WELMEC 6.6
Issue 2
May 2013

WELMEC

European Cooperation in Legal Metrology

Guide for recognition of procedures

WELMEC

European cooperation in legal metrology

WELMEC is a co-operation between the legal metrology authorities of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to packers, importers and the Competent Departments responsible for ensuring the prepackages meet the specified requirements.

The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EU Directives.

Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

Published by:
WELMEC Secretariat

E-mail: secretary@welmec.org
Website: www.welmec.org

Foreword

WELMEC Working Group 6 was set up to discuss and propose solutions for problems associated with trading of prepackaged goods between EEA countries.
It was decided to produce a guidance that clarifies the approach on packing of non – liquid products by volume.

This document gives guidance on what ‘liquid’ products are, indicates appropriate density measurements techniques for either packers and competent departments. It also gives information on trade practices that exist for non – liquid products packed by volume, especially it indicates different approach to the use of different units of measures in particular prepacked products in EEA countries.

This guidance is intended for packers, importers and competent departments. Information contained in document assist in removal of barriers to trade.

Contents

1 Requirements of a packer's 'e' mark control system

1.1 General

This document contains information about the 'e' mark, applying for recognition, setting up of a procedure of the quantity control system and the standards to be applied.

This document consists of five parts, namely:

Chapter 2 General information on the 'e' mark

Chapter 3 The quantity control system

Chapter 4 Requirements for recognising procedures

Chapter 5 'e' pre-packaging product specification

2 General information on the e-mark

This information is meant for those who produce 'e' marked prepackages after their procedures of a quantity control system have been recognised. Similar rules apply to importers, being those who import 'e' pre-packaging from countries outside the EU[1], but they may also provide evidence that they possess the necessary guarantees that the actual content of the 'e' pre-packaging complies with the standards.

This practice is conforming with the demands of the EC Directives (see Decision of the European Court in Case 96/84 – Approximation of laws – Prepackaged products)."
The whole Guide 6.6 discusses the possibility of a recognition procedure as a possible way to produce prepackages with an "e" Some countries, as the practice shows in DE, FR and GB, state clearly that, in agreement with the EC – Directives, different ways are possible.

More information can be found in WELMEC Publication 6.4, chapter 2.4.3 and WELMEC Publication 6.5, chapter 5.

2.1 What does the e-mark mean?

The 'e' mark on a prepackage means that the prepackage complies with the EU Council Directive 76/211/EEC or 75/106/EEC. These Directives set This Directive sets out requirements for the quantity of product in the prepackage, for labelling and controls.

With the e-mark the manufacturer (or importer) guarantees that the prepackage originates from a batch with a content that meets the requirements of the Council Directives' average principle, which has been agreed within the EEC area.

2.2 What does the average principle mean

The average principle means that:

- the prepackages on average do not contain less product than the quantity indicated on the package;
- only a small number of prepackages contain less product than the quantity specified on the package minus the specified permissible error;
- no prepackage contains less product than the quantity specified on the package minus twice the specified permissible error;

[1] When the EU is mentioned, EEA should be read. Member State refer to Member States of the EU and the countries of the EEA.

The specified permissible error relates to the nominal quantity (Qn) as set out in the table, which can be found at chapter 5.2.

2.3 What prepackages may bear the e-mark

This relates to prepackages manufactured in batches where the contents

- have a previously determined equal nominal quantity;
- are expressed in kg, g, l, cl or ml;
- lie between 5 g and 10kg or 5 ml and 10 l.

2.4 What way can e-marked prepackages be put on the market?

This guarantee is obtained through:

- measuring of the contents of every prepackage at the time of packing, or
- the use of a quantity control system for packing which is recognised by the national authority/Competent Department or
- supervision of the packer (importer) by the national authorities/Competent Department.

2.5 Which departments supervise "e" pre-packaging?

In each Member State the Competent Department has different responsibilities.

WELMEC Publication 6.0 gives guidance on the Competent Departments and their responsibilities.

2.6 Where can information be obtained

In each Member State the Competent Department has different responsibilities.

WELMEC Publication 6.0 gives guidance on this.

2.7 When may the ‘e’-sign be applied on a prepackage

In some Member States permission is necessary before applying the e-mark. In others packers only need to inform their Competent Department.

WELMEC Publication 6.0 gives guidance.

2.8 How can permission be obtained

Contact the Competent Department in the country of packing/import. WELMEC Publication 6.0 gives guidance on this.

2.9 Is the ‘e’ regime mandatory

In some Member States there is no difference between e-marked and non e-marked products. In others non e-marked prepackages must meet other requirements. Use of the "e"-regime is not compulsory under the law. The EU directives are "optional".

If you wish to contact the Competent Department in your country. WELMEC Publication 6.0 gives guidance.

2.10 What are the charges involved in using the e-mark

Packers applying the e-mark for certification should be aware that they will have to pay any applicable charges themselves. Some Member States have different philosophies and do not impose charges.

Contact the Competent Department in your country. WELMEC Publication 6.0 gives guidance.

2.11 How does the assessment of the procedures of the quantity control system take place?

The assessment takes place in 2 phases, namely:

a) documentary assessment of the procedures followed by
b) practical assessment in the form of an on-site inspection by the evaluator

In the event of approval this will result in recognition of the procedures.

2.12 What requirements do the procedures have to meet to be recognized?

The procedures of the quantity control system must be set up in such a way that, when properly applied, it is effectively ensured that the actual contents of the prepackages comply with the average principle.

Requirements have been set for, among other things:

- the procedures of the quantity control system itself;
- the accuracy of the control measuring devices;
- the sampling procedures;
- the handling of the sample results.

2.13 The advantages and disadvantages if the ‘e’ regime for the packer

Advantages:

- a single standard for the whole EEC area
- the average principle
- hallmark of correct filling

Disadvantages:

- there may be an investment required in control resources and/or in
- manpower

2.14 How must the data be recorded

The general rule is that:

- the records must show that the procedures of the procedures of the quantity control system are actually implemented as they were recognized
- a number of basic details must be recorded such as date, time, machine, product, quantity, etc.
- the extent to which there is compliance with the average principle should be demonstrated;
- it must be clearly stated which permitted corrections have been carried out and what the result of these were

- the records must be clearly comprehensible and it must be kept for at least a year from the date on which they were created.

Possible methods of recording measurement data are:

- manual records on control sheets or control cards;
- semi-automatic recording on a computer and printer linked to the control weighing device;
- automatic recording using, for example, a checkweigher.

2.15 What is the size of a batch?

For practical reasons, the packer and the inspector define the size of the batch in different ways.

Inspector's definition: when checking at the end of the packing line, the number of prepackages in each batch shall be equal to the maximum hourly output of the packing line, without any restrictions as to the batch size. In all other cases, the batch size shall be limited to 10 000 prepackages.

Packer's definition: the packer can define the size of his batch according to his needs and his system for identifying prepackages belonging to the batch. The requirements for e-marking shall be fulfilled for any defined batch.

2.16 Density measurement of liquids in the company control system

If prepackaged liquids are checked by weighing and are converted to volume using density then the methodology for density measurement and the associated measurement devices must be included in the assessment of the company control system.

2.17 Which control measurement devices are generally used?

- a non-automatic weighing instrument
- a checkweigher
- a automatic gravimetric filling instrument
- a volumetric measure
- An EEC measuring container bottle with accompanying measurement template.

2.18 If production is checked using random checks, how many samples must there be in the random check and how often must the random check be carried out?

The packer chooses the size and frequency of the random sample so long as he can demonstrate that the filling process is able to ensure effectively that the batches comply with the tolerances.

A number of factors, which may be taken into consideration in this, are:

- the stability of the production and/or filling process
- the type of product
- the filling rate
- the number of filler heads
- control of the filling process
- destructive or non-destructive sampling
- mechanical limitations
- degree of over-filling
- reporting time

- batch or continuous process
- corrective actions
- targets
- limits
- set points

2.19 What are the mandatory requirements for the ‘e’ mark

- the nominal quantity marked in figures which are sufficiently large;
- the ‘e’ mark itself in the prescribed form and at least 3 mm high;
- the unit of weight or volume in full or indicated by the correct symbol;
- 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

2.20 desiccating and hygroscopic products

Member States have different philosophies regarding desiccating and hygroscopic products. In some Member States prepackages must meet the requirements at the time of packaging. In other Member States prepackages must meet the requirements at another moment in time.

Packers should ask the Competent Department of their Member State. WELMEC Publication 6.0 gives guidance.

2.21 Can the ‘e’ mark also refer to the drained weight of solids in liquids?

No, the ‘e’ mark only refers to the content (product plus surrounding liquid) of the prepackages at present.

3 General information on the e-mark

3.1 Subject matter and area of applicability

This document lays down the requirements with which the quantity control system must comply, as specified the Council Directive for e-marking. It describes the elements of a company control system. The packer must set up a quantity control system with procedures to ensure that the actual contents of ‘e’ prepackages comply with the Council Directive for e-marking. The procedures of the quantity control system should be recognized. This document specifies the minimum requirements. If the packer or importer makes use of a more extensive or detailed quality system then he may, if desired, continue to make use of it as long as his system also complies with the requirements specified in this document.

3.2 Standard references

- Regulations of the certifying country
- Weights and Measures Act of the Member State
- EN - ISO 8402: Terms and definitions (1994)
- EU Council Directive 76/211/EEC

3.3 Terms and definitions

In this document the definitions and translations of WELMEC Publications 6.1 are used.

3.4 General

The packer or importer must set up procedures that effectively ensure that the e-marked prepackages meet the e-marking requirements. The packer or importer must document the procedures.

The procedures of the quantity control system apply to e-marked prepackages which are packed in the European Union or which are imported from a country outside the European Union. If the requirements specified in this document are in conflict with those, which are specified, in national legislation, then the requirements specified in the national legislation prevail.

3.5 Application

The packer or importer must submit a written application for (provisional) recognition of procedures whenever there is a new or changed quantity control system. The packer or importer must draw up the documents and data for this purpose as indicated in Chapter 4 and send these to the Competent Department.

4 Requirements for recognizing procedures

4.1 Introduction

This chapter describes the subjects that must be addressed by an e-marking packer before they can be considered to be ‘recognized procedures’. In this document the chapters describe these subjects. The ‘procedures’ must be documented before they can be recognized.

Prepackages can only be assumed to comply with the provisions of the Directive (76/211/EEC) when the prepackages have been produced in accordance with the recognised procedures. In other cases the packer must update his procedures and re-apply for recognition of them.

As an alternative to having his procedures recognized, a packer may also measure the contents of every prepackage. Packers applying the e-mark may only do so if they meet the requirements of 76/211/EEC, such as labelling. This Directive also provides for checks to be performed by the Competent Departments..

Different scenarios are suggested for different situations. Combining the alternatives might result in insufficient guarantees that prepackages meet the requirements of the Directive 76/211/EEC.

In the document notes give more guidance to the text. The notes are written in smaller text (or font) and are not requirements.

4.2 General information

legal name of packer	:	...
address of head office	:	…
postal address	:	...
		...
place of packing	:	...
		...
contact person	:	...
his/her function	:	...
phone	:	...
fax	:	...
e-mail address	:	…
Competent Department	:	...
date of first recognition	:	...

4.3 Packing lines

The following information is required per packing line:

- packers name for the filling line
- details of the prepacked product
  - name (generic name)
  - main components of the product (example: fruit, yoghurt, nuts, etc.)
  - physical properties (example: liquid, shrinking, deep frozen, etc.)
- packaging materials
  - type of packaging (glass, can, cardboard, PE foil, etc.)
  - indication of the deviation of the packaging material
- nominal quantity and the target value
  - smallest quantity
  - largest quantity
  - target value
- filling process
  - type of filling machine

- rate of filling and the number of prepackages per hour
- the number of filler heads
- smallest adjustment facility
- indication of the process deviation

Remark: a packing line can be made up out of several filling machines, if they pack the same product.

4.4 Measuring instruments

The measurements of the content of prepackages, the density of liquid product, the weight of packaging materials and other relevant measurements must be carried out by means of a legal and suitable measuring instrument.

Some measuring instruments are not subject to legal metrology. Depending on national situations equipment like for temperature measurement will not be controlled by legal metrology institutes. For those measuring instruments a different maintenance and calibration regime is necessary. The packer shall organize this regime in line with the conditions of use and behaviour.

The word "suitable" includes a number of conditions of use that arise from the need to limit the uncertainty of measurement. Example: the verification scale interval of a weighing instrument is related to the nominal quantity of product; if a company uses a larger verification scale interval they must compensate (e.g. overfill).

Measuring instruments must be checked on a regular basis by an accepted method to verify that they meet specifications.

The frequency of calibration can be determined in accordance with international standards on measurement uncertainty.

For checkweighers and multiheads separate procedures are available. For glass measuring instruments usually one calibration is sufficient. Non-automatic weighing instruments usually are calibrated 2 to 6 times per year.

Calibration does not have to be performed by an external calibration laboratory. With the right written procedures the packer can do it himself. Calibrations must be traceable to (inter)national standards. The method of calibration is often available from the supplier of the measuring instrument.

4.5 The recognized procedures

4.5.1 Definitions

All definitions are listed in WELMEC Publication 6.1.

batch

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.

lot

A lot consist of the number of the same prepackages with the same nominal quantity one filling line produces in one hour.

A lot that has been stored consists of the maximum of 10.000 of the same prepackages with the same nominal quantity.

sample

A number of prepackages drawn at random from the batch.

individual package

Individual package is everything that is meant to be left after use of the prepackage, except for items naturally in the product. Use includes consumption or subjecting to a treatment.

A prepackage is the combination of product and packaging materials. The definition of "individual package" is here to distinguish between product and packaging materials.

4.5.2 The measuring and sample methods

An employee of the packer must draw a sample of enough items of the running production on a regular basis. The content of each item in the sample is determined. Parts of this may be automated (for instance by using a checkweigher). The measuring instrument used is specified under the chapter "measuring instruments".

Sampling Frequency
The sampling frequency depends on the deviation of the filling process and the number of adjustments, but it should be at least once an hour and after adjustment. In certain situations (for instance bottle filling carousels that cannot be adjusted) a lower frequency might be possible.

Checks must be carried out before the prepackages are distributed.

Sample size
The sample size can be calculated with this formula:

$$n \geq \frac{(t_{n-1}0{,}995)^2 \times S^2}{(\text{nominal quantity} + \text{overfill} - \text{rejection limit of Competent Department})^2}$$

where:

sample size Competent Department	$t_{n-1}0{,}995$	rejection limit Competent Department (where S = estimation of standard deviation and Q_n is nominal quantity)
20	2,862	$Q_n - 0{,}640 \times S$
30	2,757	$Q_n - 0{,}503 \times S$
50	2,680	$Q_n - 0{,}379 \times S$
80	2,640	$Q_n - 0{,}296 \times S$

This calculation does not take into account subjective aspects like the packers experience and knowledge of the filling process. When this is taken into account a lower sample size might be possible.

example:

nominal quantity = 1000, standard deviation = 3, overfill = 1:
$\text{sample size} \geq \frac{2{,}640^2 \times 3^2}{(1000 + 1 - [1000 - 0{,}296 \times 3])^2} \Rightarrow \text{sample size} \geq \frac{62{,}73}{3{,}56} \Rightarrow \text{sample size} \geq 17{,}6$

Overfill

The target quantity (nominal quantity + overfill) should be the greatest of :

- the nominal quantity
- TU1 + 2 x S
- TU2 + 3,72 x S

Where ‘S’ is the estimation of the standard deviation of the production process, which might also include allowances for measurement uncertainty. If the standard deviation is larger than (target quantity – TU1) the standard deviation must be monitored.

When packaging materials are used the weight of the packaging materials is determined on a regular basis by weighing a sufficient number of packages using a weighing instrument specified at the chapter "measuring instruments".
Determination of the weight of the packaging materials is not necessary when the quantity of product is measured without packaging materials, for example when fluids are poured in a measuring glass, a product has no packaging material, when a template is used together with a measuring container bottle or when product is weighed without package.

When the standard deviation of the weight of the packaging materials are small, the average weight of the packaging materials may be used when determining the content of the prepackage (‘average tare’). Sometimes a higher sample frequency is necessary: determination per pallet or preceding the measuring of the content of the prepackage (‘average momentary tare’).

When the standard deviation of the weight of the packaging materials is too large, the content of each repackage must be determined by subtracting the weight of the package from the weight of the prepackage the package is part of (‘individual tare’).

The density of every batch of liquid products must be determined by a suitable method.

When the ‘apparent density’ is measured, the ‘density in vacuum’ is calculated by adding 0,0012 g/ml.

For some fluids the density can be derived from the brix number. The packer must provide a conversion table. The accuracy of the table must be calibrated on a regular basis.

When the density of carbonated product is determined without carbon dioxide, the measured density must be corrected. When the density of every batch is not measured, its contribution to the measurement uncertainty will increase.

4.5.3 The processing of measuring results

The content of every measured prepackage must be determined. When relevant, the weight of the packaging materials and the density must be included.

This is the relationship:

$$\text{volume of the prepackage} = 0{,}99985 \times \frac{\text{weight of the contents}}{\text{apparent density}}$$

This is a formula frequently used in e-marking software.

Control charts that are manually completed, automated systems connected to weighing instruments and automated systems in a network are accepted. A Competent Department does not have any preference.

Automated systems must be equipped with validated software.

Software is validated by comparing the readouts with manually calculated results. The approval does not include any statement of functionality of the software. Software can be approved at the request of the packer or the manufacturer of the software. If the automated system is subject to legal metrological control, then according to WELMEC 7.1, the legally relevant parts of the software should be approved, as well as validated.

Of the contents of the measured prepackages, the average or the median must be determined and presented. Also the number or percentage of the prepackages with a content below TU1 and TU2 must be established and presented.

The expanded measuring uncertainty of the combined measurements must not be larger than one fifth of the specified permissible error. If bigger than one fifth of the specified permissible error, the expanded measuring uncertainty must be compensated for by the packer.

4.5.4 The utilization of measuring and sampling results and/or possible actions

When the average of the measuring results that relate to an hour's production is less than the nominal quantity, the hour's production must be quarantined.

To quarantine means: identify as such so that the prepackages will not be put onto the market (this can be by labelling the pallet or placing the prepackages in a suitably marked area).

When sampling is used there are several methods of decisions possible:

1. When the average (or median) of a sample falls below a warning limit (often 'nominal quantity'), then packers often undertake corrective action to bring the average back on target by adjusting the filling machine. A follow up sample must be taken to ensure the action was appropriate.

2. When the average (or median) of a sample lies in a (statistically determined) range around the nominal quantity, another sample is drawn without adjustments of the filling machine. When the average of all prepackages measured in the two samples is below the nominal quantity, the filling machine is adjusted upwards. These adjustments are usually checked by a test sample. This method is less suitable when automated systems are used to calculate and present the average of an hour's production.

For the statistical background, see annex D of WELMEC Publication 6.5.

The production level to which the samples relate varies. Below are some examples:

1. The hour's production is divided into parts that are "closed" with a sample taken at the end. If the average of the averages (or medians) of the production parts is below the nominal quantity, the production parts that cause the average of the hour's production to be too low are quarantined.

2. The hour's production is divided into parts that are "enclosed" with samples taken from each end. The average of a production part is calculated by calculating the average of the two enclosing average (or median) of the enclosing samples. When the average of the averages (or medians) of the production parts in an hours production is below the nominal quantity, the parts that cause the too low average of the hours production is quarantined.

3. When the average of the samples fall below an action limit, all the prepackages since the last acceptable sample result must be isolated from delivery.

When more than a small number of prepackages in a sample has contents below the TU1 limit, the prepackages that have been produced since the previous sample must be quarantined.

Depending on the standard deviation of the filling process and the company policy:

1. When in a sample one or more prepackages is found to have contents below the TU1- and/or TU2-limit the production that is produced since the last sample is blocked from delivery.

2. When in a sample one prepackage is found to have contents below the TU1-limit (but above the TU2-limit), another sample is drawn without adjusting the filling machine. When this or the next regular sample has one or more prepackages with a contents below the TU1-limit, the prepackages that have been produced since the last satisfactory sample must be quarantined.

3. When checkweighers of multiheads are used, more than 'a small number of prepackages' below the TU1-limit cannot be produced. In that case 'small number 'is defined as '2,5%' of all produced prepackages. The correct functioning of the machines must be checked on a regular basis.

   Some machines monitor the percentage of prepackages. The rejection mechanism is usually set at the TU2-limit. When the percentage of prepackages with a contents below the TU1-limit exceeds 2½, the rejection mechanism is automatically set to the TU1-limit. When it can be set lower 'safely', it will revert to the TU2 limit.

When one or more prepackages in a sample has a contents below the TU2-limit, the prepackages that have been produced since the previous sample are quarantined.

When checkweighers of multiheads are used, when functioning normally, prepackages with a contents below the TU2- limit do not occur. The functioning of the machine must be checked on a regular basis.

When the packer samples in the same way as the Competent Department (see Council Directive 76/211/EEC), he may use the same acceptance and rejection criteria.

Prepackages that are quarantined because the average content is too low must be rectified by an acceptable method such as:

- destroyed by repacking the prepackages
- removing deficient prepackages
- mixing with another batch with an enhanced average to ensure the overall average is not below the nominal quantity
- re-labelled
- divided into lots of (maximum) 10.000 prepackages and are checked by sampling in accordance with the method that would be used by the Competent Department (see Council Directive 76/211/EEC/75/106/EEC). The lots that are acceptable can then be released, rejected lots must be rectified.

Prepackages that are quarantined because too many prepackages have contents which fall below the TU1-limit, must be rectified by an acceptable method:

- destroyed by repacking the prepackages
- removing deficient prepackages
- mixing with another batch with an enhanced average to ensure the overall average is not below the nominal quantity
- re-labelled

- divided into lots of (maximum) 10.000 prepackages and are checked by sampling in accordance with the method that would be used by the Competent Department (see Council Directive 76/211/EEC). The lots that are acceptable can then be released, rejected lots must be rectified.

Prepackages that are quarantined because too many prepackages have contents below the TU2-limit, must be rectified by an acceptable method:
- destroyed by repacking the prepackages
- re-labelled
- removing deficient prepackages

In some Member States it is also allowed to sell defective prepackages to the packer's staff, the government and educational establishments or giving them away for free, BUT only if the recipients are informed that the prepackages do not comply with the Directive and they cannot be re-sold.

4.6 Instructions to staff

The practical execution of the above must be laid down in working instructions that form part of the description of the recognized procedures and which are available at the location at which the results of the measurements are examined.

When the working instructions are part of a certified quality system the recognized procedures will refer to them. The work instructions must be validated and controlled. Employees must be trained.

Work instructions must be written in the language that the worker understands.

Sometimes (particularly with small packers) employees involved with e-marking have detailed knowledge of the recognized procedures. In such cases the work instructions do not have to cover all parts of the recognised procedure.

4.7 The records

The records that are produced while carrying out the recognized procedures should be kept for a specified period.

The specified period varies between Member States and may be for one year, during the shelf life of prepackages, until they have been checked by an inspector or until subject to market surveillance.

Usually these are the results of the samples, the determination of the weight of the packaging, density measurements, training records and calibration records. They must be traceable to (respectively) prepackages, personnel and measuring instruments. In some countries they also contain inspection, audit and surveillance reports from the Competent Department.

An example of the records should be included in the description of the recognized procedures.

The records may be kept electronically.

When prepackages are quarantined, notes relating to the cause and actions undertaken should be kept with the records.

4.8 The 'e'mark

The ‘e’-mark of the prescribed shape and size must be printed on the prepackage in the same field of vision of the nominal quantity. The minimum height is 3 mm and it must be indelible, easily legible and visible on the prepackage under normal conditions of presentation.

4.9 The annexes

With the description of the recognized procedures these are the annexes required:

- working instructions
- samples of the records
- setting target quantities, set points and other relevant parameters

5 Requirements of a packer's 'e' mark control system

This document describes in detail the basic principles used to carry out checks. The procedures of the quantity control system can be set up partly from this data.

5.1 Definitions

The EEC sign is the lower case letter 'e' as shown in the e-marking regulations. For other definitions and translation of terms, refer to WELMEC Publication 6.1.

5.2 Specific terms

The nominal quantity
The nominal quantity Qn must be in the range 5 g to 10 kg or 5 ml to 5L.

The TU1 limit
The TU1 limit is the nominal value minus the permissible minus error. (For the permissible minus error see Table 1).
The TU2 limit

The TU2 limit is the nominal value minus twice the permissible minus error. (For the permissible error see Table 1).

Table 1

Nominal quantity			Specified permissible error in minus	
in g or ml			in % of Q_n	in g or ml
5	-	50	9	-
50	-	100	-	4,5
100	-	200	4,5	-
200	-	300	-	9
300	-	500	3	-
500	-	1000	-	15
1000	-	10000	1,5	-

When using the table, the TU1 and TU2 limits are calculated in mass or volume units based on the permissible minus error expressed in % it must be rounded upwards to the next whole tenth of a gram or milliliter.

5.3 The batch size

By practical reasons, the size of the batch can be defined in different ways by the packer and the inspector.

Inspector's definition: when checking at the end of the packing line, the number of prepackages in each batch shall be equal to the maximum hourly output of the packing line, without any restrictions as to the batch size. In all other cases, the batch size shall be limited to 10 000 prepackages.

Packer's definition: the packer can define the size of his batch according to his needs and his system for identifying prepackages belonging to the batch. The requirements for e-marking shall be fulfilled for any defined batch.

5.4 The measuring equipment

In order to be able to show that the e-marked prepackages comply with the requirements, the packer must calibrate and maintain his inspection measuring and testing equipment.

The measuring equipment must be used in accordance with its specification. Measurements of volume should be performed at or calculated to 20 °C, unless frozen.

5.5 The measurement uncertainty

The measurement uncertainty of the packer is taken care of when the packer uses the right measuring equipment.

In Guide 6.4 paragraph 6.3.2 (mass determination), 6.3.3 (volume determination) and 6.3.4 (density determination) guidance is given for the use of measuring instruments.

5.6 Measuring equipment subject to legal metrological control

Measuring equipment for volume and weight must, comply with the following requirements:

- The measuring equipment model must be approved, where appropriate, depending on the national situation in relation to legal metrology control,
- The individual measuring device must be calibrated or verified.
- The national metrological institute must approve the equipment connected to the measuring device for metrological use. The connected equipment should be inspected together with
- The measuring device.
- The Competent Department must approve the software linked to the measuring device for metrological use.

5.7 The measuring method

Net weighing
The actual content of the ‘e’ prepackage is measured directly: weighing the contents of a prepackage without package.

Gross minus individual tare weight
The actual content of the ‘e’ prepackage is measured indirectly. The same packaging is weighed before and after the filling process. The difference between the two values is the net weight. The net volume of the packaged product can be determined, if required, using the density.

Gross minus average tare weight
The actual content of the ‘e’ prepackage is measured indirectly. If the average weight of the packaging is known then the net weight can be easily determined by finding the difference between the gross weight and the average weight of the packaging. The net volume of the packaged product can be determined, if required, using the density.

This method of measuring needs to specify the requirements for the spread of the weight in the packaging material and possibly the relationship of that weight to the nominal weight.

The variations in tare weight must be carefully considered when calculating the uncertainty of measurement of the content. If the uncertainty is to big the average tare cannot be used.

5.8 The assessment of ‘e’ pre-packaging

The frequency
Each batch must be assessed (see the batch definition).

There is a relationship between sample size, sample frequency and target quantity.

The assessed 'e' pre-packaging
The assessed 'e' pre-packaging consists of:

- a representative sample from the batch
- the reference test or
- representative random sample(s) from production or
- from a 100% batch check.

The approval criteria

- The actual content of the 'e' pre-packaging is on average not less than its nominal quantity.
- not more than 2,5% of the 'e' prepackages exceed the TU1 limit.
- no 'e' pre-packaging exceeds the TU2 limit.

The rejection criteria

- the actual content of prepackages is on average less than its nominal quantity.
- more than 2,5% of the prepackages exceed the TU1 limit.
- one or more prepackages exceeds the TU2 limit.

The reference test
When using the reference test for the checking of a batch it is permissible to make use of the procedure laid down in the appendix to the e-marking legislation.

Weight loss through shrinkage as a result of loss of water.
Member States have different philosophies about desiccation and absorption of moisture in product.

Sometimes a prepackage must meet the requirements at the time of packing and sometimes a prepackage must meet the requirements at the time of sale.

The drained weight
In the case of food products consisting of a solid main component packed in a liquid medium the e-marking regulations apply on the total content of these prepackages.

5.9 The inscriptions and markings

The nominal quantity
The nominal quantity of a prepackage must be specified on the outside or may be on the inside of the packaging if the packaging is clearly transparent at that location.

The nominal quantity must be expressed in:

- liters, centiliters or milliliters, for a liquid product,
- kilograms or grams for other products.

The nominal quantity must be shown in figures followed by the name of the symbol for the unit of measurement involved. The figures for nominal quantity must have a minimum height corresponding to the nominal quantity in the following table.

Table 2, size of nominal quantity

nominal quantity in g or ml larger than: up to and including:		Minimum height of figures
5	50	2 mm
50	200	3 mm
200	1000	4 mm
1000	10000	6 mm

- prefixes like ‘net’ or ‘content’ are allowed but superfluous
- prefixes ‘minimum’, ‘circa’ or ‘G/N’ (gross for net sale) are not allowed

5.10 Exceptions to the nominal quantity declaration

The basic rule which applies is that there must be a declaration for a liquid product in ml, cl or l and for a solid product in g or kg; this basic rule may be deviated from for an ‘e’ prepackages which:

- are for export to a country outside the EEC area,
- are for export to another EEC country provided the manner in which the nominal quantity is expressed does not contravene the legal provisions of the country of destination or general trade practices there,
- in the certifying country where an alternative is prescribed (for example a Commodities Act decree or a commodity board regulation), or, in the event of the lack of legal provisions, there is consensus in the general trade practices in the certifying country for the product involved.

An additional (supplementary) indication of the nominal quantity in a ‘non-metric system’ is permitted. The manner of indication of the supplementary may not be larger than the corresponding metric indication and may not be more prominent.

A double indication for the nominal quantity is permitted if the following conditions are met:

- The indication in metric units (liquid product in ml, cl, or l and solid product in g and kg), must be stated first,
- The ‘e’ sign must relate to the metric quantity,
- The supplementary indication must accompany the metric quantity,
- The size of the numerals in the supplementary indication may not be larger than those of the main indication and may not be presented more prominently

5.11 Identification of the manufacturer

A mark or inscription to identify the packer, the person arranging for the packing to be done or the importer must appear on e-marked prepackages.

Where the packer and the person arranging the packing to be done are different, the law permits either of them to be identified. When this is the case it is strongly recommended that the packer is marked. In any event the person is named on the prepackage should be able to identify the packer or importer.

5.12 The EEC sign

The e-mark must be at least 3 mm in height and must be applied to the prepackages in the same field of vision as the indication of the nominal quantity. If there is an indication of the nominal quantity in more than one place on the prepackage then this applies to each of these indications.

5.13 Quality of inscriptions and signs

The use of the EEC sign on combination packages is permitted when the combination package is sold as a whole (a combination package is made up of prepackages of different kinds, which are not intended to be sold separately).

An indication of the total quantity of a product on combination package is not permitted. The inscriptions on the individual packages in the combination package must comply with the same requirements as those specified above. They must be indelible, legible and clearly visible.

5.14 Inscriptions on multipacks

The use of the EEC sign on multipacks is permitted when the multipack[2] is sold as a whole or is made up of e-marked prepackages which could also be sold individually to consumers.

An indication of the total quantity of a product on multipacks is permitted provided that it is clear which quantity indication refers to which product.

The inscriptions on the multipack must meet the same requirements as specified above. They must be indelible, easily legible and visible on the prepackage in normal condition of presentation.

[2] The definition for multipacks is given by Regulation (EU) N^{o} 1169/2011 on the provision of food information to consumers, annex IX article 3 and 4:
'*Where a prepacked item consists of two or more individual prepacked items containing the same quantity of the same product, the net quantity shall be indicated by mentioning the net quantity contained in each individual package and the total number of such packages. The indication of those particulars shall not, however, be mandatory where the total number of individual packages can be clearly seen and easily counted from the outside and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside.*
Where a prepacked item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.'