

Chapter 1 – Introductory provisions

§ 1. Scope

This regulation prescribes rules for use of the e-mark as mentioned in annex 3 for labelling of prepackages, and requirements to the net content of prepackages which does not use the e-mark.

This regulation applies to prepackages which contains products which will be sold in constant nominal quantities which

- a) has the same value as the packer has decided,
- b) is expressed in units of weight or volume and
- c) is between 0 grams and 50 kilograms, or between 0 milliliters and 50 litres. Prepackages which use the e-mark must be between 5 grams and 10 kilograms, or between 5 milliliters and 10 litres.

This regulation does not apply to Svalbard.

§ 2. Definitions

In this regulation, the following definitions apply:

- a) *Prepackage*: the combination of a product and the individual package in which it is packed, when it is packed without the purchaser being present and the quantity of the product contained in the package has a predetermined value, and cannot be altered without the package either being opened or undergoing a perceptible modification.
- b) *Packer*: The responsible party for filling the product in the package.

Chapter 2 – Acceptance and use of the e-mark

§ 3. Acceptance of prepackages which are e-marked

Prepackages which satisfy the requirements of this regulation, can not for reasons regarding the marking required on the product, determination of the weight or volume of the product or the methods applied regarding the measuring and control in accordance with this regulation, be denied or restricted access to the market in this country.

§ 4. Requirements to e-mark prepackages

Prepackages can be marked with the e-mark as described in annex 3, if they fulfill the requirements of annex 1, points 1-3, and is subjected to metrological control as mentioned in annex 1, points 4-5 as well as annex 2.

§ 5. Message regarding use of the e-mark

Packers or importers, which wants to e-mark or import e-marked prepackages, shall report such use of the e-mark to the Norwegian Metrology Service. The e-mark can not be initiated or the e-marked products marketed before the message is approved.

The message shall include necessary information for Justervesenet to consider whether the packer or importer satisfy the requirements of this regulation. Justervesenet may prescribe further rules of which information the message shall include.

The provision of the first subsection does not apply to prepackages where the e-mark has been applied in another EEA state.

§ 6. *Inspection with the use of the e-mark*

Justervesenet may carry out metrological control and inspection at the facilities of the packer or importer, cf. annex 1 point 5.

§ 7. *Responsible party*

The packer or importer is responsible for ensuring that the prepackages fulfill the requirements to e-marking.

§ 8. *Reactions if the regulatory framework is violated*

Justervesenet may issue an order for the packer or importer to stop the use of the e-mark or sale of e-marked products if the prepackages do not satisfy the provisions of this regulation. The packer or importer can also be ordered to withdraw consignments from the point of sale.

Orders as mentioned in the first subsection can also be imposed on the seller of the e-marked prepackages.

Violation of the requirements of this regulation may result in order of infringement penalty, determined by the provisions of regulation December 20th 2007 nr. 1723 about measuring units and measuring, chapter 7.

Chapter 3 – Requirements for prepackages which are not e-marked

§ 9. *Requirements to net content and inspection*

Prepackages shall fulfill the requirements to net content in annex 1 points 1 and 2.

Prepackages shall be subject to metrological control as mentioned in annex 1 point 4.

§ 10. *Inspection of prepackages*

Justervesenet may carry out metrological control and supervision at the facilities of the packer or importer, cf. annex 1 point 5.

§ 11. *Responsible party*

If the prepackage is packed in Norway, the packer is responsible for ensuring that the prepackages fulfill the requirements to net content.

If the prepackage is packed outside of Norway, the importer is responsible for ensuring that the prepackages fulfill the requirements to net content

§ 12. Reactions if the regulatory framework is violated

Justervesenet may issue an order to the responsible party to fulfill the requirements to net content, to stop the sale of prepackages or withdraw consignments from the point of sale, if the prepacked products do not satisfy the requirements to net content.

Orders as mentioned in the first subsection can also be imposed on the seller of the prepacked products.

Violation of the requirement of net content of the prepacked products may result in order of infringement penalty, determined by the provisions of regulation December 20th 2007 nr. 1723 about measuring units and measuring chapter 7.

Chapter 4 – Miscellaneous provisions

§ 13. Fee

The processing of the message, application, control and supervision as mentioned above shall be charged as specified in regulation about measuring units and measuring § 6-4.

§ 14. Commencement

This regulation enters force on January 1st 2008.

Annex 1 to the regulation on requirements to net content etc. of prepackages

Requirements for content and marking of the prepackage

1. *Definitions*

- 1.1. The *nominal quantity* Q_n of the prepackage t is the weight or volume indicated on the package.
- 1.2. The *actual contents* of the prepackage is the quantity (expressed as weight or volume) of the product which the package in fact contains. With the exception of frozen products, the value employed for the actual contents shall be measured at or corrected to a temperature of 20 °C.

1.3. The *negative error* of the prepackage is the difference between the actual contents and the nominal quantity, when the actual contents is lowest)

2. *General requirements for net content*

The packing of the prepackages shall be secured in such a way that they fulfill the following requirements:

- 2.1. The actual contents shall not be less, on average, than the nominal quantity.
- 2.2. The proportion of prepackages having a negative error greater than the tolerable negative error laid down in table 1, shall be sufficiently small for batches of prepackages to satisfy the requirements of the tests specified in annex 2.
- 2.3. No prepackages having a negative error greater than twice the tolerable negative error given in table 1 may bear the e-mark.

The tolerable negative error in the contents of a prepackage is laid down in accordance with table 1.

The values of the tolerable negative errors given as percentages in the table, is calculated in units of weight or volume and rounded up to the nearest tenth of a gram or milliliter.

Table 1: Negative tolerances for prepacked products

Nominal quantity Qn in grams (g) or milliliters (ml)	Negativ tolerance	
	i percentage of Qn	in 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 10.000	1,5	-
10.000 to 15.000	-	150
15.000 to 50.000	1	-

3. *Inscriptions and markings*

All prepackages with liquid content shall be affixed content as nominal volume. Other prepackages shall normally be affixed nominal weight.

All prepackages made up in accordance with this regulation shall bear on the package the following markings:

- 3.1. The nominal quantity (in weight or volume) expressed in kilograms (kg), grams (g), litres (l), centilitres (cl) or millilitres (ml), and marked in figures at least:

6 mm high if the nominal quantity exceeds 1000 g/100 cl,

4 mm high if the nominal quantity is 1000 g/100 cl or less, but more than 200 g or 20 cl,

3 mm high if the nominal quantity is 200 g/20 cl or less, but more than 50 g/5 cl,

2 mm high if the nominal quantity is less than 50 g/5 cl.

The number shall be given first, followed by the symbol for the unit of measurement used.

As long as the imperial system is allowed in the EU, indication of the nominal quantity as well as the above stated may be followed by a conversion to imperial units, using the following conversion coefficients:

1 ml = 0,0352 fluid ounce

1 l = 1,760 pints or 0,220 gallon

1 g = 0,0353 ounce (avoirdupois)

1 kg = 2,205 pounds.

Markings in imperial 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 which enables identification of the packer or the responsible party for the packing, or the importer established in the EEA area.

A small 'e', as shown in annex 3, at least 3 mm high, placed in the same field of vision as the indication of the nominal weight or volume. This constitutes a guarantee that the prepackage meets the requirements of this regulation.

4. *Responsibility of the packer or importer*

The business which packs the prepackages or the party responsible for this packing, or the importer, is responsible for ensuring that the prepackages meet the requirements of this regulation. This party is responsible for ensuring that the actual contents of the prepackages are measured or checked.

The measurement or check shall be carried out by means of a legal measuring instrument which fulfills the requirements given in or in pursuance of the regulation on units of measuring and measurements.

Where the actual contents of each single prepackage is not measured, the check may be carried out by sampling. Other systems of inspection which ensures that the content of the prepackages fulfils the requirements of the regulation, may be employed. Sampling or other systems of inspection shall be performed according to guidelines approved by Justervesenet, and the results of the controls shall be written down and archived. Justervesenet shall have access to this archive to make sure that the controls are performed regularly and correctly.

The packer is obligated to follow the approved system for control, and report any changes in the company which may be of significance for the packing to Justervesenet, like changes of the control system, new filling methods or new equipment to be used for packing.

Products with quantities expressed in units of volume may fulfill the duty to control the measurement by filling in bottles used as measuring containers after the requirements of regulation December 22nd 2007 nr. 1732 on bottles used as measuring containers, cf. directive 1975/107/EC, and the requirements of this regulation.

For products imported 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.

5. *Checks to be made by the competent authority on the premises of the packer or importer*

Checks to ensure that the prepackages comply with the requirements of this regulation shall be carried out by sampling on the packer's or importers premises. This statistical sampling check shall be carried out in accordance with the rules in annex 2. Other methods may also be used, if the method is approved by Justervesenet and considered to be as effective as the method in annex 2.

The method is considered as effective as the method in annex 2 when the following requirements are fulfilled:

- 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 2.
- If, taking into account the operating characteristic curves of the two plans having as the abscissa axis $(Q_n - m)/s$
- (m = the actual average quantity of the batch
 Q_n = nominal quantity
 s = standard deviation to the actual content of the batch)

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 2.

Annex 2 to the regulation on requirements to net content etc. in prepacked products

The inspection by Justervesenet of the prepackages.

This annex lays down the procedures of the statistical check of batches of prepackages in order to meet the requirements of annex 1.

1. 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 of the package.

2. Inspection of 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 prepacked product in the sample,
- another check on the average of the actual contents of the prepacked products in the sample.

A batch of packages 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.

Destructive testing shall be limited to an absolutely essential minimum, i.e. only when non-destructive tests is impracticable. Destructive tests is normally not used on batches of less than 100 units.

2.1. Division into bathces of prepackages

- 2.1.1. A batch comprises all prepackages of the same nominal quantity, the same type and the same manufacture, 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 units.

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 point 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 samples 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 prepacked product*

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

Prepacked products 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 table 2.

The check starts with the first sample, with the number of units as indicated in the table.

The batch is considered acceptable if the number of defective units in the first sample is less than or equal to the first acceptance criterion. The inspection is finished.

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. The inspection is finished.

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 made. The number of units is indicated in table 2.

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. The inspection is finished.

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

Table 2: Non-destructive inspection of the content of single prepackages.

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

2.2.2. Destructive testing

Destructive testing shall be carried out in accordance with the “single sampling plan” as shown in table 3, and shall be used only for batches of 100 units or more.

The number of prepackages checked shall be 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.

Table 3: Destructive inspection of the content of single prepackages

Number in batch	Number in sample	Number of defective units	
		Acceptance criterion	Rejection criterion
Whatever the number (< 99)	20	1	2

2.3. Inspection of the average content of single prepackages of a batch of prepacked products

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 contents x_i of n prepacked products in a batch is greater than the value:

$$Q_n - \frac{s}{\sqrt{n}} t_{(0,995,v)}$$

where

Q_n is the nominal quantity of the prepackage

n is the number of prepackages in a batch

s is the estimated standard deviation of the actual contents of the batch

$t_{(0,995,v)}$ is the 0,995 confidence level of a student distribution with $v = n-1$, as seen in table 4.

x_i is the actual content of i -th item of a batch of n items.

Table 4: *t*-values

n	$t_{(0,995,v)}$
10	3.25
20	2.86
30	2.76
50	2.68
60	2.66
80	2.64
	2.58

And the standard deviation s is

$$s = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$$

For the criterias for acceptance of non-destructive inspection, see table 5. For the criterias for destructive control, see table 6.

Table 5: Non-destructive inspection of the average of single prepacked products

Number of batch	Number in sample	Criteria	
		Acceptance	Rejection
100 t.o.m. 500	30	$\bar{x} \geq Q_n - 0,503s$	$\bar{x} < Q_n - 0,503s$
> 500	50	$\bar{x} \geq Q_n - 0,379s$	$\bar{x} < Q_n - 0,379s$

Table 6: Destructive inspection of the average of single prepacked products

Number in batch	Number in sample	Criteria	
		Acceptance	Rejection
Alle størrelser > 99)	20	$\bar{x} \geq Q_n - 0,640s$	$\bar{x} < Q_n - 0,640s$

Annex 3 to the regulation on requirements to net content etc. in prepackages

e-mark

The e-mark mentioned in this regulation, shall be designed as shown on the figure below.

The dimensions of the figure is relative to the outer (characterized with length 1 in the figure) diameter of the circle.

