L.N. 415 of 2002

THE METROLOGY ACT
ACT NO. XXV OF 2002

Prepackaged Liquid 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:-

Citation and commencement.

1. (1) The title to these regulations is the Prepackaged Liquid Products Regulations, 2002.

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

Definitions. Cap 419.

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

"prepackage" shall refer to the combination of a product and the individual package in which it is prepacked.

"prepacked product" shall refer to a product 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. (1) These regulations shall apply to prepackages containing the liquid products listed in Annex III measured by volume for the purpose of sale in individual quantities of between 5ml and 10 litres inclusive.

(2) These regulations shall not apply to prepackages containing the products listed in Annex III which are:

(i) vatted, bottle and labelled in volumes not exceedings 0,25 litre and are intended for professional use,

(ii) intended either for consumption on board aircraft, ships and trains or for sale in duty-free shops.

Prepackages with EEC marks etc.

4. (1) The prepackages which may be marked with the EEC mark referred to in Section 3.3 of Annex I are those which comply with Annex 1.

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

5. (1) All prepackages referred to in regulation 4 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.

Placing on the market

6. (1) The placing on the market of prepackages which satisfy the requirements of these regulations may not be refused, prohibited, or restricted on grounds related to the determination of their volumes, the methods by which they have been checked or the nominal volumes where these are set forth in Annex III:

(2) Prepackages containing the products listed in Annex III 1(a) may be marketed only if they have the nominal volumes laid down in Annex III.

Prepackages containing the products listed in Annex III, 1 (a) and (b), may be marketed only if they have the nominal volumes set out in column I of the said Annex:

Provided that packages containing the products listed in Annex III (2) (a) may only be marketed if they have the nominal volumes set out in column I of that Annex.

Provided further that those packages which appear in Annex III, Section 4, may be marketed only if, they have the nominal volume set out in the said column I.

(3) Nothing in these regulations shall have the effect of prohibiting the enactment of laws, regulations or any other regulatory instrument governing the use of packaging with regards to its recycling on environmental grounds.

ANNEX I

1. OBJECTIVES

Prepackages covered by these regulations 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
Form 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	-	1,5
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 volume, shall be rounded up to the nearest one - tenth of a 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 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,

3 mm high if it is from 20 cl down to but not including 5 cl,

2 mm high if it is not more than 5 cl,

followed by the symbol for the unit of measurement used or where appropriate by the name of the unit.

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 Malta;

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 these regulations.

This letter shall have the form shown in the drawing contained in Annex II, Section 3, to Measuring Instruments Regulations, 2002

Regulation 12 of these latter regulations shall apply *mutatis mutandis*.

However, if the package is a measuring container which complies with the relevant Regulations 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 these regulations to indicate the nominal volume of the contents of the prepackage as required by regulation 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 packer or importer shall be responsible for ensuring that prepackages meet the requirements of these regulations.

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 or the 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 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, in conformity with the provisions of these regulations.

In order to fulfil this requirement, the packer must carry out production checks in accordance with procedures recognized by the Authority and 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.

Where goods are imported 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.

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 Regulations relating thereto and filled under the conditions prescribed in these regulations and in that on measuring container bottles.

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 these regulations shall be carried out by the Authority 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 acceptable 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 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 curves 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 Authority shall be regarded as comparable with that recommended in Annex II if, taking into account the operating characteristics curves of the two plans having as the abscissa axis $\frac{\bar{V}_n - m}{s}$ (^{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

These regulations shall not preclude any checks that may be carried out by the Authority in the course of trade, in particular for the purpose of verifying that prepackages meet the requirements of the Regulations.

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 Regulations 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, be 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 Minister, acting on the advice of the Authority, may prescribe regulations establishing the procedure for measuring the actual contents of a prepackage.

2. REQUIREMENTS FOR MEASURING 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 making 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 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 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

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

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

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

In this formula:

V_n	nominal volume of the contents of the preapackage,
s	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 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 :

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

2.3.2.2. and the estimated value of the standard deviation 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 $\left(\frac{\sum_{i=1}^{n} x_i}{n} \right)^2$
- the corrected sum : $SC = \sum_{i=1}^{n} x_i^2 - \left(\frac{\sum_{i=1}^{n} x_i}{n} \right)^2$
- 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	$\bar{x} \geq V_n - 0.503s$	$\bar{x} < V_n - 0.503s$
> 500	50	$\bar{x} \geq V_n - 0.379s$	$\bar{x} < V_n - 0.379s$

Criteria for non – destructive testing

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

ANNEX III

Liquids	Nominal volume of contents in litres	
	I Definitively allowed	II Temporarily allowed
1. (a) Wine of fresh grapes; fresh grape must with fermentation arrested by the tradition of alcohol including wine made of unfermented grape juice blended with alcohol except for wines included in Common Customs tariff subheadings 22.05 A and B and liqueur wines (CCT subheading ex 22.05 C); grape must, in fermentation or with fermentation arrested otherwise than by the addition of alcohol (CCT heading No 22.04)	0.10 - 0.187([1]) - 0.25 - 0.375 0.50 - 0.75 - 1 1.5 - 2 -3 4 - 5 6 – 8 - 9 - 10	0.35 - 0.70 - 0.73 1.25
(b) 'yellox' wines entitled to use the following designation of origin : 'Cotes du Jura', ' Arbois' , 'L'Etoile' and 'Chateau - Chalon'	0.62	
(c) Other non-sparkling Beverages, for example,Cider, perry and mead (CCT subheading 22.07 B II)	0.10 - 0.25 - 0.375 0.50 - 0.75 - 1 1.5 - 2 - 5	0.35 – 0.70
(d) Vermouths and other Wines of fresh grapes flavoured with aromatic extracts (CCT heading No 22.06); liqueur wines (CCT subheading ex 22.05 C)	0.005 up to 0.10 0.10 - 0.20 - 0.375 0.50 - 0.75 - 1 1.5 3 - 5	
2. (a) - Sparkling wines (CCT subheading 22.05 A)	0.125 - 0.20 - 0.375 0.75 - 1.5 - 3	0.10 - 0.25 - 0.70
- Wine in bottles ' mushroom ' stoppers held in place by ties or fastenings, and wine otherwise put up with an excess pressure of not less than one bar but less than one bar but less than three bar, measured at a temperature of 20 °C (CCT subheading 22.05 B)	4.5 - 6 - 9	
(b) Other fermented sparkling Beverages, for example, cider, perry and mead (CCT subheading 22.07 B I)	0.10 - 0.20 - 0.375 0.75 - 1 - 1.5 3	0.125

[1] Value relating only to consumption on board aircraft, ships and trains and to sales in duty-free shops.

Liquids	Nominal volume of contents in litres	
	I Definitively allowed	II Temporarily allowed
3. (a) Beer made from malt (CCT heading No 22.03), excluding acid beers	0.25 - 0.33 - 0.50 0.75 - 1 - 2 3 - 4 - 5	0.35
(b) Acid beers, gueuze	0.25 - 0.375 - 0.75	
4. Spirits, other than those of (CCT headings No 22.08); liqueurs and other spirituous beverages; compound alcoholic preparations (known as 'concentrated extracts') for the manufacture of beverages (CCT heading No 22.09)	0.02 - 0.03 - 0.04 0.05 - 0.10 (2) 0.20 - 0.50 - 1 1.5 - 2 - 2.5 3 0.35 - 0.70 - 1.125 (2) - 4.5 - 5 (2) - 10 (2)	
5. Vinegar and substitutes for vinegar (CCT heading No 22.10)	0.25 - 0.50 - 0.75 1 - 2 - 5	
6. Olive oils (CCT subheading 15.07 A), other edible oils (CCT subheading 15.07 D II)	0.25 - 0.50- 0.75 1 - 2 - 3 5 - 10	
7. - Milk, fresh, not concentrated or sweetened (CCT heading ex 04.01), excluding yoghourt, kephir, curdled milk, whey and other fermented or acidified milk - Milk- based beverages (CCT subheading 22.02 B)	0.20 - 0.25 - 0.50 0.75 - 1 - 2	0.10
8. (a) Water, including spa waters and aerated waters (CCT heading No 22.01)	0.125 - 0.20 - 0.25 0.33 - 0.50 - 0.75 1 - 1.5 - 2	all volumes below 0.20 - 0.35 - 0.45 0.46 - 0.70 - 0.90 0.92 - 1.25
(b) Lemonade, flavoured spa waters and flavoured aerated waters and other non-alcoholic beverages not containing milk or milk fats, (CCT subheading 22.02 A) excluding fruit and vegetable juices falling within CCT heading No 22.07 and concentrates	0.125 - 0.20 - 0.25 0.33 - 0.50 - 0.75 1 - 1.5 - 2	all volumes below 0.20 - 0.70

(2) Values intended exclusively for trade use.

Liquids	Nominal volume of contents in litres	
	I Definitively allowed	II Temporarily allowed
(c) Beverages labelled as alcohol-free aperitifs	0.10	
9. Fruit juices (including grape must) Or vegetable juices, whether or not containing added sugar, but unfermented and not containing spirit falling within CCT subheading 20.07 B, Fruit Juices and Similar Products Order, 1998 (LN 242 of 1998)	0.125 – 0.20 – 0.25 0.33 – 0.50 – 0.75 1 – 1.5 - 2	all volumes below 0.125 – 0.70 0.18 – 0.35 (in cans only)