

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)

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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. ^[F1]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. ^[F2]

2.6.]

Textual Amendments

- F1** 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 \(78/891/EEC\)](#).
- F2** 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. [F1The 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.

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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.

[^F15. 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

$$\frac{Q_n - m}{s}$$

(¹), 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*.

[^{F1}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 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 %.

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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, 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 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 $v = n - 1$ 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

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

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— 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	$\bar{x} \geq Q_n - 0.640s$	$\bar{x} < Q_n - 0.640s$

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(1) $[\overset{\text{F1}}{m}] = \text{actual batch mean.}]$

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Textual Amendments

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