WELMEC 6.4

Issue 1

WELMEC

European cooperation in legal metrology

Guide for packers and importers of e-marked prepacked products

June 2005

Foreword

WELMEC is a co-operation between the legal metrology services 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 manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC 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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Content

ANNEXES:

1 INTRODUCTION

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

The content is based on legal requirements, the interpretation of them by WELMEC and practical solutions and recommendations.

The means of recognising procedures by the competent department depends on the legislation of the Member State of the EEA.

In chapter 2 the content is of the e-marking regulations is set out, in chapter 3 the role of the competent departments is explained. The most important concepts are explained in chapter 4.

In chapter 5, requirements are given that apply to every e-marked prepackage. The major part of this chapter deals with the conditions concerning the marking of the prepackages.

Chapter 6 concerns the procedures. The chapter provides information about what is addressed in the recognition of the procedures and what the criteria are.

The procedures that the packer has to follow and the role of the competent department are set out in chapter 7.

The guide should not be regarded as definitive. 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.

The reader should check the validity of the document to ensure that it has not been changed. If errors are found in the document this should be drawn to the attention of WELMEC.

2 REQUIREMENTS FOR LABELLING OF PREPACKAGES

The requirements for the labelling of prepackages corresponds to the EEC-Directives 75/106/EEC and 76/211/EEC concerning prepackaging by weight or by volume, as amended by directive 78/891/EEC, and implemented in the national legislation of the Member States.

The Labelling requirements for foodstuffs reflect the marking requirements of Directive 2000/13/EC.

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

These Directives do not cover packages made up by number, length or area nor catchweight product – that is product not made up to a pre-determined constant quantity.

2.1 The removal of trade obstacles with border crossing traffic (trade between countries, members of the EEA)

Effect:

The Member States of the EEA may not refuse, forbid or limit the putting on the market of e-marked prepackages that meet the requirements.

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

Effect:

A prepackage that carries an e-mark, contains on average at least the nominal quantity.

In addition requirements exist to restrict the proportion of the prepackages with a content below the tolerance limits, TU1 and TU2[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 manufacturer, contractor, filler or the importer can be identified;
- the prescribed letter e, as a sign that the prepackage satisfies the requirements of the Directives.

2.3 The requirements with regard to the maximum permitted errors in the content of prepackages

Effect:

The e-marked prepackages need to satisfy the tolerances. (see chapter 5)

Inspection is done statistically by means of samples; this official control is regulated by the e-marking regulations. The sample size with corresponding acceptance and rejection criteria is dependent on the size of the lot and whether the test is destructive or not.

2.4 The responsibilities of the manufacturer or the importer concerning the actual content of the prepackage.

Effect

[1] These limits are discussed in paragraph 5.1.

The manufacturer or, in case of import from countries outside the EEA, the importer is responsible for ensuring that the prepackages meet the requirements.

The responsibilities mean that checks are needed to confirm that the equipment used to make up the prepackages is legal and suitable and that records are available for competent departments to verify. Checks shall be so organised so as to effectively guarantee the quantity of product in a prepackage.

These can be satisfied in the following way:

2.4.1 measuring while filling (hand filling)

During the filling the actual content of the prepackage is measured by means of a legal and suitable measurement instrument. The filling occurs by hand and is based on reading the measuring instrument.

2.4.2 recognizing procedures

When the actual content of every individual prepackage is not measured, the options concerning process control are many but they need to be such as to effectively ensure that the prepackages meet the requirements. The determination of whether this requirement is met is determined by the competent department 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 the EEA, therefore movement within the EEA does not involve import / export for the purposes of the Directive. The importer has the same responsibilities as a packer but the Directive recognizes that they may not physically come into contact with the prepackages being imported.

The Directive states, “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 is dependent on the national legislation.

Some of the acceptable guarantees include:

a) evidence from a competent department in a Member State,
b) evidence from an EEA accepted competent department in the exporting country,
c) records of checks carried out by a competent sub-contractor at the place of first entry into the EEA,
d) to obtain records from the packer and to carry out checks to verify the data contained in them.

Evidence referred to in a) and b) above shall state that the quantity control system had been assessed and that the controls and records guarantee compliance with the requirements of the Directive.

3 THE ORGANIZATION OF THE SUPERVISION OF THE GOVERNMENT

3.1 The competent department

Checks to ensure that prepackages comply with the requirements of this Directive shall be carried out by the competent departments of the Member States 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 checks should cover the adequacy of the quantity control system, confirm that it was being followed, and that its appropriateness had been regularly reviewed. This will include:

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

Checks on 'e' marked products and the quantity control system used for their production should be carried out at packers' and importers' premises generally at least once a year for those importing, exporting or packing prepackages. Member States have various ways of determining the frequency of visits, which include assessing

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

Checks 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 of Directive 76/211/EEC. The operating characteristic curve of the reference test is in Annex D.8. See also Annex I of WELMEC document 6.3.

The Directives do 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 Directives.

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. Domestic legislation may control goods outside these limits or sold by reference to length, area and number.

The Competent Department shall recognize the quantity control system in the way specified in national legislation. For the methods of recognition used in each Member States, refer to WELMEC 6.0. This may also result in an approval to mark prepackages with the 'e' mark.

Where there have been changes in the quality system theses changes need to be recognized 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 6.6

4 HISTORY

4.1 e-marked prepackaging

The e-mark can only relate to indications of quantity of product in e-marked prepackages that are produced in a predetermined constant quantity.

A prepackage is defined as the combination of a product and the individual package in which it is prepacked.

An individual package is everything that is meant to be left over after use, except for items naturally in the product and sometimes, when a drained weight is declared, fluids. 'Use' includes consumption or subjecting to a treatment.

A product is prepacked when it is placed in a package of whatever nature without the purchaser being present and the quantity of product contained in the package has a predetermined value and cannot be altered without the package either being opened or undergoing a perceptible modification.

The content of a (pre)package is the quantity of product in a (pre)package.

Other definitions are available in WELMEC Publication 6.1.

As European and international harmonisation continues, definitions may change. Please check with your national competent department or WELMEC.

4.2 The recognized procedures

The purpose of the recognized procedures of the packer is to guarantee that the e-marked prepackages produced satisfy the Directives' requirements.

The recognized procedures need to contain adequate measures to ensure that only prepackages that meet the requirements are put on the market.

The method of recognizing procedures is subject to national legislation.

5 THE REQUIREMENTS FOR e-MARKED PREPACKAGES

5.1 The tolerances

The Directive specifies the following requirements (sometimes referred to as the 3 Packers rules) for the actual content of e-marked prepackages:

- the average contents of the prepackages shall not be less than the nominal contents;

- only a small number of prepackages may have a content below the nominal quantity minus the maximum permissible error (TU1-limit) (not more than 2.5%[2]). These prepackages are known are referred to as 'defectives'.

- no prepackage with a content less than the nominal quantity minus twice the maximum permissible error may bear the e-mark (TU2-limit) These packages are sometimes referred to as "inadequates"

The tolerable negative error (TNE) is dependent on the nominal quantity (marked quantity) of the prepackage, and is:

Nominal quantity Q_n	tolerable negative error (TNE)	
In g or ml	As a % of Q_n	g or ml
5 – 50	9	-
50 – 100	-	4,5
100 – 200	4,5	-
200 – 300	-	9
300 – 500	3	-
500 - 1 000	-	15
1 000 - 10 000	1,5	-

Where a percentage value does not calculate to an exact 0,1g or ml TU value is always rounded up to the next 0,1 g or ml.

Calculation example:

For a prepackage with a nominal quantity of 150 g, the maximum tolerable negative error is 4,5 % of 150 g, which gives a TNE of 6,75 g. This is rounded up to 6.8 g.

A prepackage with a nominal quantity of 250 g has a maximum tolerable negative error which is directly indicated in the table, namely 9 g.

5.2 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 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.

[2] The Directive specifies an acceptable number of prepackages below TU_1 for each of reference test sample size. The proportion of prepackages below TU_1 needs to be sufficiently small, in general it appears that not more than 2.5% below TU_1 is appropriate.

5.3 Drained weight

Under current legislation the e-mark will apply to the net contents of the prepackage, that being the solid product and the liquid medium in which it is packed (including when the liquid is frozen).

5.4 The inscriptions

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,
- kilograms or grams for other products.

The nominal quantity must be shown in figures followed by the name or the symbol for the measurement unit involved. The figures for a nominal quantity must have a minimum height as given 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
-	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 generally not permitted.

5.5 Exceptions to the nominal quantity declaration

The normal requirement 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 ‘e’ prepackages which:

- are for export to a country outside the EEC area,
- are for export to another EEC country as long as the manner in which the nominal quantity is expressed does not contravene the legal provisions of the receiving country or general trade practices there,
- the receiving country prescribes a unit of measurement (for example in a domestic 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 the that country for the product involved.

A supplementary indication of the nominal quantity in a ‘non-metric system’ is allowed.

The numbers and letters of these other values 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 of the measurement unit (liquid product in ml, mL, cl, cL, L or l and solid product in g and kg), must be stated first,
- The ‘e’ sign must relate to this,
- The supplementary indication must also comply with the tolerances,

- 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 predominantly and must accompany the principal indication.

5.6 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.

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

5.7 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 the requirement applies for each of these indications.

The form of the ‘e’ mark is specified in the Directive and can be found in Annex 4.

5.8 Manner of inscriptions and signs

The inscriptions for the indication of the nominal quantity, the identification of the manufacturer or filler and the EEC sign must be indelible, legible and clearly visible under normal conditions of purchase.

5.9 Inscriptions on multipacks

Where more than one statement is given on a multi-pack, e.g. ‘4 x 10 g e 40 g’ the ‘e’ applies to the quantity which the packer controls. Where the individual items could be sold separately this would, in this example, be 10 g. Where the individual items are not appropriate for selling singularly it would be the 40 g.

The Food labelling directive (2000/13/EEC article 8 paragraph 2) requires:

- *Where a prepackaged item consists of two or more individual prepackaged 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. Indication of these particulars shall not, however, be compulsory 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 prepackaged 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. Community provisions or, where there are none, national provisions need not, in the case of certain foodstuffs, require indication of the total number of individual packages.*

The term ”multi pack“ is also defined in the similar way by article 4 of Directive 80/232/EEC.

6 THE REQUIREMENTS CONCERNING THE PROCEDURES

6.1 Introduction

In this chapter, the criteria for evaluating procedures are given step by step. The order of the subjects corresponds to the one in the questionnaire (annex I).

First of all the criteria concerning the suitability of a procedures are listed (6.2.), afterwards an explanation of how the specified measurements can be carried out is provided (6.3.). Also in this section are the requirements for different measurement methods. In section 6.4. the interpretation of measurement results is explained, and section 6.5 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 6.6. The final section 6.7 deals with the records that have to be made and retained by the packaging company.

6.2 The suitability of the procedures

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 quantity packed, and the variation of the individual packages round this average, give important indications for the quality of the process, and how it should be controlled.

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

- Are the measurement results representative for the total (hour) production?

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

  Note: In case of a control by sampling system, the uncertainty of the sample may not used to the benefit of the packer. A sample is by definition assumed to be representative of the sampled lot.

- Are variations of the production process noticed quickly and reliably?

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

  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.

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 drift in the packing process. This also applies for monitoring prepackages below the TU1- and TU2-limits.

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 the process is no longer in control will require the quarantine of all the packages back to the last (good) check however much production that affects (this may be anything from 10 minutes on a fast line to several hours on a slow line. One way the packer can minimise amount of prepackages requiring quarantined is to carry out frequent checks.

6.3 The methods of measurements

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

6.3.1 Introduction

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

1. Destructive:
The e-prepackage is emptied for a direct determination of the weight or volume of the quantity or product in the prepackage.
This method is not very popular because with each determination a prepackage is destroyed, and it is not always possible to extract all the product from the package.

2. Gross weight minus individual tare:
The same package is weighed before and after the filling process. The difference between the two measurement values is the weight of the product. For liquid products, with the aid of the density, the volume of the product can be calculated.

3. 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 of the quantity of product. If the uncertainty is too big (see below), gross weighing minus individual tare may 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 contents can be calculated by subtracting the average weight of the packaging materials from the weight of the prepackage. For liquid products, with the aid of the density, the volume of the product in the prepackage can be calculated.

The weight determination (mass) is an important measurement in recognized packing procedures. The common measurements are:
- mass
- volume
- density

For measurements, which play a decisive role in a trade transaction, it is necessary that they are obtained on legal measuring instruments (as specified in National Legislation). Measuring instruments must always be suitable.

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

A packer must take the measurement uncertainty into account. The quantities of mass, volume and density contribute to the measurement uncertainty.

6.3.2 Mass determination

For the determination of mass a weighing instrument is the most suitable instrument. Weighing instruments, which are used for trade purposes must be legal.

The metrological legislation may make 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.

Below are the general criteria for the use of weighing instruments, which are then followed, by additional criteria for each specific type of weighing instrument.

General criteria for the use of weighing instruments are:

- Depending upon National Legislation, the weighing instrument may need to be type approved and the individual weighing instrument verified. In addition to this, the user must calibrate or check the instrument regularly.
- The accuracy of the weighing instrument is dependent upon the purpose for which it is used. The criteria listed below describe the requirements 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. In the case of type approved weighing instruments the peripheral equipment, which may be connected, may be detailed in the Type Approval Certificate.
- The weighing instrument has to be set up on a stable, non-vibrating surface and out of any draught.
- The weighing instrument should be calibrated or checked regularly during use.

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

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

The suitability of a NAWI relates to the verification scale interval (e). The verification scale interval is a measure of the deviation of the indication of the weighing instrument. The verification scale interval is specified on the data plate.

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.

The relationship is derived from the guidance that the verification scale (e) shall be less than or equal to 1/10 TNE of the nominal quantity.

Table 3

Verification scale interval (e)	Nominal quantity
0,1 g	≥ 5 g
0,2 g	≥ 10 g
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”. For NAWIs without a verification scale interval, the value of the smallest display interval or graduation can be regarded as the verification interval for the purposes of using the table.

An instrument with a larger scale interval may be used, but the packer will need to compensate, e.g. by over-filling.

When using two-pan weighing instruments, verified or calibrated weights have to be used on the weight pan. However, instead of weights, an empty package may also be used, to establish the tare weight. The package must be representative of all the packages 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 use, and it will have to be repaired/replaced.

Additional criteria for the use of checkweighers:
An automatic checkweigher is a device in a production line over which all of 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.

If the automatic checkweigher divides the prepackages into classes of weight based on the measurements, and counts the number of prepackages in each class, then the use of the instrument is limited by its systematic (mean) and random (standard deviation) errors. If the checkweigher records every measurement, then random and systematic errors will be evident.

For instruments complying with OIML R51 the maximum systematic (mean) error is derived from the verification interval and the maximum random (standard deviation) error is dependant upon the accuracy class X(x). The relationship between the verification scale interval and the nominal quantity of the prepackage is as shown in Table 3 above. Good practice will require an accuracy class X(1) or better, unless compensated for.

For instruments that do not comply with OIML R51, the zone of indecision "U_n “ may be specified instead of the standard deviation, although U_n is equal to six times the standard deviation. The value of the zone of indecision is determined at the first inspection of the relevant instrument and is described on the data plate. The zone of indecision shall not exceed 2/5 TNE, unless compensated for.

Two times the standard deviation (s) of the quantity of the prepackages, should not be larger than TNE unless compensated for.

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.

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 checkweighers, but this procedure is not usually adequate, unless it takes dynamic weighing into account.

An example 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).

- The checkweigher is not suitable as controlling weighing instrument if the mean and/or standard deviation exceed the in service tolerance

- If the repair or adjustment of the checkweigher is not immediately possible, then the production results must be compensated for.

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 weigh the nominal quantity by means of a single fill or by means of more than one fill from one or more weighing units.

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. In addition to the general criteria, all AGFIs shall satisfy the suitability requirements below. If the instrument incorporates a checkweigher facility, which is used to adjust the filling parameters of the AGFI, the instrument shall also satisfy the requirements for checkweighers.

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.

The suitability of the gravimetric filling instrument is determined by the setting (systematic) error and the deviation from the average (random) error. For instruments that comply with OIML R61 these errors are dependant upon the accuracy class of the instrument and are independent of the scale interval. It will be possible to use class X(1) instruments or better. An instrument with a larger class may be used if compensated.

Because the maximum setting error is 0.25 x MPD[3] x class, the packer has to raise the set point by this error.

The performance of the AGFI has to be checked regularly.

An example test procedure:

- Withdraw 20 prepackages from the line. Measure the prepackages on a legal NAWI with a verification scale interval (e) of 1/10 TNE. Note the individual weights and calculate the mean.

- The AGFI is not suitable as controlling weighing instrument if the individual weights deviates more from the mean by more than the in-service tolerance.

- If the repair or adjustment of the AGFI is not immediately possible, then the production results must be compensated for.

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.

[3] MPD: maximum permissible deviation

6.3.3 Volume determination

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.

For the maximum verification scale interval, a similar table as that applicable to the verification scale interval for non-automatic weighing instruments applies:

Verification scale interval (e)	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

In the above table the relationship between the verification scale interval of the capacity measurement and the tolerable negative error of the prepackage is given. This table is not mandatory but represents best practice. A measure with a larger scale interval may be used, but a packer may need to compensate for this.

The following indirect measurements of the volume are also allowed.

- Measuring container bottles (MCBs) and certified templets.
  Measuring container bottles are bottles, which have been manufactured in compliance with Directive 75/107/EEC such that they can be used as measuring containers. When these bottles are filled to a certain level or to a certain percentage of their brim capacity, then the quantity of fluid which they contain is known. The characteristic mark (in the bottom or bottom-edge) is a reversed epsilon (3).
- The use of a measuring container bottle is one of the ways to satisfy the obligation to measure or control the quantity when manufacturing prepackages. For this, a calibrated templet must be used. The control on the manufacturing of Measuring Container Bottles 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.
- mass determination and density measurement

Based on the mass of a quantity of product and the density, the volume can be calculated. Depending on the desired accuracy of the mass determination the standards set in section 6.3.2. are appropriate.

6.3.4 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

- a digital electronic density meter

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.

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.

Data of the methods and applicability for the listed measuring instruments is given on the next page.

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

Some liquid products need different methods of measuring the density: ice-cream, yoghurt with fruits etc.

There is a relationship between the actual density (in vacuum) and the apparent density (in air): the actual density approximates to the apparent density + 0,0012 g/ml.

The uncertainty in density determination shall be calculated and taken into account in the total uncertainty in determination of the quantity of product in the prepackages.

Summary of arithmetic methods of density measurement and volume calculation for prepackages

<table>
<tr><th>(1)
Equipment for density measure-ment</th><th>(2)
Scale interval of weigh instrument</th><th colspan="3">(3)
Use of extra equipment</th><th>(4)
Density
ρ_o (g/cm^3)</th><th>(5)
Volume Calculation (cm^3)</th></tr>
<tr><td>Aero meter scale interval 0,001. ρ_o</td><td>---</td><td rowspan="3">Thermo-meter</td><td rowspan="3">Thermo-statically controlled bath</td><td>Measuring Cylinder with sufficiently high level</td><td>ρ_o directly read out, no corrections needed.</td><td rowspan="5">$V = \frac{0,99985\ m}{\rho_o - 0,0012}$

V = volume pre packing (ml) or (cm^3)

m = mass of product in pre-packing (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 rowspan="2">ρ_o not directly read out

$\rho_o = 0,99985\frac{m_v}{V_o} + 0,0012$

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-series)</td><td>---</td><td colspan="3">Thermometer and thermostat if they are not built in</td><td>ρ_o direct 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">Thermos tatically controlled bath</td><td rowspan="2">Filled bottle from bottle-line</td><td>ρ_o not direct read out

$\rho_o = 0,9970\ \frac{m_v}{m_w} + 0,0012$
m_v= mass product in bottle or tin
m_w= mass distillate 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

$\rho_o = 0,9970\ \frac{m_v}{m_w + m_a + m_v} + 0,0012$

m_a = mass product + water In bottle</td></tr>
</table>

6.4 The interpretation of the measurements

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

6.4.1 Control-charts

The measurements indicated by a verified and suitable measuring instrument (weighing instruments, measuring flask or templet 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.

6.4.2 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 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. The available software-programs must be approved by the competent department.

An approved software-package has an identification code, which is known by the competent department.

A company is permitted to develop its own e-software (or have it developed on its behalf). This software also has to be approved by the competent department.

The requirements applicable to the e-software, are given in an annex to this document.

6.5 Actions after the process evaluation

The packing process will be monitored by measurement checks. If a check indicates that the average is below the action limit, or the variation of the process is too large, then the process needs adjustment. The corrective action will be relatively simple.

When corrective action is necessary, the batch concerned must be quarantined. It is essential that no package from the batch leaves the factory.

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 or transferring the batch to n identified separate location in the warehouse.

A number of corrective actions may be taken:

a) destroying the prepackages.
   If the costs of corrective action are too high relative to the value of the product, then there is no option but to destroy the packages. This involves opening the package. The product can afterwards be re-packed or otherwise re-used.
b) removing the quantity indication and selling the prepackages unmarked where this is permitted.
c) mixing the batch with prepackages that are correctly produced.
   This method is acceptable if the mean quantity is only slightly less than the nominal quantity.
   The mixed production must have a mean quantity that is greater than, or equal to, the nominal quantity. It can be necessary to take samples from the new batch so that the mean quantity is guaranteed.
d) removing deficient packages. This can be most easily achieved by simply passing the packages over a verified checkweigher.

6.6 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 is 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 persons involved.

These instructions should be written in such a way that the experience of the worker is reflected.

6.7 Records

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

The records should include:

a. 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
- control charts (or similar) for the average (mean or median) and variation (standard deviation or range) of the process.
- process characteristics that were used for targets and limits
- maintenance log for the equipment

b. a logbook with details of 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 .The records must be retained for inspection by the competent department for at least 1 year after the date of origin.

Sample data must be stored for at least one year, cumulative and other data shall be kept for one year after the expiry of the product (unless otherwise specified by legislation or in the certification of the system).

Annex 1: QUESTIONNAIRE

Not all member states require formal recognition of procedures. Where domestic 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 may be a mandatory requirement. Consult your national competent department.

1. **The packer's details**

- company name
- address of packing plant
- postal address
- name and function and/or position in the company of the contact person of the contact person
- telephone- and fax number
- nature of the company; manufacturer / contract 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 should be considered:
- designation of the packing line
- product
  - name
  - main constituents
  - physical characteristics like e.g. liquid, frozen, dried .
- packing material
- nominal quantity and the target value
- packing process
  - kind of packing machine
  - fill speed
  - number of units
  - minimum adjustment
  - standard deviation

4.1. **Evaluation of the e marked packages**

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

A statement of whether records are obtained by:
- 100% control, or
- sampling

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

The method by which the average content of the packages and the variation in the content of the individual packages

4.2. **The determination of the quantity of product in a prepackage**

The method for determining the net quantity in the prepackages must be stated whether by:
- net-weighing or,
- gross-weighing minus individual tare or,
- 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
- 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.

Indicate the total expanded combined standard uncertainty (k=2) in measuring the quantity of product in the prepackages and state which uncertainty components have been considered.

5. **Measuring instruments**

For verified measuring instruments the following should be indicated:
- mark and type
- purpose of use
- records of the verification and stamping plate
- software identification if it has an automatically registered measurement mean.

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

Each measuring instrument must be checked and calibrated periodically. For each measuring instrument, the following should be indicated:
- manner of control or calibration
- frequency of control or calibration

6. **Control over unsatisfactory batches**

Procedures for identifying batches, so that unsatisfactory batches can be quarantined.

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

7. **Tasks and responsibilities**

Provide a brief organization 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.

8. **Record keeping**

What records are produced from the procedures to be recognized? 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 the process, control of non standard prepackages, rectification of non standards prepackages, maintenance of equipment, training & competence of personnel.

Annex 2: SUITABLE SOFTWARE

WELMEC Working Group 7 gives general requirements for software.

The starting points for the evaluation of the software are:

1. The software has to give clear and correct information, needed to control the production of prepackages.
2. 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 of 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.
- For calculations of the average and the standard deviation, it has recommended that the following formulae should be used:

  1. for the sample average: $\overline{X} = \frac{1}{n}\sum_{i=1}^{n} Xi$

  2. for the sample standard deviation with samples: $s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(xi - \overline{x})^2}$

  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:

$$\text{volume} = \frac{0{,}9985 \times \text{weight of the product}}{\text{density} - 0{,}0012} \text{ ml}$$

where the indication of the weighing instruments has to be in g and the density has to be 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 to one decimal place further than the equipment is capable of measuring.
- The records may be saved digitally.

Permitted variations

- A permitted 2,5% threshold for e-marked prepackages which pass the TU1-limit must not operate cumulatively, but should be reset every hour.
- Any adjustment to correct the target quantity must not lead to deliberate filling below the nominal quantity.
- The software must be identifiable by means of an identification code. The identification code must be easily available to the competent department.

Annex 3: EXAMPLE OF INSTRUCTION FOR "BOTTLE USED AS A PYCNOMETER"

For the determination of the density of light-carbonated drinks or non-homogeneous fluids, with glass bottles or cans as pycnometer.

The procedure mentioned below must be performed at 20°C, with all weighings in grams.

Nr.	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 nr.3 = (nr.2 - nr.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 nr.6 = (nr.1 - nr.5)						g
7. Weight of the container filled to the top with water						g
8. Weight of the water under nr. 7 nr.8 = (nr.7 - nr.5)						g
9. Density of the product in vacuum $nr.9 = nr.4 * \frac{nr.6}{nr.8 - nr.3} + 0{,}0012$						g/cm^3
10. Volume of product $nr.10 = \frac{(nr.8 - nr.3)}{0{,}9970}$						ml

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

EXAMPLE OF INSTRUCTION "HEIGHT MARKED BOTTLE":

For the determination of the density of carbonated drinks or non-homogeneous fluids with the height marked bottle used as a pycnometer.
The method below 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.

Nr.	1	2	3	4	5	
1. Weight of bottle filled with product (note a)						g
2. Density in air of demineralised water at 20°C	0,9970 g/cm^3					
3. Weight of the empty bottle (note b)						g
4. Weight of product (g) nr 4 = (nr.1 - nr.3)						g
5. Weight of the bottle filled to the height mark with demineralised water						g
6. Weight of the water under nr. 5 nr.6 = (nr.5 - nr.3)						g
7. Density of the fluid = $nr.7 = nr.2 * \frac{nr.4}{nr.6} + 0,0012$						g/cm^3
8. Volume of product $nr.8 \quad \frac{nr.6}{0.9970}$						ml

a) The closed bottle has to be weighed
b) The bottle has to be very clean and blown well dry.

Annex 4: THE FORM OF THE ‘e’ MARK

This is specified in Directive 71/316/EEC, and can also be found on the WELMEC WG6 website at www.welmecwg6.org.