Council Directive of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (76/211/EEC)

COUNCIL DIRECTIVE

of 20 January 1976

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

(76/211/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 products 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 weight or volume of the product contained in the prepackage, should be presented;

Whereas it is also necessary to specify the tolerable negative 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 to the provisions laid down;

Whereas Article 16 of Council Directive 71/316/EEC 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[(3)], as last amended by the Act of Accession[(4)], provides that the harmonization of the requirements for marketing certain products, in particular as regards the measurement and marking of prepacked quantities, may be covered by separate Directives;

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 products**[**[F1] with the exception of those referred to in the Council Directive 75/106/EEC 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, and**]** intended for sale in constant unit nominal quantities which are:

— equal to values predetermined by the packer,

— expressed in units of weight or volume,

— not less than 5 g or 5 ml and not more than 10 kg or 10 l.

Textual Amendments

F1 Deleted by Directive 2007/45/EC Of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC.

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 the package either being opened or undergoing a perceptible modification.

Article 3

1 The prepackages which may bear the EEC sign specified in section 3.3 of Annex I are those which comply with this Directive and with Annex I thereto.

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 weight or volume of the product, known as ‘nominal weight’ or ‘nominal volume’, which they are required to contain.

2 Prepackages containing liquid products shall be marked with their nominal volume and prepackages containing other products shall be marked with their nominal weight, except in the case of trade practice or national regulations which provide otherwise and which are identical in all Member States, or in the case of contrary Community rules.

3 If trade practice or national regulations are not the same in all Member States for a category of products or for a type of prepackage, those prepackages must at least show the metrological information corresponding to the trade practice or national regulations prevailing in the country of destination.

4 Until the expiry of the transitional period during which the use of the imperial units of measurement appearing in Annex II to Council Directive 71/354/EEC of 18 October 1971 on the approximation of the laws of the Member States relating to units of measurement[(5)], as amended

by the Act of Accession, is authorized in the Community, the indication of the nominal weight and/or nominal volume of the contents expressed in SI units of measurement in accordance with section 3.1 of Annex I to this Directive shall, if the United Kingdom or Ireland so desires, be accompanied on their national territories by an indication of the equivalent value in imperial units of measurement (UK), calculated on the basis of the following conversion factors:

1 g	=	0.0353 ounces (avoirdupois),
1 kg	=	2.205 pounds
1 ml	=	0.0352 fluid ounces,
1 l	=	1.760 pints or 0.220 gallons.

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 markings required to be borne by such prepackages pursuant to this Directive, the determination of their volume or weight, or the methods by which they have been measured or checked.

[*F2**Article 6*

The Commission is empowered to adopt delegated acts in accordance with Article 6a amending Annexes I and II to adapt them to technical progress.**]**

Textual Amendments

F2 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

[*F3**Article 6a*

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of power referred to in Article 6 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[(6)].

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Article 6 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.**]**

Textual Amendments

F3 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

Article 7

1 Member States shall bring 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.

4 During the same period, the Member States which have implemented 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 section 1 of Annex I, even if they do not bear the EEC sign referred to in section 3.3 of Annex I, on the same basis and under the same conditions as those prepackages which comply with all the requirements of the Directive.

5 The checks provided for by Annex I, section 5 shall be carried out by the competent authorities of the Member State of destination when prepackages manufactured outside the Community are imported into the territory of the Community in a Member State which has not yet implemented the Directive in accordance with this Article.

6 Member States shall ensure that the text of the main provisions of national law which they adopt in the field covered by this Directive is communicated to the Commission.

Article 8

This Directive is addressed to the Member States.

ANNEX I

1. OBJECTIVES

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

1.1. the actual contents shall not be less, on average, than the nominal quantity;

1.2. the proportion of prepackages having a negative error greater than the tolerable negative error laid down in 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 in 2.4 may bear the EEC sign provided for in 3.3.

2. DEFINITIONS AND BASIC PROVISIONS

2.1. The nominal quantity (nominal weight or nominal volume) of the contents of a prepackage is the weight or volume indicated on the prepackage, i.e. the quantity of product which the prepackage is deemed to contain.

2.2. The actual contents of the prepackage are the quantity (weight or volume) of product which it in fact contains. In all operations for checking quantities of products expressed in units of volume, the value employed for the actual contents shall be measured at or corrected to a temperature of 20 °C, whatever the temperature at which packaging or checking is carried out. However, this rule shall not apply to deep frozen or frozen products, the quantity of which is expressed in units of volume.

2.3. The negative error of a prepackage is the quantity by which the actual contents of the prepackage are less than the nominal quantity.

2.4. **[**[F4]The tolerable negative error in the contents of a prepackage is fixed in accordance with the table below:

Nominal quantity Qn in grams or millilitres	**Tolerable negative error**	
	as % of Qn	**g or ml**
5 to 50	9	—
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 10 000	1.5	—

When using the table, the values of the tolerable negative errors shown as percentages in the table, calculated in units of weight or volume, shall be rounded up to the nearest one-tenth of a gram or millilitre.**]**

2.5. **[**[F5]. . . . .

2.6. . . . . **]**

Textual Amendments

F4 Substituted by Commission Directive of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on prepackaging (78/891/EEC).

F5 Deleted by Commission Directive of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on prepackaging (78/891/EEC).

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. **[**F4The nominal quantity (nominal weight or nominal volume) expressed in kilograms, grams, litres, centilitres or millilitres, and marked in figures at least 6 mm high if the nominal quantity exceeds 1 000 g or 100 cl, 4 mm high if it is from 1 000 g or 100 cl inclusive down to but not including 200 g or 20 cl, 3 mm high if it is from 200 g or 20 cl down to but not including 50 g or 5 cl, 2 mm high if it is not more than 50 g or 5 cl, followed by the symbol for the unit of measurement used or where appropriate by the name of the unit in accordance with Directive 71/354/EEC, as last amended by Directive 76/770/EEC.

Markings in imperial (UK) units shall be in letters and figures of dimensions not larger than those of the corresponding markings in SI units.**]**

3.2. a mark or inscription enabling the competent departments to identify the packer or the person arranging for the packing to be done 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 weight or nominal volume, constituting a guarantee by the packer or the importer that the prepackage meets the requirements of this Directive.

This letter shall have the form shown in the drawing contained in section 3 of Annex II to Directive 71/316/EEC.

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

4. RESPONSIBILITY OF THE PACKER OR IMPORTER

The packer or importer shall be responsible for ensuring that prepackages meet the requirements of this Directive.

The quantity of product contained in a prepackage (or packing quantity), known as the ‘actual contents’, shall be measured or checked by weight or volume on the responsibility of the packer and/or importer. 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 contents are not measured, the check carried out by the packer shall be so organized that the quantity of the 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 those departments the documents containing the results of such checks, in order to certify that these checks, together with any corrections and adjustments which they have shown to be necessary, have been properly and accurately carried out.

In the case of imports from non-EEC countries, the importer may instead of measuring and checking provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility.

In the case of products in quantities expressed in units of volume, one of several methods of meeting the measuring and checking requirements is to use, when making up the prepackage, a measuring container of the type defined in the Directive relating thereto, filled under the conditions prescribed in that Directive and herein.

[F4 5. CHECKS TO BE CARRIED OUT BY THE COMPETENT DEPARTMENTS ON THE PREMISES OF THE PACKER OR OF THE IMPORTER OR OF HIS AGENT ESTABLISHED IN THE COMMUNITY

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 packer's premises or, if this is not practicable, on the premises of the importer or of 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.

Thus as regards the criterion for the minimum contents, a sampling plan used by a Member State shall be regarded as comparable with that recommended in Annex II if the abscissa of the 0.10 ordinate point of the operating characteristic curve of the first plan (probability of acceptance of the batch = 0.10) deviates by less than 15 % from the abscissa of the corresponding point of the operating characteristic curve of the sampling plan recommended in Annex II.

As regards the criterion for the mean calculated by the standard deviation method, a sampling plan used by a Member State shall be regarded as comparable with that recommended in Annex II if, taking into account the operating characteristic curves of the two plans having as the abscissa axis

$\frac{Q_m - m}{\sigma}$

(7), the abscissa of the 0.10 ordinate point of the curve of the first plan (acceptance probability of the batch = 0.10) deviates by less than 0.05 from the abscissa of the corresponding point of the curve of the sampling plan recommended in Annex II.**]**

6. OTHER CHECKS CARRIED OUT BY THE COMPETENT DEPARTMENTS

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

Article 15 (2) of Directive 71/316/EEC shall apply *mutatis mutandis*.

[F4ANNEX 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 of the Directive and of Section 5, Annex I thereto.

1. REQUIREMENTS FOR MEASURING THE ACTUAL CONTENTS OF PREPACKAGES

The actual contents of prepackages may be measured directly by means of weighing instruments or volumetric instruments or, in the case of liquids, indirectly, by weighing the prepacked product and measuring its density.

Irrespective of the method used, the error made in measuring the actual contents of a prepackage shall not exceed one-fifth of the tolerable negative error for the nominal quantity in the prepackage.

The procedure for measuring the actual 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 covering the actual contents of each prepackage in the sample,

— another check on the average of the actual 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; it is less effective than the non-destructive test.

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. Prepackage batches

2.1.1. The batch shall comprise all the prepackages of the same nominal quantity, the same type and the same production run, packed in the same place, which are to be inspected. The batch size shall be limited to the amounts laid down below.

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, without any restriction as to batch size.

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 the actual contents of a prepackage

The minimum acceptable contents shall be calculated by subtracting the tolerable negative error for the contents concerned from the nominal quantity of the prepackage.

Prepackages in the batch whose actual contents are less than the minimum acceptable contents shall be considered defective.

2.2.1. Non-destructive testing

Non-destructive testing shall be carried out in accordance with a double sampling plan as shown in the table below:

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, thebatch 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 and:

— 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 this check,

— if the aggregate number of defective units is greater than or equal to the second rejection criterion, the batch shall be rejected.

Number in batch	**Samples**			**Number of defective units**	
	Order	**Number**	**Aggregate number**	**Acceptance criterion**	**Rejection criterion**
100 to 500	1st	30	30	1	3
	2nd	30	60	4	5
501 to 3 200	1st	50	50	2	5
	2nd	50	100	6	7
3 201 and over	1st	80	80	3	7
	2nd	80	160	8	9

2.2.2. Destructive testing

Destructive testing shall be carried out in accordance with the single sampling plan below and shall be used only for batches of 100 or more.

The number of prepackages checked shall be equal to 20.

— If the number of defective units found in the sample is less than or equal to the acceptance criterion, the batch of prepackages shall be considered as acceptable.

— If the number of defective units found in the sample is equal to or greater than the rejection criterion, the batch of prepackages shall be rejected.

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

2.3. Checking of the average actual 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 contents x_i of n prepackages in a sample is greater than the value:

$$Q_n - \frac{s}{\sqrt{n}} \times t_{(1-\alpha)}$$

In this formula:

Q_n = the nominal quantity of the prepackage,
n = the number of prepackages in the sample for this check,
s = the estimated standard deviation of the actual contents of the batch,
$t_{(1-\alpha)}$ = 0.995 confidence level of a Student distribution with ν = n — 1 degree of freedom.

2.3.2. If x_i is the measured value for the actual 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

$$\frac{1}{n}\left(\sum_{i=1}^{i=n} x_i\right)^2$$

— the corrected sum

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

— 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 the batch of prepackages for checking the mean:

2.3.3.1. Criteria for non-destructive testing

Number in batch	**Number in sample**	**Criteria**	
		Acceptance	**Rejection**
100 to 500 (inclusive)	30	$\bar{x} \geq Q_n - 0.503s$	$\bar{x} < Q_n - 0.503s$
> 500	50	$\bar{x} \geq Q_n - 0.379s$	$\bar{x} < Q_n - 0.379s$

2.3.3.2. Criteria for destructive testing

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

(**1**) OJ No C 48, 25.4.1974, p. 21.

(**2**) OJ No C 109, 19.9.1974, p. 16.

(**3**) OJ No L 202, 6.9.1971, p. 1.

(**4**) OJ No L 73, 27.3.1972, p. 14.

(**5**) OJ No L 243, 29.10.1971, p. 29.

(**6**) **[**[F3]OJ L 123, 12.5.2016, p. 1.**]**

(**7**) **[**[F4]m = actual batch mean.**]**

Textual Amendments

F3 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

F4 Substituted by Commission Directive of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on prepackaging (78/891/EEC).