WELMEC

European Cooperation in Legal Metrology

Guide for packers and importers of ℮-marked prepacked products

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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.

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1 Introduction

1.1. WELMEC Working Group 6 (WG 6) was set up to discuss, and propose solutions for, the problems associated with the trading of prepackaged products between Member States. It was decided that a set of documents for Competent Departments, packers and importers should be produced. The intention of the documents is to achieve a uniform level of compliance.

1.2. This document is part of a series of documents published by WELMEC, which are primarily intended to provide guidance to all those concerned with the application of Directives 76/211/EEC and 2007/45/EC (referred to as "the Directives") for prepacked products. The documents are intended to lead to a uniform interpretation and enforcement of the directives and assist in the removal of barriers to trade. "Directive" refers only to Directive 76/211/EEC.

Documents agreed by WELMEC are published on their website at http://www.welmec.org/latest/guides.html

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If any of the above documents are unclear, does not give guidance on a specific matter or is incorrect, please notify the secretary or convenor of WELMEC WG6-Prepackages.

1.3 This guide serves as a manual for packers using the e-mark who want to have their procedures recognised in accordance with the Directive, or who want to modify procedures that have already been recognised.

Where in this document the term "Member State" is used, this means countries of the European Economic Area (EEA), Turkey and Switzerland.

The content considers the legal requirements of the Directives and provides practical solutions and guidance on meeting them.

The means by which Competent Departments recognise procedures depend on the legislation of the Member State.

1.4 Section 2 sets out the requirements for e-marked prepackages, and in section 3 the role of the Competent Departments is explained. The most important concepts for recognised procedures are explained in section 4. Section 5 gives guidance on the issues the procedures used by packers need to address.

1.5 Only the courts can interpret the law. If a packer or importer fails to meet the requirements of the Directive, the penalties might include the withdrawal of recognition or a fine. This depends on the laws of the Member State.

2 Overview of the requirements for e-marked prepackages

The requirements for the labelling of prepackages is specified in the Directives concerning prepackaging by weight or by volume, and implemented in the national legislation of the Member States.

The following most important requirements relate only to prepackages marked with an e-mark.

The Directives do not cover prepacked products made up by number, length or area nor catchweight products, the latter being products of variable weight.

2.1 The removal of trade obstacles with border crossing traffic (trade between Member States)

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

2.2 Guidance to the consumers concerning the nominal quantity of the product contained in the prepackages

On average, the quantity of product contained in an e-marked prepackage will be at least the labelled (nominal) quantity. In addition, requirements exist to restrict the proportion of the prepackages with a quantity of product below the tolerance limits[1].

The following markings have to be indicated on each prepackage:

- on prepackages containing liquid products, the nominal volume and in other cases the nominal weight, followed by the symbol or the name of the unit of measurement
- a mark or inscription from which the packer, contract packer or the importer can be identified and
- the prescribed letter "e", as a sign that the prepackage satisfies the requirements of the Directive.

2.3 The requirements with regard to the quantity of product contained in prepackages

The e-marked prepackages need to satisfy three quantity requirements (see section 4.1).

Inspection by authorities, referred to in the Directive as "Competent Departments", is done statistically by means of random samples. This official control is specified by the Directive. The sample size with corresponding acceptance and rejection criteria is dependent on the size of the batch and whether the test involves the destruction of the prepackages or not.

[1] Tolerance limits are discussed in section 4.1.

2.4 The responsibilities of the manufacturer or the importer concerning the actual quantity of product contained in the prepackage

The manufacturer or, in case of prepackages imported from countries outside the Member States, the importer is responsible for ensuring that the prepackages meet the requirements of the Directives.

The packer has two options:

1. where measuring equipment is used for *making up prepackages* (that is where the quantity of product contained in each prepackage is measured), the measuring instrument shall be legal and suitable or
2. the packer may perform *checks on prepackages* to ensure that the prepackages meet the requirements. This is an option also available for the importer.

Measuring instruments used for checking shall be legal and suitable.

For both of the above:

- legal means complying with national metrological legislation and
- suitability 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 packer uses a larger verification scale interval they must compensate (e.g. overfill).

Suitability is covered in section 5.3 on measuring instruments of this guide.

Records of checks are required to be made available for Competent Departments to verify. Checks shall be so organised as to effectively guarantee the quantity of product contained in a prepackage.

These checks can be satisfied as mentioned in the following sections.

2.4.1 Measuring while filling

The quantity of product contained in a prepackage (or packing quantity), known as the "actual contents", shall be measured by means of a legal and suitable measurement instrument. The filling may occur by hand when it is based on reading the measuring instrument. Automatic gravimetric filling instruments may also be used as they also accomplish the weighing of the content of each prepackage.

2.4.2 Recognising procedures

When the actual quantity of product contained in every individual prepackage is not measured, the options concerning process control are many. However, they need to be such as to effectively ensure that the prepackages meet the requirements of the Directive. The determination of whether these requirements are met is determined by the Competent Departments based on an evaluation of the procedures.

2.4.3 Import from third countries

For the purposes of the Directive, an importer is someone who brings prepackages into a Member State. Therefore movement within the Member States does not involve import/export for the purposes of the Directive. The importer has the same responsibilities as a packer, but the Directive recognises that they may not physically come into contact with the prepackages being imported.

The Directive states[2] "In the case of imports 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." What is considered acceptable in the opinion of the Competent Departments should be based on its credibility, such as:

a) evidence from an internationally recognised National Metrology Institute

b) evidence from an accredited inspection or a certification body[3] regarding prepackages packed, or the quality system of the packer in the exporting country

c) records of checks carried out under the responsibility of the importer at the place of first entry into a Member State, this may be a competent third party and

d) to obtain records from the packer outside of Member States and to carry out checks to validate the data contained in them.

The Competent Department should be contacted to discuss the acceptability of other guarantees.

Evidence referred to in a) and b) above shall state that the quantity control system of the packer in the third country has been assessed.

Note that "assessed" does not mean "recognition of procedures" as envisaged in the Directive.

The word "competent" under c) could be read as someone certified according to an appropriate ISO standard.

[2] Directive 76/211/EEC, Annex I, 4.

[3] Proper scope and accredited/certified against proper standards.

3 The responsibilities of the Competent Department

3.1 The reference test

Checks to ensure that prepackages comply with the requirements of the Directives shall be carried out by the Competent Department. Generally this happens by sampling on the packers' premises, or if this is not practicable, on the premises of the importer or his agent established in the Community. The check is referred to as a reference test.

The reference test shall be done by means of statistical sampling check 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 1.5 of the Directive. The operating characteristic curve of the reference test can be found in Annex D of WELMEC Guide 6.5 "Guidance on Controls by Competent Departments on "e" marked Prepackages". See also Appendix 3 of WELMEC Guide 6.3 "Guidance for the Harmonised Implementation of Council Directive 76/211/EEC as amended".

The reference test is not appropriate for use in a packer's control system.

3.2 Other checks

The Directive does not preclude any checks, which may be carried out by the Competent Departments at any stage in the marketing process, in particular for the purpose of verifying, that prepackages meet the requirements of the Directive.

The checks could cover the adequacy of the quantity control system, confirm that it is being followed, and that its appropriateness has been regularly reviewed. This may include:

- the labelling of the product
- the accuracy and suitability of the equipment and whether it is adequately maintained
- the adequacy of the records, and their accuracy, by checking prepackages from the appropriate batch, and
- the quantity of product contained in prepackages.

3.3 Visit frequency

Member States have various ways of determining the frequency of visits, which include assessing:

- the number of prepackages produced
- the area of distribution
- the value of the product packed
- the quality system in use
- the number of complaints received, and
- the level of compliance found on visits.

3.4 Recognition of quantity control system

The Competent Department shall recognise the quantity control system in the way specified in national legislation. This may also result in an approval to mark prepackages with the e-mark.

Where there have been changes in the quality system, these changes need to be recognised by the Competent Department before they are brought into use. Guidance on recognition of the packer's procedure for carrying out production checks is given in WELMEC Guide 6.6 "Guide for Recognition of Procedures".

3.5 Other prepacked products

The Directives control products packed with a weight or volume quantity declaration between the limits of 5 g or 5 ml and 10 kg or 10 l. National legislation may control prepackages outside these limits or prepackages sold by reference to length, area and number. These prepacked products may not be marked with an e-mark.

For further information see WELMEC Guide 6.10 “Information on Controls on Prepacked Products“.

4 Detailed requirements for e-marked prepackages

4.1 The tolerances

The Directive specifies the following requirements (sometimes referred to as "The 3 Packers Rules") for the actual quantity[4] of product contained in e-marked prepackages[5]:

- the average quantity of product of the prepackages shall not be less than the nominal quantity
- only a small number of prepackages may have a quantity of product below the nominal quantity minus the tolerable negative error (TU1-limit)[6]. These prepackages are also referred to as "defectives"
- no prepackage with a quantity of product less than the nominal quantity minus twice the tolerable negative error (TU2-limit) may be e-marked. These prepackages are sometimes referred to as "inadequates".

The tolerable negative error (TNE) is dependent on the nominal quantity (marked quantity) of the prepackage, and is seen in Table 1.

Table 1: Tolerable negative error of the nominal quantity[7].

Nominal quantity, Q_n (g or ml)	**Tolerable Negative Error (TNE)**	
	as % of Q_n	**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 1 000	-	15
1 000 to 10 000	1.5	-

Where a percentage value does not calculate to an exact 0.1 g or ml, the TNE value is always rounded up to the next 0.1 g or ml.

Example:

For a prepackage with a nominal quantity of 145 g, the maximum TNE is 4.5 % of 145 g, which gives a TNE of 6.525 g. This is rounded up to 6.6 g.

TU1 = 145 – 6.6 = 138.4 and TU2 = 145 – 2 x 6.6 = 145 - 13.2 = 131.8 g

[4] Directive 76/211/EEC uses the term "actual contents" instead of "actual quantity".

[5] Directive 76/211/EEC, Annex I, 1.

[6] The Directive specifies an acceptable number of prepackages below TU1 for each reference test sample size. The proportion of prepackages below TU1 needs to be sufficiently small, in general it appears that not more than 2.5% below TU1 is appropriate.

[7] Directive 76/211/EEC Annex I, 2.4.

A prepackage with a nominal quantity of 250 g has a maximum TNE which is directly indicated in Table 1, namely 9 g. The TNE is in the same unit of measurement as the nominal quantity.

Note: Where the packaging design does not permit the entire product to be used by the consumer, it is good practice not to include the product which is inaccessible/trapped in the nominal quantity.

4.2 The effects of desiccation or absorption of moisture

Member States have different philosophies about the treatment of desiccating and hygroscopic products. In some Member States a prepackage must meet the requirements of the Directives at the moment of prepacking and in other Member States a prepackage must meet the requirements at the moment of sale. Packers should ask their Competent Department for information.

For more guidance, see WELMEC Guide 6.11 "Information on Prepackages, whose Quantity Changes after Packing".

4.3 Drained weight

Regulation (EU) 1169/2011 requires the net quantity of the food to be labelled, and that the net quantity is considered to be equivalent to other quantities mentioned in legislation, such as the nominal quantity in Directive 76/211/EEC.

According to this the e-mark therefore applies to the net quantity.

If the food is presented in a liquid medium, Regulation (EU) 1169/2011 requires that the net quantity and the drained net weight must be declared.

In the case of ice glazed food the legislation requires that the net quantity applies to the food excluding the glaze. According to this the e-mark applies to the food without the glazing.

For guidance on drained weight, see WELMEC Guide 6.8 "Drained weight", this reflects the CODEX requirement[8] that the declaration of drained weight be subject to enforcement by reference to an average system of quantity control.

4.4 The nominal quantity

The nominal quantity of a prepackage must be marked in such a way as to be indelible and clearly visible under normal conditions of purchase. This means that it needs to appear on the outside, or it could be on the inside of the packaging if the packaging is clearly transparent at that location.

The nominal quantity must be expressed in:

- litres, centilitres or millilitres, for a liquid product, or
- kilograms or grams for other products.

[8] CODEX STAN 1-1985 *(Rev. 1-1991)* GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS mentions in this in footnote 6

The nominal quantity must be shown in figures followed by the name or the symbol for the measurement unit involved. The only symbols permitted for the above units of measurement are l, L, cl, cL, ml or mL for liquid products, and kg or g for other products.

The figures for a nominal quantity must have a minimum height as given in Table 2.

In case of a nominal quantity expressed in mass and volume, the procedures of the packer shall cover the monitoring of both units.

For certain wines and spirits the nominal quantity must be one of those stated in Directive 2007/45/EC when packed within the specified ranges.

Table 2: Size of nominal quantity[9].

Nominal quantity, Q_n (g or ml)	Minimum heights of figures (mm)
$Q_n \leq 50$	2
$50 < Q_n \leq 200$	3
$200 < Q_n \leq 1\,000$	4
$1\,000 < Q_n \leq 10\,000$	6

- Prefixes like "net" or "content" are allowed but superfluous, and
- prefixes "minimum", "circa" or "G/N" (gross for net sale) are not permitted.

- Exceptions are for export to a country outside the EEC area
- are for export to another Member State as long as the manner in which the nominal quantity is expressed does not contravene the national legislation of the receiving country or general trade practices there, and
- the receiving country prescribes a unit of measurement (for example in a national law such as a Commodities Act decree or a commodity board regulation), or, in the event of the lack of legal provisions, complies with general trade practices in that country for the product involved.

4.5 Exceptions to the nominal quantity declaration

The normal requirement is that there must be a declaration in ml, cl or l for a liquid product in g or kg and for a solid product. This basic rule may be deviated from for e-marked prepackages which:

A supplementary indication[10] of the nominal quantity in a "non-metric system" is allowed. The numbers and letters of these supplementary indications may not be larger than the corresponding metric indication and may not be more prominent.

[9] Directive 76/211/EEC, Annex I, 3.1.

[10] As specified in Directive 80/181/EEC.

Where the nominal quantity is expressed in more than one unit of measurement, the following conditions should be met:

- the indication of the nominal quantity (ml, mL, cl, cL, l or L for liquid product, g or kg for solid product), should be stated first
- the e-mark must relate to this
- the other indication must also comply with the same quantity requirements and must not be misleading[11]
- the size of the numerals in the other indication should not be larger than those of the main indication and should not be presented more prominently and must accompany the principal indication, and
- the documentation of the packer or importer must show that the other indication also complies with the tolerances.

Where a prepackage is marked with more than one indication of quantity[12], all indications should be in close proximity to each other, shall not be more prominent than the required marking, and the quantity to which each indication refers shall be unambiguous. Where quantity markings are repeated on the packaging they should all contain the same information. The e-mark relates to the nominal weight or volume.

Note: OIML recommends that if the prepackaged product is labelled on more than one location of its packaging, the information on all labels shall be equivalent[13].

4.6 Identification of the manufacturer

An identifying 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.

The packer, the person arranging for the packing to be done or the importer must be located within a Member State.

Where the packer and the person arranging the packing to be done are different, the Directive permits either one of them to be identified. When this is not the packer, it is recommended that the packer is marked. Whoever is named on the prepackage shall be able to identify the packer or the importer.

4.7 The e-mark

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 the requirement applies for each of these indications.

The form and shape of the e-mark is shown in Annex 4.

[11] As required by the unfair commercial practices directive, Directive 2005/29/EC.

[12] For example an indication of weight and volume, weight and drained weight, net weight and gross weight.

[13] OIML R79 (1997), section 6.3.

4.8 Manner of inscriptions and signs

The inscriptions for the indication of the nominal quantity, the identification of the packer or importer and the e-mark must be indelible, legible and clearly visible under normal conditions of purchase. In addition to that, the international recommendation recommends[14] the information to be on the principal display panel which is defined as "front-of-pack".

4.9 Inscriptions on multipacks

Where a prepackage consists of two or more individual prepackages containing the same nominal quantity of the same product, that nominal quantity shall be indicated by the nominal quantity contained in each individual prepackage and the total number of such prepackages. The indication of this nominal quantity and the total number of prepackages is not mandatory where the total number of individual prepackages can be clearly seen and easily counted from the outside and where at least one indication of the nominal quantity contained in each prepackage can be clearly seen from the outside.

Where a collection of prepackages of different products and/or of different nominal quantities are combined within packaging, the mandatory information on each prepackage must be repeated on the packaging, unless it is clearly visible through the packaging.

Where a prepackage consists of two or more prepacked products, which are not intended as units of sale and are not marked as mentioned above, the nominal quantity shall be calculated by totalising the quantities of these packaged items. The e-mark must be in the same field of vision as the nominal quantity and if there are other quantities specified it will help avoid confusion if the e-mark is placed alongside the nominal quantity.

[14] OIML R79 (1997), sections 3.1 and 5.1.

5 The requirements concerning the procedures

5.1 Introduction

In this section, the criteria for evaluating procedures are given step by step. The order of the subjects corresponds to the one in the questionnaire in Annex 1.

First of all, the criteria concerning the suitability of the procedures are listed (section 5.2), followed by an explanation of how the specified measurements can be carried out (section 5.3). In this section, the requirements for different measurement methods are also described. In section 5.4 the interpretation of measurement results is explained, and section 5.5 addresses the actions that should be taken as a result of them. This will include the identification and allocation of responsibilities of employees for corrective actions, which is covered in section 5.6. The final section 5.7 deals with the records that have to be made and retained by the packer.

5.2 The suitability of the procedures

5.2.1 Process characteristics

The production of prepackages is a process. The characteristics of this process are highly dependent upon the nature of the product which is packed, the type of package and the way in which it is filled.

After studying it, a model can be made from each packaging process. Characteristics, such as the average packed quantity and the variation of the individual packages around this average, gives important indications for the quality of the process, and how it should be controlled.

5.2.2 Suitable procedures

The procedures have to ensure, through control and correction of the packaging process, that the e-marked prepackages put on the market satisfy the requirements of the Directive. It is impossible to give definitive criteria for the determination of "suitability". However, there are a number of aspects, which play an important role in the evaluation:

a) are the measurement results representative for the total (hour) production?

It is good practice that the packer checks every (production) hour. In other words, at least once an hour the average quantity of product of the produced prepackages must be determined and evaluated. The same applies for the number or percentage of prepackages with quantity of product less than the TU1 and TU2 limits.

When the standard deviation of the prepackages exceeds half the TNE, then this needs to be compensated for.

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

- the nominal quantity
- TU1 + 1.96 x standard deviation, or
- TU2 + 3.72 x standard deviation.

Note: the factor '1.96' refers to not more than 2.5 % below TU1. Some countries use the factor '2.05' which refers to not more than 2 % below TU1.

The packer could round the factor '1.96' to '2' making it easier for him to check his production. A factor of '2' refers to not more than 2.3 % below TU1.

b) are variations of the production process noticed quickly and reliably?

Variations in the filling process that cause prepackages to fail to meet the requirements of the Directive must be identified. In general a deviation must be detected within an hour, since every hour's production must meet the requirements of the Directive.

Note: It is not usually acceptable for the packer to discover a deviation of the filling process more than an hour after its occurrence. In such a case a complete hour's production would have to be quarantined and corrected.

c) It is good practice for the packer to carry out a check on every (production) hour, although this is not a requirement of the Directive. Checks might be carried out at longer intervals, provided that the quantity control system is set up appropriately to take into account the drift in the packing process. This also applies for monitoring prepackages below the TU1- and TU2-limits.

d) Changes in the packing process need to be detected quickly and reliably. The effectiveness of the process control is sometimes measured by the "average run length" taken to detect the change.

Any checks that detect that the process is no longer in control will require the quarantine of all the packages back to the last good check. This may be anything from 10 minutes on a fast line, to several hours on a slow line. One way the packer can minimise the amount of prepackages requiring quarantine is to carry out frequent checks.

5.3 The control measurements

The following is not mandatory but is considered to be good practice.

5.3.1 Introduction

With each method of process evaluation the actual quantity of product contained in a prepackage must be determined regularly. A number of methods can be followed to determine the actual quantity of product.

a) Destructive

The prepackage is emptied for a direct determination of the weight or volume of the product contained in the prepackage.

This method is not very popular as each determination destroys a number of prepackages, and it is not always possible to extract the entire product from the prepackages.

b) Gross weight minus individual tare

The same prepackage is weighed before and after the filling process. The difference is the weight of the product. For liquid products, with the aid of the density, the volume of the product can be calculated.

c) Gross weight minus mean tare

In this case the variations in weight of the packing material must be carefully considered when calculating the uncertainty of measurement for the quantity of the product. If the uncertainty is too big (see below), gross weighing minus individual tare should be used.

This measurement method is only suitable if the standard deviation (s) of the tare weight is less than 1/10 TNE of the nominal quantity.

If the average weight of the packaging material is known, then the weight of the product can be calculated by subtracting the average weight of the packaging material from the weight of the prepackage. For liquid products, with the aid of the density, the volume of the product contained in the prepackage can be calculated.

The mean tare should be checked for each new batch of packaging material to ensure the correct figure is used.

d) Equipment

The weight determination (mass) is an important measurement in recognised packing procedures. The common measurements are:

- mass
- volume, and
- density.

For measurements, which play a decisive role in a trade transaction, it is a requirement that they are obtained on legal measuring instruments (depending upon national legislation). Measuring instruments must always be suitable. The word "suitable" includes a number of conditions of use that arise from the need to limit the uncertainty of measurement.

If the errors of the measuring instruments, despite of the use of legal and suitable measuring instruments, leads to systematic under filling, corrective or preventative action must be taken.

5.3.2 Weight determination

For the determination of weight, a weighing instrument is the most suitable instrument.

The instrument(s) that a packer uses to determine whether a prepackage or a batch of prepackages complies with the Directive, shall be legal and suitable. Other weighing instruments are not controlled.

The metrological legislation makes a distinction between automatic and non-automatic weighing instruments. The types of automatic weighing instruments, which are important for e-marking, are checkweighers and automatic gravimetric filling instruments.

In the following, the general criteria for the use of weighing instruments are listed, followed by additional criteria for each specific type of weighing instrument.

The general criteria for the use of weighing instruments are:

- all instruments have to be legal and suitable. Depending on national legislation, different means of "legal" exists. This include the need for type approval, certification, verification and periodic verification

- in addition to the above, the weighing instrument should be calibrated or checked regularly under responsibility of the packer
- the accuracy needed for a weighing instrument is dependent upon the purpose for which it is used. The additional criteria listed below give guidance for each type of weighing instrument
- the weighing instrument shall be used according to its specification and, where applicable, its type approval certificate
- peripheral equipment may be connected to the weighing instrument. To find out if that is allowed, the packer may consult the manufacturer of the instrument
- the weighing instrument has to be set up on a stable, non-vibrating surface and out of any draught and installed according to the intended design, and
- when the standard deviation of the prepackages exceeds half of TNE, then this needs to be compensated for (seek advice from the Competent Department).

The packer shall assure that the software, which is used to record the weighing results, has been validated before use. The guidance for the software is given in Annex 2.

5.3.3 Additional criteria for the use of non-automatic weighing instruments (NAWI)

When the quantity of product contained in prepackages is determined by sampling, a NAWI is often used for the control performing a static weighing. NAWIs may also be used to test automatic weighing instruments and density measurements.

The suitability of a NAWI relates to the verification scale (e) interval and the weighing range (Min, Max), which are specified on the data plate of the NAWI.

Note: Some NAWIs designated as "multi-interval" or "multi-range" instruments have more than one value for e. The values are then designated by e_1, e_2, … , e_i which are specified on the data plate of the NAWI.

Table 3 shows the relationship between the verification scale interval of the NAWI and the nominal quantity of the prepackage. This table is not mandatory but represents good practice. Domestic requirements may exist, may be different and (in part) require more accurate equipment.

For processes with standard deviation $\sigma < 0.2$ TNE, as a rule of thumb, it would be advantageous for the packer to choose $e \approx \sigma$ or smaller[15].

Table 3: The relationship between the verification scale interval of the NAWI and the nominal quantity of the prepackage.

Verification scale interval (e)[16]	Nominal quantity
0.1 g	≥ 5 g
0.2 g	≥ 10 g

[15] This allows the packer to get a better estimate of the process standard deviation.

[16] The relationship is derived from the guidance that maximum permitted error (MPE) of the instrument shall be less than or equal to 1/10 TNE of the nominal quantity.

0.5 g	≥ 25 g
1 g	≥ 110 g
2 g	≥ 330 g
5 g	≥ 1670 g
10 g	≥ 3330 g
20 g	≥ 6670 g

Table 3 applies to weighing instruments marked with the verification scale interval "e" (respectively e_i).

A NAWI with a larger scale interval may be used, but the packer will then need to compensate for the possible extra error in the measurement.

Example: A product is marked 500 g and a packer uses a NAWI with a 5 g scale interval (e = 5 g) to fill the packaging with the product.

A verified class III NAWI with e = 5 g will have a maximum permitted in service error at 500 g of 5 g.

From Table 3 above, for a nominal quantity of 330 g or more the verification scale interval of a suitable NAWI needs to be no larger than 2 g.

The NAWI being used has a larger scale interval (5 g) and so to ensure that the quantity requirements are all met the packer needs to compensate for the extra error, 5 g – 2 g = 3 g, on the NAWI.

This can be accomplished in several ways, including overfilling to the next scale interval (505 g) and taring off the packaging with 3 g of weights.

Further advice can be obtained from your competent department[17],

When using two-pan weighing instruments, verified or calibrated weights have to be used on the weight pan. However, instead of weights, an empty prepackage may also be used, to establish the tare weight. The prepackage must be representative of all the prepackages for that batch.

Correct functioning of the NAWI shall be checked regularly. This control is simple to perform with verified or calibrated weights.

If the weighing instrument deviates by more than the "in service" tolerance, then it is no longer suitable for legal use, and it will have to be repaired, replaced or put out of service for legal use.

5.3.4 Additional criteria for the use of checkweighers

An automatic checkweigher is a weighing instrument in a production line over which all the prepackages are passed and which, in its simplest form, measures the gross weight of individual prepackages.

The additional requirements applicable to automatic checkweighers depend on what is done with those measurements.

Good practice will require a checkweigher of at least an accuracy class X(1) or XIII(1), with a verification scale interval according to Table 3. One of class X(2) or XIIII(2) may

[17] See for details: http://www.welmec.org/welmec/working-groups/welmec-wg6-members-email-addresses.html

be used, but the packer will then need to compensate by increasing the target quantity, TU1 & TU2 limits or correcting measuring results[18].

NOTE: The checkweighers are verified with the present types and nominal quantity of the prepackages. If a new type and/or different nominal quantity of prepackages is produced, it may be necessary to have the checkweigher verified again so that it covers a larger range and/or another type.

For older instruments that do not comply with OIML R51 (1996) or R51 (2006) nor with MID[19], the zone of indecision "U_n" may be specified instead of the standard deviation.

The value of the actual zone of indecision "U_a" is determined at the first verification and at every re-verification of the instrument and is marked on the data plate of the checkweigher. The zone of indecision shall not exceed 2/5 TNE, unless compensated for.

The performance of each checkweigher has to be checked regularly to determine the mean error and standard deviation (or zone of indecision). Often a procedure is specified by the manufacturer of the checkweigher. Such a procedure shall take dynamic weighing into account in order to reach best appropriation. The monitoring of the checkweigher should include ensuring that the reject mechanism is functioning correctly

Where a NAWI is used to assess, set up and monitor a checkweigher then the verification scale interval generally needs to be one-tenth of the value in Table 3. Where the verification scale interval of the C/W is less than 1 g, seek advice from the Competent Department.

An example of test procedure:

- Weigh the same prepackage 20 times and make sure that the checkweigher records the individual weight results, if possible with a resolution that is 10 times higher. Record the mean and standard deviation (or zone of indecision)
- If the mean and/or standard deviation exceed the in service tolerance, then it is not suitable for legal use, and it will have to be repaired, replaced or put out of service for legal use and cannot be used as a control instrument.
- In this case the packer's control shall be dealt with using another appropriate and legal measuring instrument.

Annex 5 shows a test procedure[20] that can only be used in countries where it is legal to use non-verified checkweighers.

5.3.5 Additional criteria for the use of an automatic gravimetric filling instrument (AGFI)

An AGFI fills packages with predetermined and virtually constant weight. An AGFI may realise the nominal quantity by means of a single fill, or by means of more than one fill in one or more weighing units.

[18] For instruments complying with OIML R51-1 (1996), OIML R51-1 (2006) or MID (among others annex MI-006 Section II) the maximum systematic (mean) error is derived from the verification interval and the maximum random (standard deviation) error is dependent upon nominal quantity and factor x that quantifies the maximum permissible standard deviation.

[19] MID: Directive 2004/22/EC, Annex MI-006: Automatic weighing instruments.

[20] This procedure is based on the procedure used in the UK.

If the AGFI includes software for the recording of the weighing results and adjustment of the filling parameters, then it is suitable as a weighing instrument for controlling e-marked prepackages. If the instrument incorporates a checkweigher facility, which is used to adjust the filling parameters of the AGFI, the instrument shall also be legal and suitable as a checkweigher.

The suitability of the AGFI is determined by the setting (systematic) error and the deviation from the average (random) error. For instruments complying with OIML R61 (1996), OIML R61 (2004) or MID (among others Annex MI-006, section III), these errors are dependent upon the accuracy class of the instrument and are independent of the scale interval. A class X(1) instruments or better is suitable but an instrument of a less accurate class may be used if the larger permitted error is compensated for (for example by correcting the measuring results).

Because the maximum setting error for an AGFI is 0.25 x MPD[21] x class, the packer has to raise the set point by this value or to carefully evaluate the setting error to optimise compensation.

The performance of the AGFI has to be checked regularly.

An example of test procedure:

- Withdraw 20 prepackages from the line. Measure the quantity of product contained in the prepackages on a legal NAWI with a verification scale interval of 1/10 or less of the verification scale interval of the AGFI. Note the individual weights and calculate the mean
- The AGFI is not suitable as a controlling weighing instrument if the individual weights deviate from the mean by more than the in-service tolerance or if the mean value deviates more from the preset value of the fills than the in-service tolerance
- If the repair or adjustment of the AGFI is not immediately possible, then, depending on national rules for control of instruments in service, either the production results must be compensated for or the packers control shall be dealt with on another appropriate and legal measuring instrument.

Note: The performance of an AGFI is very much dependent on the nature of the product that is weighed. If the product is sticky or has a large particulate, this can lead to significant and apparently unexpected inaccuracies. The same applies if the AGFI is used with too large rate of operation.

5.3.6 Volume determination

The reference temperature for volume measurements is 20 °C.

The volume can be directly determined by emptying the product into a liquid measure, or indirectly determined based on measurements of density and weight.

Measures of capacity must be verified or calibrated according to national requirements.

Table 4 gives guidance for the maximum verification scale interval. This table is not mandatory but represents best practice. A measure with a larger scale interval may be used, but a packer may then need to compensate for this, e.g. by overfilling to compensate for the larger error of measurement.

[21] MPD: Maximum Permissible Deviation.

Table 4: The relationship between the verification scale interval of the measurement capacity and the nominal quantity of the prepackage.

Verification scale interval (e)[22]	Nominal quantity
0.1 ml	≥ 5 ml
0.2 ml	≥ 10 ml
0.5 ml	≥ 25 ml
1 ml	≥ 110 ml
2 ml	≥ 330 ml
5 ml	≥ 1670 ml
10 ml	≥ 3330 ml
20 ml	≥ 6670 ml

5.3.6.1 Measuring container bottles (MCBs) and certified templates

MCBs are bottles, which have been manufactured in compliance with Directive 75/107/EEC, and therefore can be used as measuring containers. When these bottles are filled to a certain level or to a certain percentage of their filled brimful, then the quantity of liquid, which they contain at 20 °, is known. The mark indicating conformity with Directive 75/107/EEC (marked in the bottom or bottom-edge) is a reversed epsilon (3).

The control on the manufacturing of MCBs is the responsibility of the Competent Department. The granting of type approval and the verification of the templet is also the responsibility of the Competent Department.

5.3.6.2 Mass determination and density measurement

Based on the mass of a quantity of product and the density, the volume can be calculated.

Density determination

The density of fluids can be determined with:

- a pycnometer made of metal or glass (or package like a pycnometer)
- a plunge body (a so called gamma-sphere),
- a measuring flask
- a measuring cylinder
- a specific measure
- a hydrostatic weighing instrument
- an areometer, or
- a digital electronic density meter.

[22] The relationship is derived from the guidance that MPE of the instrument shall be less than or equal to 1/10 TNE of the nominal quantity.

The first five measuring methods mentioned also require the use of an approved, verified and suitable weighing instrument.

In some cases an internal calibration is acceptable (for example a pycnometer, an areometer, a specific measure or an electronic density meter) provided that the procedure and the available results are shown to be sufficiently accurate. A check can be made using distilled water whose density at 20 °C is 0.998 2 g/ml, and with air whose density is 0.001 2g/ml.

The actual volume of the prepackage has, with exception of frozen or deep-frozen products, to meet the requirements at a temperature of 20 °C. For this reason it is therefore sensible to also carry out the density measurement at 20 °C or, if measured at other temperatures, the density is temperature compensated accordingly. Practically, if the volume is measured at a lower temperature than 20 °C, and is correct according to the volume declaration, then it will have a larger volume at 20 °C, and so will also be correct.

Data of the methods and applicability for the listed measuring instruments is given in Table 5.

Examples of instructions for different types of density measurements are given in Annex 3[23].

Some liquid products need different methods of measuring the volume: ice-cream, yoghurt with fruits etc. For more guidance see OIML G14 (2011)[17].

There is a relationship between the actual density, ρ_o, and the apparent density (in air), ρ_a. This is

$$\rho_o = 0.99985\ \rho_a + 0.0012$$

For practical reasons, the actual density, ρ_0, is approximately the apparent density, ρ_a, + 0.0012 g/ml, which may be used as long as the total measurement error is less than 0.2 TNE.

The uncertainty in density determination should be taken into account in the determination of the quantity of product contained in the prepackages.

Where the density of each batch of product is not determined then the density figure used must be the maximum expected to fulfil the responsibility that "… the checks carried out … shall be so organized that the quantity of contents is effectively ensured."

[23] OIML G14 (2011): Density measurement.

Table 5: Summary of arithmetic methods of density measurement and volume calculation for prepackages.

<table>
<tr><th>Equipment for density measure-ment</th><th>Scale interval of weighing instrument</th><th colspan="3">Use of aid-equipment</th><th>Density ρ_o (g/cm^3)</th><th>Volume calculation (cm^3)</th></tr>
<tr><td>Areometer
scale interval
$0.001 \cdot \rho_o$</td><td>---</td><td rowspan="3">Thermo-meter</td><td rowspan="3">Thermo-statically controlled bath</td><td>Measu-ring cylinder with suffici-ently high level</td><td>ρ_o directly read out, no corrections</td><td rowspan="6">$V = \frac{0.99985 \cdot m}{\rho_0 - 0.0012}$

V = volume prepacking (ml) or (cm^3)

m = mass of product in prepacking (value weighing instrument)</td></tr>
<tr><td>Pycno-meter in metal or glass

100 ml</td><td>d ≤ 0.1 g</td><td rowspan="2"></td><td>ρ_o not directly read out
$\rho_0 = 0.99985 \cdot \frac{m_v}{V_0} + 0.0012$

m_v = mass of product in measuring instrument (g)
V_o = volume of measuring instrument (cm^3)</td></tr>
<tr><td>Plunge body (gamma-sphere)

100 ml</td><td>d ≤ 0.1 g</td></tr>
<tr><td>Electronic density meter (DMA-serie)</td><td>---</td><td colspan="3">Thermometer and thermostat if they are not built in</td><td>ρ_o directly read out</td></tr>
<tr><td>Height marked bottle and bottle or tin as pycno-meter</td><td>d ≤ 0.1 g</td><td rowspan="2">Thermo-meter</td><td rowspan="2">Thermo-statically controlled bath</td><td rowspan="2">Filled bottle from bottle-line</td><td>ρ_o not directly read out
$\rho_0 = 0.9970 \cdot \frac{m_v}{m_w} + 0.0012$
m_v = mass of product in bottle or tin
m_w = mass of distilled water in bottle or tin</td></tr>
<tr><td>Bottle or tin as pycno-meter filled up with water</td><td>d ≤ 0.1 g</td><td>ρ_o not directly read out
$\rho_0 = 0.9970 \cdot \frac{m_v}{m_w - m_a + m_v} + 0.0012$

m_a = mass of product + water added to top of bottle</td></tr>
</table>

5.4 The interpretation of the measurements

All relevant measurements have to be organised in a clear way. Only when this has been done, it is possible to give an accurate interpretation of the measurement results. The data can be processed manually or automatically.

5.4.1 Control charts

The measurement indicated by a verified and suitable measuring instrument (weighing instruments, measuring flask or templet, sometime referred to as a template, and measuring container bottles) is recorded or marked on a control chart.

There are different types of control charts. However, on a control chart two aspects of the measurement must always be shown, namely the average and the spread of the measurement results.

WELMEC 6.5, Annex E Quantity Control by Sampling provides guidance on establishing a suitable system.

5.4.2 Automatic data-processing (e-software)

When the measurement results from the measurement instruments are automatically processed, recorded and presented, then less manual input is required and therefore there is a smaller chance that mistakes will be made. However, before such an automated system can be applied, it will be necessary to demonstrate that the system works in a fail proof way. If e-software is used, the packer has to prove that the production meets the criteria for the e-marked prepackages according to the Directive.

There are different rules for software in the Member States (seek advice from the Competent Department). A company is permitted to develop its own e-software (or have it developed on its behalf). This software should also be validated. Approved software-packages, having identification codes, known by the Competent Department, is used in some Member States.

The requirements applicable to the e-software are given in Annex 2.

5.5 Actions after the process evaluation

An adjustment of the filling process should be identified by the measuring checks and, when identified at the time of packing, it will be relatively simple to correct.

When a corrective action is necessary to a batch that is produced or when a measuring check shows inadequate prepackages (< TU2), the batch concerned must be quarantined.

Packages that have been quarantined must be clearly marked to prevent accidental distribution of the packages.

These marks can be a mark applied to the batch. Alternatively, the batch can be transferred to a separate location in the warehouse.

A number of corrective actions may be taken:

- Destroying the prepackages is a possibility, if the costs of corrective actions are too high relative to the value of the product. The product can afterwards be re-packed or otherwise re-used
- New quantity indication or removing the quantity indication and selling the prepackages without an e-mark where this is permitted

- Mixing the batch with prepackages that comply with the Directive. This method is not acceptable if the batch has inadequate units (< TU2)
- The mixed production must fulfil the requirements of the Directive and documentation is necessary
- Removing deficient prepackages by measuring the quantity of product contained in all the prepackages in the batch. The new reduced batch must fulfil the requirements of the Directive and documentation is necessary. This can easily be done by passing the prepackages over a verified checkweigher.

5.6 Responsibilities and competences

It is important to establish what the tasks, competences and responsibilities of the employees involved in the prepackaging are.

For each employee consideration of the following points are essential:

- do they have the right information to be able to carry out their tasks correctly?
- do they have the necessary competencies?
- do they have to deal with potentially conflicting interests (e.g. quality vs. quantity)?

Adherence to the procedures has to be demonstrable for all employees involved.

Instructions should be written in such a way that the experience of the employee is reflected.

5.7 Records

The packer must record all relevant factors that affect the recognised procedures. The records should provide evidence that the packer has followed the recognised procedures.

The records should include:

- all the measurement results, that is:
  - in case of a sample system, the sample records
  - in case of 100% control, the hourly surveys
  - tare samples
  - density measurements, where this is used to determine volume
  - control charts (or similar) for the average (mean or median) and variation (standard deviation or range) of the sample quantities
  - process characteristics that were used for targets and limits, and
  - a maintenance log for the equipment.
- a logbook with particularities about the production. This logbook should include clear details of circumstances under which a batch was quarantined including the cause of the problem and the corrective action taken.

All records must be simple and clear. All records need to be retained as long as the prepackages are intended to remain in the distribution chain with a minimum of 1 year.

Records of the other checks that packers carry out, e.g. on their measuring instruments, should be kept long enough to show that they have met their specifications.

Annex 1 Questionnaire - Information about the packer

Not all Member States require formal recognition of procedures. Where national legislation requires formal recognition of procedures and any modification to them, the completed questionnaire signed by an authorised person should be sent to the national Competent Department. Seek advice from the national Competent Department.

1. The information of the packer

- company name
- address of packing plant
- postal address
- name of the contact person and his function and/or position in the company
- telephone- and fax number, and
- nature of the company; contract packer / packer / importer.

2. The reason for this request

3. Records of the product and the packing process

In order to answer this section the following subjects are treated:

- designation of the packing line
- product
  - name
  - main constituents, and
  - physical characteristics like e.g. liquid, frozen, dried.
- packing material
- nominal quantity and the target value
- packing process
  - kind of packing machine
  - filling speed
  - number of units
  - minimum adjustment, and
  - standard deviation.

4. Evaluation of the e-marked prepackages

The batch size can be expressed in terms of the number of packages or by the time taken to produce the batch.

A statement of whether records are obtained by:

- 100 % control, or
- sampling.

With sampling, the sample size and the minimal number of samples per batch must be stated.

The packer needs to provide information on the following subjects:

- calculation of the target quantity
- how the quantity of product contained in the prepackages is calculated
- action (and if wanted warning) limits for monitoring the filling process, and
- how the variation in the quantity of product contained in the individual prepackage is to be monitored, usually by the range or standard deviation of the sample, together with the appropriate control limits (action and possible warning limits).

5. The determination of the quantity of product contained in a prepackage

The method for determining the actual quantity of product contained in the prepackages must be stated by:

- net-weighing
- gross-weighing minus individual tare
- gross-weighing minus mean tare, or
- volume measurement.

In case of "gross-weighing minus mean tare", it should also indicate the following:

- the determination of the value of the mean tare
- the variation in actual tare, and
- the frequency of the tare determination.

If a determination of the volume relies on weighing, the method of density determination and the manner of the conversion of weight to volume should be included.

6. Measuring instruments

For verified measuring instruments the following should be indicated:

- brand and type
- purpose of use
- records of the verification and stamping plate, and
- software identification, if it has an automatically registered measurement mean.

For non-verified measuring instruments, an indication of the accuracy of the equipment should be given instead of the records of verification and stamping plate.

Each measuring instrument must be checked and calibrated periodically. For each measuring instrument, the following should be indicated:

- manner of control or calibration, and
- frequency of control or calibration.

7. Control over unsatisfactory batches

Procedures for identifying batches should be in place, so that unsatisfactory batches can be identified and then quarantined for rectification.

It must be indicated what is done with such a batch, including quarantining and disposal, and how these actions are administered.

8. Tasks and responsibilities

Provide a brief organisation scheme to indicate by whom the different tasks are performed and what their responsibilities are.

Clear work instructions must be given to those responsible for the packing process. Copies of these instructions must be included in the application.

9. Record keeping

What records are produced from the procedures to be recognised? In what format and for how long are these records kept?

Include copies of all the relevant procedures, e.g. determination of process characteristics, targets/limits/set points, monitoring of the process, control of non-standard prepackages, rectification of non-standard prepackages, maintenance of equipment, training and competence of employees.

Annex 2 Suitable software

WELMEC Working Group 7 gives general requirements for software according to measuring instruments.

The starting points for the evaluation of the software are:

- the software has to give clear and correct information needed to control the production of prepackages, and
- the software has to execute all programmed functions correctly.

In some Member States software is subject to metrological control. The software has to satisfy the following:

- the measurement results have to be transferred accurately from the measuring device to prevent transcription errors
- calculations of packing material, density and limits have to be executed correctly
- correct calculation of a batch's standard deviation, average quantity and the number and/or percentage of prepackages with a quantity below the TU1/TU2 limits
- if an automatic weighing instrument has a reject mechanism, the rejected prepackages may not be included in the calculation or presentation, and
- for calculations of the average and the standard deviation, it is recommended that the following formulae should be used:

  - for the sample average

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

  - for the sample standard deviation with samples

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

With 100% control the term "n-1" is replaced with "n".

For volume declared prepackages, the formula used for the conversion of weight to volume has to be identified in the manual of the software.

It is recommended that the following formula is used for the conversion:

$$\mathrm{V} = \frac{0.99985 \cdot \mathrm{m_{product}}}{\rho_0 - 0.0012}$$

- where the indication of the weighing instruments is in g and the density, ρ_o, is in g/ml. The correction factors convert the differences in density between the mass standards, air and the product.

Uncertainties may never be used to the advantage of the packer.

Records

- A record must be produced at least once an hour
- when product variables are changed, the "old" variables must be recorded together with the associated sample results. When this has been done, everything including the new target quantity and control limits must be recalculated, and new variables may be introduced
- it must be impossible to delete the existing data until after it has been recorded
- the values of the TU1- and TU2-limits must be calculated and the average quantity must be calculated to a decimal place further than the equipment is capable of measuring, and
- the records may be saved digitally.

Annex 3 Examples of instruction for "Bottle used as pycnometer"

The procedure in Table 6 should be performed at 20 °C, with all weighings in grams.

Include the weights of a (glass) strike to ensure the container is filled correctly at no. 2 and 7.

Table 6: Determination of the density of light-carbonated drinks or non-homogeneous fluids, with glass bottles or cans as pycnometer.

No.	1	2	3	4	5	
1. Gross weight of filled container						g
2. Gross weight of filled container, filled to the top with demineralised water						g
3. Weight of added water no. 3 = (no. 2 - no. 1)						g
4. Density in air of demineralised water at 20 °C	0.9970 g/cm^3					
5. Weight of the empty container Note: The bottle has to be very clean and blown well dry!						g
6. Weight of the product no. 6 = (no.1 - no. 5)						g
7. Weight of the container filled to the top with water						g
8. Weight of the water no. 8 = (no. 7 - no. 5)						g
9. Density of the fluid $\text{no. } 9 = \text{no. } 4 \cdot \frac{\text{no. } 6}{(\text{no. } 8 - \text{no. } 3)} + 0.0012$						g/cm^3
10. Volume of product $\text{no. } 10 = \frac{(\text{no. } 8 - \text{no. } 3)}{0.9970}$						ml

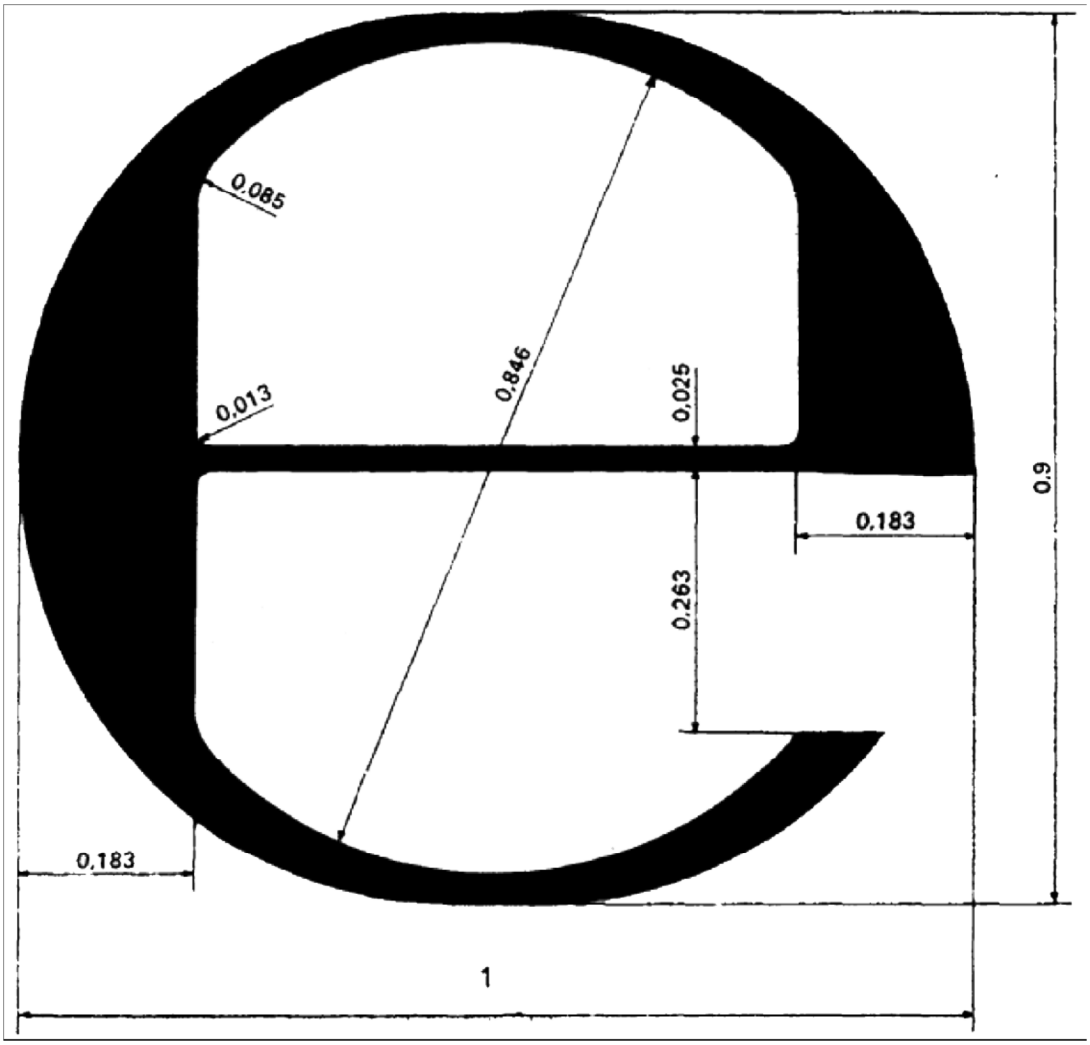
The procedure in Table 7 should be performed at 20 °C with the bottle on a level surface. Mark the bottle where the bottom of the meniscus of the liquid lies.

Table 7: Determination of the density of carbonated drinks or non-homogeneous fluids, with the height marked bottle used as a pycnometer.

No.	1	2	3	4	5	
1. Weight of bottle filled with product Note: The closed bottle has to be weighed.						g
2. Density in air of demineralised water at 20 °C	0.9970 g/cm^3					
3. Weight of the empty bottle Note: The bottle has to be very clean and blown well dry!						g
4. Weight of product (g) no. 4 = (no. 1 - no. 3)						g
5. Weight of the bottle filled to the height mark with demineralised water						g
6. Weight of the demineralised water no. 6 = (no. 5 - no. 3)						g
7. Density of the fluid $\text{no. } 7 = \text{no. } 2 \cdot \frac{\text{no. } 4}{\text{no. } 6} + 0\ 0012$						g/cm^3
8. Volume of product $\text{no. } 8 = \frac{\text{no. } 6}{0.9970}$						ml

Annex 4 The form of the e-mark

The form of the e-mark is specified in Annex II, 3.3.2.2 of Directive 2009/34/EC.



Annex 5 Guidance for assessing and using non-verified average recording checkweighers

The Directive 76/211/EEC, Annex I paragraph 4 requires the measurement or check shall be carried out by means of a legal measuring instrument.

The procedure in this Annex[24] can be used as guidance in countries where they have taken the option not to control this type of instrument according to the Measuring Instruments Directive. In these countries it is legal to use non-verified checkweighers (C/W's). If in doubt contact your local Competent Department for advice.

Non-verified C/W's have not necessarily been through the type approval process and so the packer using this type of instrument needs to assess the C/W's capability for their product, line speed and configuration, and then set it up and monitored it appropriately. General guidance on suitability is provided in section 5.3 above.

As mentioned in section 5.3.4 above, a class XIII(1) C/W with a scale interval not exceeding the values in Table 3 are suitable. Such a C/W has an in-service maximum permissible standard deviation equal to 1/15th TNE of the nominal quantity of the prepackages being checked. The following guidance will ensure that if the C/W being assessed does not perform within the tolerances for a class XIII(1) C/W, then allowances will ensure that the prepackages checked and accepted will meet the quantity requirements specified in the Directive.

a. Best practice is to assess the capability as follows:

i. The assessment needs to be carried out using packs of at least the heaviest, lightest and, where used, two mid-range nominal quantities being checked, at the fastest line speeds to be used for these nominal quantities.

   The packer should then use the in service tolerances for the standard deviation and mean error

ii. Clear the registers on the C/W

iii. Feed 1 prepackage onto the line prior to the C/W and remove it after it comes off the C/W and repeat this a further 59 times (total 60 passes), noting the individual weights indicated by the C/W

iv. Weigh the prepackage (W_{nawi}), on a verified non-automatic weighing instrument (NAWI), which has a verification scale interval 1/10th of the value in Table 3. Where the verification scale interval in Table 3 is less than 0.1 g seek advice from the Competent Department.

v. Obtain from the C/W the standard deviation (s_c) and calculated average weight of the 60 packs ($W_{c/w}$). If the standard deviation, s_c, is greater than 1/15th TNE for the prepackages checked the set points need to be enhanced, see b, iv) below

vi. Calculate the mean error, (ME) = $W_{c/w}$ - W_{nawi}. If this mean error exceeds one scale interval on the C/W then the C/W should be adjusted, or if this is not possible it should be taken into account, see b, iv) below

vii. Manually calculate the average and standard deviation calculations using the individual weights indicated by the C/W for each of the 60 weights. Compare these calculated results with the results indicated by the C/W, to ensure that the software carries out correct calculations

viii. Keep records of the assessment showing the mean (average) error, standard

[24] Note that this procedure is based on the procedure used in the UK.

deviation and the calculations to validate that the calculations in the C/W software have been performed correctly.

b. Set point calculations

i. The above standard deviation test uses only 1 prepackage to assess the variability of the C/W. Therefore the estimation of the C/W standard deviation, s_c, does not take into account the variability of the tare (package) weight. The set points need to take into account the variability (standard deviation) of the tare, s_t. These independent variables can be combined using:

$$s_{C/W} = \sqrt{s_c^2 + s_t^2}$$

ii. The set points need to take into account the average tare weight for the product and are referred to as Q_n', T1' and T2'

iii. If the performance of the C/W does not fall within the criteria in a, v) and/or a, vi) above then the set points will need to be enhanced

If the standard deviation of the C/W exceeds 1/24th of the TNE for the prepackage, then the set points need to be increased by $3s_{C/W}$ – 1/8th TNE.

If the mean error exceeds one scale interval on the C/W, then the set point needs to be adjusted by the excess.

To minimise the number of prepackages rejected, ensure that the filling average is set to at least the target quantities specified in section 5.2.2.

iv. Make records of the above calculations.

c. Set up checks

i. Before the start of every run, check the performance of the C/W by passing one prepackage of the nominal quantity to be packed over the instrument 10 times and ensuring that the difference between the NAWI weight and the C/W average is less than 0.1 TNE

ii. Multiply the standard deviation (from a, vii)) (n = 60) by 1.45 to obtain an action limit. If the standard deviation of the C/W check (n = 10) is less than this action limit there is no evidence to indicate that the C/W is not functioning correctly

iii. Check the set points and reject mechanism by passing prepackages made up to values of Q_n set point (Q_n') ± 2s, T1 set point (T1') ± 2s and T2 set point (T2') ± 2s and ensure that, depending on the way the C/W is programmed, the underweight prepackages are rejected properly into a secure receptacle

iv. Make records of all the checks, including before and after adjustment readings.

d. Monitoring production of packaged goods

i. Ensure the quantity of product contained in the prepackages of each 1 hour's production has a mean equal to or greater than the nominal quantity, Q_n

ii. At change of shift or product carry out a 10 pack C/W check as in c, i) and ii) above

iii. At the end of a run, check that the average quantity of product contained in each hour's production of prepackages is OK, and that the reject mechanism is still working correctly

iv. If any problem is found prepackages produced since the last acceptable check

must be isolated and either rectified or reworked

v. Records of all the above must be made, including the quantity of prepackages rejected and how they have been corrected or disposed.

e. Review

i. Whenever there are any changes that may affect the C/W a re-assessment should be made. Changes may include, for example, packing line configuration, speed, nominal quantity, packaging and product formulation

ii. Review the records to ensure the frequency of checks is appropriate to ensure that the quantity requirements are being met all the time

iii Where the records of C/W monitoring shows that its performance, without alteration, is consistent, the period between checks can be extended. It is good practice to carry out checks at least every month.

iv. Records of the above should be made.

Annex 6 Revisions made to this Guide

Issue	Date	Significant changes from previous issue
2	June 2015	In this issue the guidance has been reformatted and generally expanded to be of more use to packers and importers. 1 Introduction now includes a list of all WELMEC publications relating to prepackages The previous chapters 3 & 4 have been combined into the new chapter 3, which explains the responsibilities of the Competent Department. The previous chapters 5 and 6 are now re-numbered 4 and 5. Subsequent chapters have been re-numbered. 5.3.3 now contains an example on how to compensate for large measurement error Annex 5 has been added to provide guidance on the use of unverified checkweighing instruments Annex 6 has been added to indicate the changes made in this issue of document WELMEC 6.4