L.N. 417 of 2002

THE METROLOGY ACT
ACT NO. XXV OF 2002

Making-Up by Weight or By Volume of Certain Prepackaged Products Regulations, 2002

IN exercise of the powers conferred by article 19 of the Metrology Act, the Malta Standards Authority has made the following regulations:-

Commencement and citation.

1. (1) The title of these regulations is the Making-Up by Weight or by Volume of Certain Prepackaged Products Regulations, 2002.

(2) These regulations shall come into force on such date or dates as the Authority may by notice in the Gazette appoint and different dates may be so appointed for different purposes and different provisions of the regulations.

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2. For the purposes of these regulations, all the definitions in the Malta Standards Authority Act shall apply, and in addition, in these regulations, unless the context otherwise requires:

"prepackage" shall mean the combination of a product and the individual package in which it is prepacked;

"prepacked product" shall refer to 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

Scope

3. These regulations relate to prepackages containing products with the exception of those referred to in other regulations relating to the making-up by volume of certain prepackaged liquids, intended for sale in constant unit nominal quantities which are:

a) equal to values predetermined by the packer,
b) expressed in units of weight or volume,
c) not less than 5 g or 5 ml and not more than 10 kg or 10 l.

Prepackages with EEC marks etc.

4. (1) The prepackages which may bear the EEC sign specified in regulation 3(3) of Annex I are those which comply with these regulations and with Annex I thereto.

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

Indication of weight or volume of product

5. (1) All prepackages referred to in regulation 5 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.

(3) If trade practice or national regulations are not the same in Malta and the country of destination 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.

6. The Authority may not refuse, prohibit or restrict the placing on the market of prepackages which satisfy the requirements and tests laid down in these regulations for reasons concerning the markings required to be borne by such prepackages pursuant to these regulations, the determination of their volume or weight, or the methods by which they have been measured or checked.

ANNEX I

1. OBJECTIVES

Prepackages covered by these regulations 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. The tolerable negative error in the contents of a prepackage is fixed in accordance with the table below:

Nominal quantity Q_n in grams or millilitres	Tolerable negative error	
	as % of Q_n	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.

3. INSCRIPTIONS AND MARKINGS

All prepackages made up in accordance with these regulations 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 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 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, 2mm 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 Schedule 1 of the Metrology Act , 2002;

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 these Regulations.

This letter shall have the form shown in the drawing contained in item 3 of Annex II to the Measuring Instrument Regulations, 2002.

Regulation 12 of these latter regulations 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 these regulations.

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 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-EU 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 regulations relating thereto, filled under the conditions prescribed in those regulations and herein.

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 MALTA

Checks to ensure that the prepackages comply with the provisions of these regulations shall be carried out by the competent departments 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 Malta.

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 the Authority shall be regarded as comparable with that recommended in Annex II if the abscissa of the 0.10 ordinate point of the operating characteristics 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 the competent Authority 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 $\frac{Qn-m}{s}$, ([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

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

Regulation 15 (2) of the Measuring Instruments Regulations, 2002, shall apply *mutatis mutandis*.

[1] m = actual batch mean.

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 regulation 5 of these regulations and of item 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.

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, 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	1 st 2 nd	30 30	30 60	1 4	3 5
501 to 3 200	1 st 2 nd	50 50	50 100	2 6	5 7
3 201 and over	1 st 2 nd	80 80	80 160	3 8	7 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

$$\bar{x} = \frac{1}{n} \sum x_i$$

of the actual contents x_i of n prepackages in a sample is greater than the value:

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

In this formula :

Q_n the nominal quantity for 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 $\nu = n-1$ 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:

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

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:

$$\sum_{i=1}^{n} x_i^2$$

- the square of the sum of the measured values:

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

then

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

- the corrected sum:

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

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

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