THE ACTUAL VOLUME OF THE CONTENTS OF PREPACKAGES

The actual volume of the contents of prepackages may be measured directly by means of volumetric measuring instruments or indirectly by weighing and measuring density.

Irrespective of the method used, the error made in measuring the actual volume of the contents of a prepackage shall not exceed one-fifth of the particular tolerable negative error for the nominal volume of the contents of the prepackage. The procedure for measuring the actual volume of the contents of a prepackage may be the subject of domestic regulations in each Member State.

2. REQUIREMENTS FOR CHECKING BATCHES OF PREPACKAGES

The checking of prepackages shall be carried out by sampling and shall be in two parts:

- a check on the actual volume of the contents of each prepackage in the sample,
- another check covering the average of the actual volumes of the contents of the prepackages in the sample.

A batch of prepackages shall be considered acceptable if the results of both these checks satisfy the acceptance criteria.

For each of these checks, there are two sampling plans:

- one for non-destructive testing, i.e., testing which does not involve opening the package,
- the other for destructive testing, i.e., testing which involves opening or destroying the package.

For economic and practical reasons, the latter test shall be limited to the absolutely essential minimum, and it is less effective than the former.

Destructive testing shall therefore be used only when non-destructive testing is impracticable. As a general rule it shall not be applied to batches of fewer than 100 units.

2.1. Composition of the prepackage batch

- 2.1.1. The batch shall be made up of all the prepackages of the same type and the same production run which are to be inspected.

- 2.1.2. When prepackages are checked at the end of the packing line, the number in each batch shall be equal to the maximum hourly output of the packing line. In other cases the batch size shall be limited to 10 000.
- 2.1.3. For batches of fewer than 100 prepackages, the non-destructive test, where carried out, shall be 100%.
- 2.1.4. Before the tests in 2.2 and 2.3 are carried out, a sufficient number of prepackages shall be drawn at random from the batch so that the check requiring the larger sample can be carried out.

For the other check, the necessary sample shall be drawn at random from the first sample and marked.

This marking operation shall be completed before the start of measuring operations.

2.2. Checking of minimum acceptable volume of the contents of a prepackage

- 2.2.1. The minimum acceptable volume of the contents shall be calculated by subtracting the tolerable negative error for the nominal volume of the contents concerned from the nominal volume of the contents of the prepackage.
- 2.2.2. Individual units in the batch whose actual volume of contents is less than the minimum acceptable volume of contents shall be considered defective.
- 2.2.3. For checks by sampling, one of the following sampling plans (single or double) shall be used, to be chosen by each Member State.

2.2.3.1. *Single sampling plan*

The number of prepackages checked shall be equal to the number in the sample, as indicated in the plan:

- if the number of defective units found in the sample is less than or equal to the criterion for acceptance, the batch of prepackages shall be considered acceptable for the purpose of this check,
- if the number of defective units found in the sample, is equal to or greater than the criterion for rejection, the batch of prepackages shall be rejected.

2.2.3.1.1. Non-destructive testing plan

Number in batch	Number in sample	Number of defective units	
		Acceptance criterion	Rejection criterion
100 to 150	20	1	2
151 to 280	32	2	3
281 to 500	50	3	4
501 to 1 200	80	5	6
1 201 to 3 200	125	7	8
3 201 and over	200	10	11

2.2.3.1.2. Destructive testing plan

Number in batch	Number in sample	Number of defective units	
		Acceptance criterion	Rejection criterion
Whatever the number (≥ 100)	20	1	2

2.2.3.2. *Double-sampling plan*

The first number of prepackages checked shall be equal to the number of units in the first sample as indicated in the plan:

- if the number of defective units found in the first sample is less than or equal to the first acceptance criterion, the batch shall be considered acceptable for the purpose of this check,
- if the number of defective units found in the first sample is equal to or greater than the first rejection criterion, the batch shall be rejected,
- if the number of defective units found in the first sample lies between the first acceptance criterion and the first rejection criterion, a second sample shall be checked, the number of units in which is indicated in the plan.

The defective units found in the first and second samples shall be added together:

- if the aggregate number of defective units is less than or equal to the second acceptance criterion, the batch shall be considered acceptable for the purpose of the check,
- if the aggregate number of defective units is greater than or equal to the second rejection criterion, the batch shall be rejected.

2.2.3.2.1. *Non-destructive testing plan*

Number in batch	Samples			Number of defective units	
	Order	Number	Aggregate number	Acceptance criterion	Rejection criterion
100 to 150	1st	13	13	0	2
	2nd	13	26	1	2
151 to 280	1st	20	20	0	3
	2nd	20	40	3	4
281 to 500	1st	32	32	1	4
	2nd	32	64	4	5
501 to 1 200	1st	50	50	2	5
	2nd	50	100	6	7
1 201 to 3 200	1st	80	80	3	7
	2nd	80	160	8	9
3 201 and over	1st	125	125	5	9
	2nd	125	250	12	13

2.2.3.2.2. *Destructive testing plan*

Number in batch	Samples			Number of defective units	
	Order	Number	Aggregate number	Acceptance criterion	Rejection criterion
Whatever the number (≥ 100)	1st	13	13	0	2
	2nd	13	26	1	2

2.3. Checking of average actual volume of the contents of the individual prepackages making up a batch

2.3.1. A batch of prepackages shall be considered acceptable for the purpose of this check

if the mean value $\bar{x} = \frac{\sum x_i}{n}$ of the actual volume of the contents x_i of n prepackages

in a sample is greater than the value:

$$V_n - \frac{s}{\sqrt{n}} \cdot t_{(1-\alpha)}$$

In this formula:

V_n = the nominal volume of the contents of the prepackage,

s = the estimated standard deviation of the actual volume of the contents of the batch,

n = the number of prepackages in the sample for this check,

$t_{(1-\alpha)}$ = 0.995 confidence level of a student distribution with $\delta = n - 1$ degree of freedom.

2.3.2. If x_i is the measured value for the actual volume of the contents of the i -th item in the sample containing n items, then:

2.3.2.1. the mean of the measured values for the sample is obtained by the following calculation:

$$\bar{x} = \frac{\sum_{i=1}^{i=n} x_i}{n}$$

2.3.2.2. and the estimated value of the standard deviation s by the following calculation:

— the sum of the squares of the measured values: $\sum_{i=1}^{i=n} (x_i)^2$

— the square of the sum of the measured values: $\left(\sum_{i=1}^{i=n} x_i\right)^2$ then $\left(\frac{\sum_{i=1}^{i=n} x_i}{n}\right)^2$

— the corrected sum: $SC = \sum_{i=1}^{i=n} (x_i)^2 - \left(\frac{\sum_{i=1}^{i=n} x_i}{n}\right)^2$

— the estimated variance $v = \frac{SC}{n-1}$

The estimated value of the standard deviation is $s = \sqrt{v}$

2.3.3. Criteria for acceptance or rejection of batches of prepackages tested in this check:

Criteria for non-destructive testing

Number in batch	Number in sample	Criteria	
		Acceptance	Rejection
≤ 500	30	$\bar{x} \geq V_n - 0.503 s$	$\bar{x} < V_n - 0.503 s$
> 500	50	$\bar{x} \geq V_n - 0.379 s$	$\bar{x} < V_n - 0.379 s$

Criteria for destructive testing

Number in batch	Number in sample	Criteria	
		Acceptance	Rejection
Whatever the number (≥ 100)	20	$\bar{x} \geq V_n - 0.640 s$	$\bar{x} < V_n - 0.640 s$

ANNEX III

Liquids	Nominal volume of contents in litres	
	I Finally permitted	II (*) Provisionally permitted
1. (a) Wine of fresh grapes; grape must with fermentation arrested by the addition of alcohol (CCT heading No ex 22.05 C) except for liqueur wines	0.10 — 0.25 — 0.35 0.375 — 0.50 — 0.70 0.75 — 1 — 1.5 2 — 5	0.20 — 0.36 — 0.475 0.60 — 0.68 — 0.72 0.95 — 1.75 — 1.88
(b) Other non-sparkling fermented beverages, for example, cider, perry and mead (CCT heading No 22.07 B II)	0.10 — 0.25 — 0.35 0.375 — 0.50 — 0.70 — 0.75 — 1 — 1.5 — 2 — 5	0.20 — 0.33 — 0.36 0.72
(c) Vermouths and other flavoured wines of fresh grapes (CCT heading No 22.06) liqueur wines (CCT heading No 22.05 C)	0.10 — 0.375 — 0.50 0.75 — 1 — 1.5	0.20 — 0.35 — 0.36 0.68 — 0.70 — 0.72
2. (a) Sparkling wines (CCT heading No 22.05 A+B)	0.10 — 0.125 — 0.20 0.375 — 0.75 — 1.5 3	0.57 — 0.77
(b) Other fermented sparkling drinks for example, cider, perry and mead (CCT heading No 22.07 B I)	0.10 — 0.125 — 0.20 0.375 — 0.75 — 1 1.5 — 3	0.57 — 0.77
3. Beer made from malt (CCT heading No 22.03): — acid beers, gueuze	0.25 — 0.33 — 0.50 0.75 — 1 — 2 — 3 4 — 5 0.375	0.18 (in cans only) 0.20 — 0.30 — 0.35 (in cans only) 0.45 — 0.66 — 3.8
4. Spirits and other spirituous beverages (CCT heading No 22.09)	0.05 — 0.10 — 0.20 0.35 — 0.375 — 0.50 0.70 — 0.75 — 1 1.5 — 2 — 2.5 3	0.25 — 0.36 — 0.60 0.72
5. Vinegar and substitutes for vinegar (CCT heading No 22.10)	0.25 — 0.50 — 0.75 1 — 2 — 5	0.35 — 0.7 — 1.5 2.5
6. Edible oils (CCT heading No 15.07 A I) (CCT heading No 15.07 D II)	0.10 — 0.25 — 0.50 1 — 2 — 3 — 5	0.375 — 0.625 — 0.75 1.5 — 2.5

Liquids	Nominal volume in litres	
	I Finally permitted	II (*) Provisionally permitted
7. Milk and milk based beverages sold by volume (CCT heading No 04.01) (excluding yoghurt and kephir, CCT heading No 22.02 B)	0.10 — 0.2 — 0.25 0.50 — 0.75 — 1 2 — 3 — 4	0.22 — 0.33 — 0.6
8. (a) Waters, including spa waters and aerated waters (CCT heading No 22.01)	all volumes below 0.20 — 0.20 — 0.25 0.33 — 0.50 — 0.70 0.75 — 1 — 1.5 2	0.35 — 0.45 — 0.47 0.90 — 0.94
(b) Lemonade, flavoured spa waters and flavoured aerated waters and other non-alcoholic beverages not including fruit and vegetable juices (CCT heading No 22.02 A)	all volumes below 0.20 — 0.20 — 0.25 0.33 — 0.50 — 0.70 0.75 — 1 — 1.5 2 — 3 — 4 5	0.35 — 0.45 — 0.47 0.60 — 0.90 — 0.94
9. Fruit juices and vegetable juices, whether or not containing added sugar, but unfermented and not containing spirit and non-concentrated fruit juices (CCT heading No 20.07)	all volumes below 0.125 — 0.125 — 0.20 0.25 — 0.33 — 0.50 0.70 — 0.75 — 1 1.5 — 2 — 3 4 — 5	0.18 — 0.35 (only in cans)

(*) As regards the prepackages whose nominal volumes are out in Column II, Article 5 shall, in respect of countries which permitted free circulation of these prepackages on 31 December 1971, apply only till 31 December 1980, except for the prepackages specified under heading 8 (a) which shall apply up to 31 December 1988.

Note: The liquids mentioned in points 1 (a) and (b), 4, 8 (a) and (b) and 9 may be put up for sale in the Community only in prepackages having the nominal volume of the contents as shown in the above table and conforming to the relevant regulations or to the normal commercial practice in the Member State of origin of the liquid, whether packing is carried out in the Member State of origin or in another State.