

On the basis of article 25 paragraph 2 and article 26 paragraph 2 the Law on Metrology („Official Gazette of MNE” no. 79/08), Ministry of Economy has adopted

RULEBOOK ON PREPACKAGED PRODUCTS *

(The Rulebook has been published in the „Official Gazette of Montenegro”, No. 56/2011, dated 25 November 2011)

Article 1

This Rulebook prescribes metrological requirements which have to fulfill by the quantities of prepackaged products, kind of marking of the quantities and permissible error of actual quantities from the indicated nominal quantities, the list of nominal quantities of the prepackaged products, the size, form and kind of placing of conformity assessment mark of prepackaged products, such as procedure of testing and kind of documenting of assessments the quantity of prepackaged products with prescribed requests.

Article 2

The prepackaged product is the combination of a product and the individual package in which it is pre packed.

The quantity of contents is quantity of products at the prepackaged products expressed by the numeric value and legal measuring units.

The nominal quantity (nominal weight or nominal volume) of the contents (Q_n) 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.

The constant nominal quantity is nominal quantity of products which remain the same during the lifetime of prepackaged products.

The actual quantity (actual weight or actual volume) of the prepackage is the quantity of product which it in fact contains.

The obligatory values of nominal quantities of contents are the values of nominal quantities of contents which are prescribed as obligatory.

The drained mass of products is the mass of contents at the prepackaged products which is considered after draining of filled liquid, after certain time.

The batch of prepackaged products includes all prepackaged products of the same nominal quantity, the same kind, produced at the same production cycle and filled at the same place.

The packer is the subject which fills the products at the storing cover, creating prepackaged product, before putting in the market.

The negative error of a prepackaged (T) is the quantity by which the actual contents of the prepackage are less than the nominal quantity.

The tolerable negative error in the contents of a prepackage (T1) is the tolerable negative error of actual quantity of the contents from the nominal quantity of the contents, for the certain acceptable limit of error.

The limit of tolerable negative error of the quantity of content (T1) is the quantity of the content which is equal to the difference of nominal quantity of products (Qn) and the double tolerable negative error (T2%).

The limit of non tolerable quantity of content (T2) is the quantity of content which is equal to the difference of nominal quantity of content (Qn) and the double tolerable negative error (2xTNE).

The acceptable level of quality (AQL) is the maximum tolerable percentages of prepackaged products at the batch which is not fulfilling the metrology requirements, by which the batch will be accepted by the statistical testing.

Article 3

This Rulebook relates to prepackaged products intended for sale in constant unit nominal quantities which are:

- 1) equal to values predetermined by the packer;
- 2) expressed in units of weight or volume;
- 3) not less than 5 g or 5 ml and not more than 10 kg or 10 L.

This Rulebook is not related to the:

- 1) prepackaged products which are intended for the supply of trains, ships and airplanes;
- 2) prepackaged products which are packed for the final consumer and the basis of the contracts;
- 3) free of charge sample which are indicated as the free of charge;
- 4) prepackaged products which contain the drugs;
- 5) prepackaged products which contain poisons and explosive products;
- 6) prepackaged products sale at the duty free stores.

Article 4

If the products is placed at the liquid filled (water, salted water, acid, fruit and vegetable juice at the conserves), beside the total quantity of the content, on that prepackaged products shall be also indicated and drained quantity of the product.

The drained quantity of the weighed products shall be expressed at the :

- 1) volume measuring units, in the case of liquid (liter, centiliter or milliliter);
- 2) mass measuring units, in the case of other products (kilogram or gram).

Liquid filled in, can be at liquid, frozen or deep frozen state.

Article 5

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.

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

- 1) the actual contents shall not be less, on average, than the nominal quantity;
- 2) the proportion of prepackages having a negative error greater than the tolerable negative error indicated at the table, shall be smaller than 2% for batches of prepackages to satisfy the requirements of the tests specified in Annex I which is integral part of this Rulebook.

Tolerable negative error of certain nominal quantity is as follow:

Nominal quantity Qn [g] or [ml]	Tolerable negative error	
	% from Qn	[g] or [ml]
5 to 50	9	-
50 to 100	-	4,5
100 to 200	4,5	-
200 to 300	-	9
300 to 500	3	-
500 to 1000	-	15
1000 to 10000	1,5	-

When 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 milliliter.

No prepackage having a negative error greater than twice the tolerable negative error, may bear the conformity sign mentioned at the article 8 of this Rulebook.

Article 6

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.

By prepackaged products which content is marked as drained mass, only drained mass will be measured.

The prescription of paragraph 2 of this article, is not apply to deep frozen or frozen products, the quantity of which is expressed in units of volume.

Article 7

The marking of prepackaged products shall be affixed in such a manner as to be indelible, easily legible and visible on the prepackage.

The marking of quantity of contents is not permitted using the prefix „minimum” „circa” or „G/N” (bruto/neto).

The nominal quantity of prepackaged products shall be expressed in numbers, after it the legal measuring unit or sign of units will be placed.

The size of mark presenting the nominal quantity of prepackaged products shall be as follow:

Nominal quantity Qn		The size of mark
[g]	[cl]	[mm]
Qn <= 50	Qn <= 5	2
50 < Qn <= 200	5 < Qn <= 20	3
200 < Qn <= 1000	20 < Qn <= 100	4
Qn > 1000	Qn > 100	>= 6

Article 8

The prepackaged products which fulfill the requirements of this Rulebook can be marked by conformity marks, 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.

Placing of conformity mark, the packer or the importer constituting a guarantee that the prepackage meets the requirements of this Rulebook.

The look and form of the conformity mark "e" is given at Annex 2 which is integral part of this Rulebook.

Article 9

The conformity mark "e" can be used to mark prepackaged products:

- 1) of the same nominal quantity of content;
- 2) if nominal quantities of content are no less than 5 g or 5 ml, or greater than 10 kg or 10 liters;
- 3) if the value of the quantity is stated in prescribed measurement units;
- 4) if the marks correspond to the sizes prescribed in Article 7 paragraph 4 of this Rulebook;
- 5) if the testing with the appropriate measuring instruments is being conducted periodically;

- 6) after noticing and submitting documentation of prepackaged products compliance with metrology requirements to the Bureau of Metrology (hereinafter: the Bureau);
- 7) if the required metrological tests from section 2.2 of Annex 1 of this Rulebook have been passed.

Prepackaged products that have a negative error greater than twice of the tolerable negative error, mentioned in Article 5 of this Rulebook, shall not be subjected in commercial activities and must be removed from the market, regardless of whether they are marked with the conformity mark "e".

Article 10

Testing of prepackaged products is performed by the manufacturer, importer or his agent at retail facilities and at the laboratory of the Bureau.

Testing of prepackaged products includes:

- 1) determining the size of the batch under the assumption that they are homogeneous;
- 2) taking the appropriate sample randomly;
- 3) determining the mean value of packaging weight in which the prepackaged product is packed;
- 4) determining the mean value of the nominal quantity;
- 5) examining the deviation of the actual quantity from nominal quantity.

If testing is done by the manufacturer, checking of quantity of content is done immediately after the finishing of production.

Finishing of production is a period of time, from the moment of putting the product in packaging to the moment that the contents of prepackaged products stabilizes (technologically, biochemical and biologically), after which it can be used.

A statement about the date of finishing of production is taken from data which is supplied by the manufacturer directly from the production facility or documents of the manufacturer.

Article 11

Manufacturer prepares a report on conformity testing of prepackaged products with the metrological requirements, in accordance with the rules of quality systems.

The report referred to in paragraph 1 of this article should contain the following information:

- 1) name and address of packer of the prepackaged products;
- 2) name of the product (type, nominal quantity of content, packaging label);
- 3) weight of packaging in which the prepackaged products has been previously packed;
- 4) mean value of quantity of content;

- 5) deviation from the prescribed value;
- 6) date and time of testing;
- 7) signature of the person who performed the test.

The report on conformity testing of prepackaged products with the metrological requirements should be kept by the manufacturer until the next inspection.

Article 12

Packer or importer shall ensure that prepackaged products meet the requirements of this Rulebook.

Importer of prepackaged products can, instead of measuring and testing, obtain documentation issued by relevant institutions abroad, submit it to the Bureau, after which prepackaged products can be put on the market.

The quantity of product contained in the prepackaged product is examined by measuring the weight or volume, using legal measuring instruments which have appropriate metrological characteristics for performing the necessary procedures.

Metrological characteristics of legal measuring instruments, mentioned in paragraph 3 of this article, which are used for testing, are given in Annex 3 which is an integral part of this Rulebook.

Article 13

Prepackaged products of the same nominal quantity, can be manufactured, imported or placed on the market only if they, at the time of completion of the production, meet the following criteria:

- 1) the actual amount of the charge are not on average less than the nominal amount of filling, or the mean value of prepackaged product in the group is not less than the nominal amount of charge;
- 2) the limits of negative tolerable error (T1), are not exceeded;
- 3) twice the value of negative tolerable error (T2), is not exceeded.

Article 14

Prepackaged products are proper if:

$$Q \geq Q_n$$

$$Q \geq T_1 \quad T_1 = Q_n - T$$

Prepackaged products are inconsistent if:

$$T_1 \geq Q > T_2 \quad T_2 = Q_n - 2xT$$

Prepackaged products are defective if:

$$Q \leq T_2$$

Where:

Q-actual quantity of content

Q_n-nominal quantity of content

T- tolerable negative error
T1-limit of tolerable negative error
T2-limit of double tolerable negative error

If it is confirmed that the prepackaged product is defective, the entire batch of products should be withdrawn from the market.

Article 15

The testing of prepackaged products, is based on a sampling method, which is given in Annex 1 of this Rulebook.

Each batch must include samples of product units produced in the same conditions.

Article 16

The actual content of prepackaged products can be measured directly, using legal measuring instruments or in the case of liquids, indirectly by weighing of prepackaged products and measuring their density.

Measurement error of actual quantity content of packaged product should not exceed one fifth of tolerable negative error for the nominal quantity of prepackaged product.

Article 17

Prepackaged products can be placed in the market if they are pre packed in the accordance with prescribed nominal quantities.

Where two or more individual prepackages make up a multi pack, the nominal quantities shall apply to each individual prepackage.

The obliged nominal quantities value of prepackaged products have been listed at the Annex 4 which is integral part of this Rulebook.

Article 18

Aerosol dispensers shall indicate the nominal total capacity of the container, which shall be such as not to create confusion with the nominal volume of the contents.

Prepackaged products which are in the form of aerosol dispenser, intended to putting in the market, need not to be marked with the nominal weight of their contents.

Article 19

This Rulebook shall enter into force on the eight day following its publishing in the "Official Gazette of Montenegro".

Number: 0904 – 2155/5
Podgorica, 17 November 2011.

Minister, Vladimir Kavacic, PhD

** In this Rulebook the Council Directive 76/211/EEC 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 and Directive 2007/45/EC Of the European Parliament and of the Council of 5 September 2007 laying down Rulebook on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC, have been transposed.*

THE METHOD OF TESTING OF PRAPACKAGED PRODUCTS

For the purpose of testing of prepackaged products the following criteria shall be fulfilled:

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.

2. Requirements for checking batches of prepackages

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

- 1) a check covering the actual contents of each prepackage in the sample,
- 2) another check on the average of the actual contents of the prepackages in the sample.

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

- 1) one for non-destructive testing, i.e., testing which does not involve opening the package,
- 2) 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.

A batch of prepackages shall be considered acceptable if the results of both these checks satisfy the acceptance criteria, as declared at the point 2.2 of this Annex.

2.1. Prepackage batches

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.

For batches of fewer than 100 prepackages, the non-destructive test, where carried out, shall be 100 %.

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 1:

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

Table 1. Non-destructive testing in accordance with a 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:

- 1) is less than or equal to the first acceptance criterion, the batch shall be considered acceptable for the purpose of this check,
- 2) is equal to or greater than the first rejection criterion, the batch shall be rejected,
- 3) 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:

- 1) less than or equal to the second acceptance criterion, the batch shall be considered acceptable for the purpose of this check,
- 2) greater than or equal to the second rejection criterion, the batch shall be rejected.

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.

Destructive testing shall be carried out in accordance with a single sampling plan as shown in the table 2:

Number in batch	Number in sample	Number of defective units	
		Acceptance criterion	Rejection criterion
≥ 100	20	1	2

Table 2. Destructive testing in accordance with a single sampling plan

The number of prepackages checked shall be equal to 20, If the number of defective units found in the sample is:

- 1) less than or equal to the acceptance criterion, the batch of prepackages shall be considered as acceptable.
- 2) equal to or greater than the rejection criterion, the batch of prepackages shall be rejected.

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:

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

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:

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

- 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, are presented at the table 3 and 4.

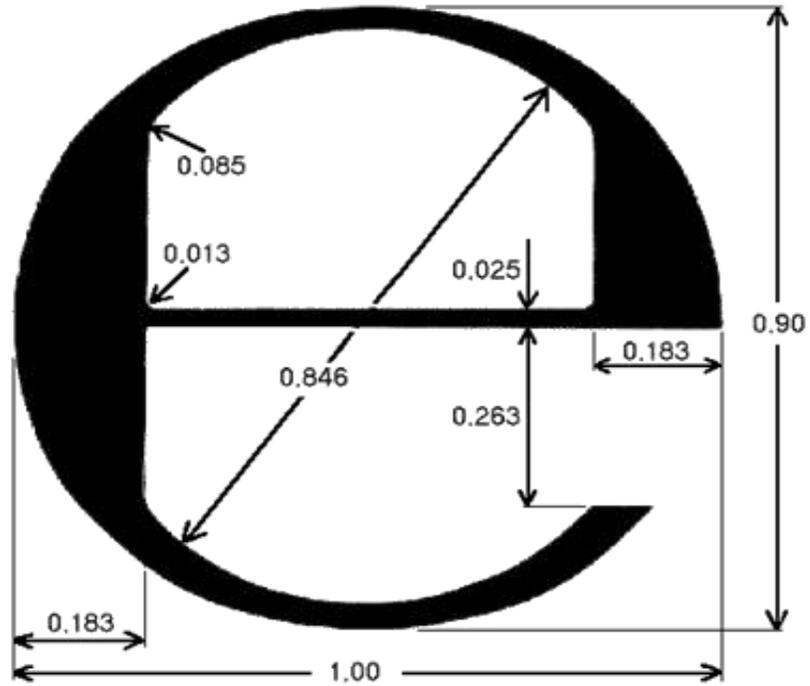
Number in batch	Number in sample	Criteria	
		Acceptance	Rejection
100 to 500 (inclusive)	30	$x \geq Q_n - 0.503s$	$x < Q_n - 0.503s$
> 500	50	$x \geq Q_n - 0.379s$	$x < Q_n - 0.379s$

Table 3. Criteria for non-destructive testing

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

Table 4. Criteria for destructive testing

The CONFORMITY MARK „e”



The smallest size of the mark is 3 mm

METROLOGICAL CHARACTERISTICS OF LEGAL MEASURING INSTRUMENTS USED FOR TESTING OF PREPACKAGED PRODUCTS

The legal measuring instruments from the article 12 paragraph 3 of this Rulebook can be used for the testing if they have a Certificate of verification and if the error of measurements is not higher then 1/5 of tolerable negative error (T2%) of nominal quantity of content of prepackaged products which are tested.

If the non automatic weighing instruments will be used as the control instruments, the value of the scale of verification („e”), shall not be higher then the values declared at the table 5.

Nominal quantity Q_n [g] or [ml]	Maximum tolerable value of the scale of verification [g]
5 to 10	0,1
10 to 50	0,2
50 to 150	0,5
150 to 500	1,0
500 to 2500	2,0
2500 to 10000	5,0

Table 5. The value of the scale of verification („e”) by the non automatic weighing instruments

If the automatic weighing instruments will be used as the control instruments, then the sum of the maximum tolerable error of automatic balance during the operation and a half of nominal area of selectivity of the automatic balance shall not be higher then 1/5 of tolerable negative error (T2%) of tested prepackaged products.

This sum can not be less then 0,6 g.

For the testing of non packed backer products and the products without any cover, the balances used at the stores and shops can be used as the control balances.

If the measuring vessels will be used for the direct determination of the volume of the nominal content of prepackaged products, the value of the scale of verification („e”), shall not be higher then the values declared at the table 5 of this annex.

ANNEX 4

RANGE OF NOMINAL QUANTITIES OF CONTENTS OF PREPACKAGES

Still wine	On the interval from 100 ml to 1500 ml only the following 8 nominal quantities: [ml] 100 — 187 — 250 — 375 — 500 — 750 — 1000 — 1500
Yellow wine	On the interval from 100 ml to 1500 ml only the following nominal quantity: [ml] 620
Sparkling wine	On the interval from 125 ml to 1500 ml only the following 5 nominal quantities: [ml] 125 — 200 — 375 — 750 — 1500
Liqueur wine	On the interval from 100 ml to 1500 ml only the following 7 nominal quantities: [ml] 100 — 200 — 375 — 500 — 750 — 1000 — 1500
Aromatized wine	On the interval from 100 ml to 1500 ml only the following 7 nominal quantities: [ml] 100 — 200 — 375 — 500 — 750 — 1000 — 1500
Spirit drinks	On the interval from 100 ml to 2000 ml only the following 9 nominal quantities: [ml] 100 — 200 — 350 — 500 — 700 — 1000 — 1500 — 1750 — 2000

1. The products which are sold on the basis of the volume in [ml]

Still wine	(2204, except 220410, 220421 to 220429) *
Yellow wine	2204 * (The wine of kind „Vins jaunes” which are marked as "Côtes du Jura", "Arbois", "L'Etoile" and "Château-Chalon")
Sparkling wine	220410 *
Liqueur wine	(220421 to 220429) *
Aromatized wine	2205 *
Spirit drinks	2208 *

2. The definition of the products which are sold on the basis of the volume

*A tariff mark, on the basis of the Order on harmonization of the custom nomenclature tariff for the year 2011. („Official Gazette of MNE” no. 79/10 and 31&11).