

WELMEC 6.10

Issue 1

# WELMEC

European cooperation in legal metrology

## Information on Controls on Prepacked Product, including Implementation of Council Directive 76/211/EEC



July 2011

# WELMEC

European cooperation in legal metrology

WELMEC is a cooperation between the legal metrology services of the Member States of the European Union and EFTA.

This document is one of a number published by WELMEC to provide guidance and assistance to packers, importers and competent departments responsible for prepacked products.

The documents 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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# 1 Introduction

- 1.1 This document is part of a series of documents published by WELMEC that cover requirements for prepacked products:
- 6.0 Introduction to WELMEC documents on prepackages
  - 6.1 Definitions of terms
  - 6.2 Translations of terms
  - 6.3 Guidance for the Harmonised Implementation of Council Directive 76/211/EEC
  - 6.4 Guide for packers and importers of 'e' marked prepacked products
  - 6.5 Guidance on Controls by Competent Departments
  - 6.6 Guide for recognition of procedures
  - 6.7 Guide for Market Controls on Prepackages for Competent Departments
  - 6.8 Guidance for the Verification of Drained Weight
  - 6.9 Prepackages - Uncertainty of Measurement
  - 6.10 Information on Controls on Prepacked Product**

These documents represent the opinion of WELMEC and are published on their website ([www.welmec.org](http://www.welmec.org)).

This series of documents primarily intends to provide guidance to all those concerned with the application of directives 76/211/EEC and 2007/45/EC on prepackages (the Directives) and of non harmonised areas related to prepacked product such as drained weight requirements. They are intended to lead to a uniform interpretation and enforcement of these Directives and assist in the removal of barriers to trade.

## Disclaimer

- 1.2 The Working Group recognised the importance of international trade and at their meeting of 15 May 1998, agreed that the World Trade Organisation acceptance of International Organisation for Legal Metrology (OIML) Recommendations be reflected in its work. Consequently OIML Recommendations<sup>1</sup> have been noted in this document for guidance, it being recognised that domestic legislation may differ from these recommendations. It is also recognised that only the Courts can definitively interpret the legislation, and this document does not affect domestic legislation. This document is a recommendation of best practice based on the opinions of the experts in the Working Group.

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<sup>1</sup> OIML R 79 (1997): Labelling requirements for prepackaged products, and  
OIML R 87 (2004): Quantity of product in prepackages, and  
OIML R138 (2007): as amended in 2009: Vessels for commercial transactions

## 2 Background

2.1 Member States of the European Economic Area have implemented the Council Directives 75/106/EEC of 19 December 1974 and 76/211/EEC of 20 January 1976 in their national legislation. The Directives deal with marking and quantity requirements for 'e' marked prepackages.

2.2 The European Commission carried out a review of the Directives<sup>2</sup> and consulted the stakeholders on their views and concerns. The conclusions included that:

“The Public Consultation has confirmed broad support for the existing legislation. No major issues have emerged that cannot be treated by guidance based on the current legislation. Member States would have it in their own hands to simplify by withdrawing any legislation that is parallel with EC rules and this would lead to de facto total harmonisation as advised by the SLIM team. Expanding the scope as advised by the SLIM team would still fall short of international standards, while little evidence was provided indicating that there are many products of over 10kg/l that require such harmonisation. Definitions that need to be clarified can be taken care of by means of guidance and drained weight can also be harmonised on the basis of tolerances in the current legal provisions.

The Commission services will in first instance proceed with stakeholders and authorities on an interpretative document that can serve as a basis for further guidance to be coordinated with stakeholders.

The public consultation has brought to light a few subjects which could be the subject of regulatory change:

- making the current EC rules total,
- eliminating the e-mark,
- including catchweight products.

However, there is currently insufficient justification to proceed with a proposal for a change to the current legislation.”

2.3 Subsequently the Directives were amended by Directive 2007/45/EC of 5 September 2007, which revoked Directives 75/106/EEC and 80/232/EEC and amended Directive 76/211/EEC.

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<sup>2</sup> Metrological Requirements for Prepackaged Products, Brussels, 24 August 2005

- 2.4 Directive 2007/45/EC also recognised that unit pricing<sup>3</sup> gives consumers information to judge value for money, and so prohibits national legislation from requiring products to be made up in specified nominal quantities. It permits a transitional period for existing requirements for butter, coffee, dried pasta and milk until 11 October 2012 and for white sugar until 11 October 2013.
- 2.5 This directive also makes it mandatory for certain wines and spirits to be sold in specified quantities, whether or not the prepackage is 'e'-marked; although prepackages are exempt from this requirement when they are sold in duty-free shops for consumption outside the European Union.

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<sup>3</sup> Directive 98/6/EC of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers.

### 3 Aim of document

- 3.1 This document aims to make transparent the different ways by which the European Legal Metrology Cooperation Members and Associate Members have implemented the amended legislation and how they control other prepacked product.
- 3.2 The document also intends to deal with some of the issues identified by the European Commission's review that could be addressed by guidance, and also give clarity on the requirements for prepacked products in Member States. The production of this document was agreed at the WELMEC WG6 meeting in May 2007 in resolution 172.
- 3.3 To assist in cross-referencing, the wording from directive 76/211/EEC (the Directive) is in italics and the paragraph numbers in Parts 8 to 10 of this document relate to the paragraph reference in the appropriate Annex of the Directive. It will be evident that not all of the Directive's Annexes have been quoted as these parts contain non-contentious requirements.
- 3.4 The document is structured so that sections 5 to 11 deal with the national implementation of the Directives 76/211/EEC and 2007/45/EC, and section 12 with other issues such as requirements for non-e-marked prepackages.
- 3.5 It is hoped that this document will assist packers, importers and Competent Departments to:
- clarify Directives where they are vague,
  - clarify the requirements for both 'e' and non-'e'-marked prepackages,
  - assist in removing any problem areas by laying down guidelines which may be useful for when the Directives are reviewed,
  - assist WELMEC countries in aligning their legislation to remove any barriers to trade, and
  - assist other countries wishing to implement quantity controls that will enable packages to comply with the Directive.

#### 4 **Definitions**

Where a term is not defined in European legislation, the OIML definition is used.

4.1 The Directive defines 'prepackage' in article 2 as being: "the combination of a product and the individual package in which it is prepacked".

4.2 The Directive defines when a product is 'prepacked' by stating:

- 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.

4.3 The Directive does not define terms such as 'packer' and 'importer' and so national implementation of the Directive has given rise to different interpretations which are identified later in the document.



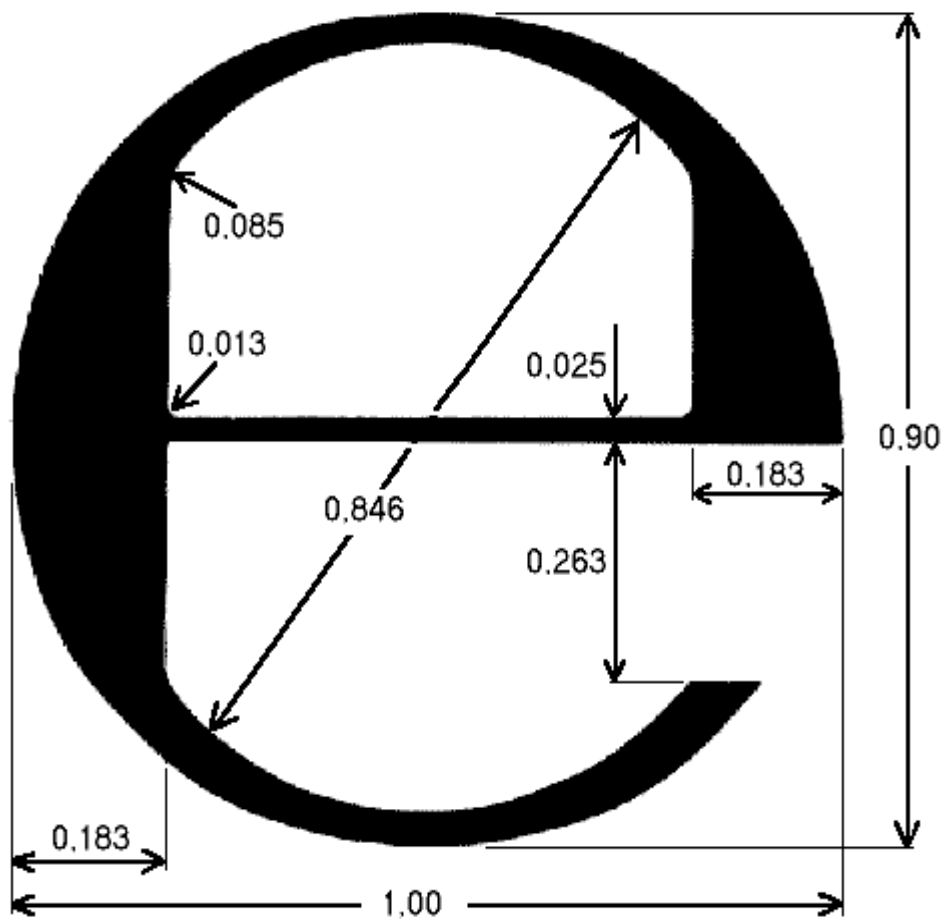
## 5 Scope of the Directive

- 5.1 Article 1 of the Directive specifies the prepackages that are controlled, they are prepackages containing products intended for sale in constant unit nominal quantities which are:
- equal to values predetermined by the packer,
  - expressed in units of weight or volume, and
  - not less than 5 g or 5 ml and not more than 10 kg or 10 L.
- 5.2 The interpretation of the above is that prepackages bearing an e-mark shall comply with the Directive. Depending on national legislation prepackages without the e-mark may have the same requirements as those in the Directive. This document clarifies this national implementation
- 5.3 The scope of the Directive does not restrict the way that prepackages are sold and so includes both business-to-consumer transactions (B2C) as well as business-to-business (B2B) transactions.
- 5.4 The Directive does not control any other products, for example where they:
- are weighed out while the purchaser is present, for instance at the delicatessen counter,
  - are in open packing material, for example a French loaf (baguette) in an open sleeve or an open punnet of strawberries,
  - are prepackages not made up to a predetermined quantity and are individually weighed. These prepackages are generally referred to as 'catchweight' products, and
  - have a marked quantity outside the above ranges of weight or volume, or where the marked quantity is expressed in terms of length, area or number.
- 5.5 Member States' domestic legislation controls these products and these requirements vary.

## 6 'e'-marked prepackages

6.1 The Directive states, in article 3, that prepackages may bear the EEC sign or mark defined if they comply with the requirements of Annex I to the Directive, which covers labelling and quantity requirements.

6.2 The form of the 'e'-mark is shown in the drawing contained in Council Directive 2009/34/EC<sup>4</sup> and takes the form:



<sup>4</sup> See OJ L114 from 7.5.2009 p10, CELEX 32009L0003, Annex II 3.3.2.2

6.3 'e'-marked prepackages are required to be subject to the specified metrological controls, generally referred to as the 'reference test'. The frequency of this control is not specified and is left for Member States to decide. From the information in WELMEC document 6.0 it seems that the frequency is generally annually. In some Member States the frequency is dependent on the risk the business poses and is related to:

- the area of distribution,
- the value of the product,
- the difficulty of packing, and
- the results of previous tests, including quantity control systems audits.

6.4 A generic risking system is based on the following initial risk and frequency:

- sold from packer's own premises                      low risk                      every 5 years
- regional distribution in a country                      medium                      every 2 years
- international distribution                      high risk                      annually

**Table 1: Frequency of inspection visits to packers and importers of 'e'-marked prepackages for whatever purpose.**

Member State	How determined	Intervals
BE, FR, LT, RS	Market share & result of previous check	Typical frequencies range from 1 to 4 years
GB	Risk, based on distribution & value of goods	1 year for importers & packers with international distribution 2 years, national distribution 5 year otherwise (local distribution)
AL, AT, CH, CZ <sup>5</sup> , DE, DK, FI, NO, PT, RO, SI		Annually
PL		Where the distribution area is unknown then the frequency should be every 2 years
NL	Government priority (funding)	In 2006 & 2007 - no inspections, but there were in 2008 and 2009
MT, SK		2 years
CY, BG, EE, GR, IS, IT, SE	Depending on our Dept's priorities	Not specified. However, inspections take place right after a complaint arises
LU		3 years + checks after complaints
LV, SI		Typically range from 1 to 3 years
IE	Developing risk based approach	Dependent on 'e' marked, packer or importer involved & final destination Complaints immediately investigated.

<sup>5</sup> Upon a contract

## **7 Indication of Quantity**

- 7.1 An indication of quantity is required by article 4 of the Directive, and products listed in section 2 of the Annex to Directive 2007/45/EC (wines and spirits) can only be marketed if they are prepacked in the nominal quantities listed in section 1 of the Annex to that Directive.
- 7.2 The nominal quantity has to be expressed in metric units, and this may be accompanied by an indication expressed in imperial units. There does not seem to be a prohibition on the use of other units of measurement (e.g. USA) or other quantities (e.g. weight with immediate wrappers).
- 7.3 The marked quantity on the prepackage is referred to as the 'nominal volume' or 'nominal weight' and is the intended quantity of the product in the prepackage. In line with OIML R87(2004) 'packaging' is defined as: "Everything of the prepackage that is intended to be left over after use of the product, except for items naturally in the product. Use includes consumption or subjecting to a treatment."
- 7.4 With the present definitions the 'drained net weight' required by article 8 of the Food Labelling Directive 2000/13/EC cannot be the nominal quantity of the prepackage. Guidance on the requirements and method of test for drained weight is specified in WELMEC document 6.8.
- 7.5 Prepackages containing liquids shall be marked with their nominal volume. The actual volume of the contents of a prepackage is the volume of liquid it in fact contains. In all checking operations the value employed for actual volume of the contents shall be measured at, or corrected to, a temperature of 20 °C, regardless of the temperature at which packaging or checking is carried out. However this rule shall not apply to deep frozen or frozen products where the quantity is expressed in units of volume.
- 7.6 There is no definition given for a liquid although the normal interpretation is something that pours easily at 20 °C. Definitions for 'liquid' used by Member States Competent Departments are given in Table 2.

**Table 2: Definition and guidance on what is ‘liquid’.**

Member State	Definition or guidance
GB	A liquid product is normally considered to be a product that, at 20 °C, will easily pour. The time taken for this operation is likely to be less than a minute, with the quantity of product left in the packing material likely to be less than 1% of the nominal quantity. Where doubt exists over whether a product is a liquid product within the meaning of this definition it should be marked by weight
AT, DE	Similar to GB; also non liquid products have a quantity expressed by volume if this meets the customers’ needs (examples: cream, peat, potting soil)
FR	When in doubt, use unit of mass
AL, BE, BG, CH, CY, CZ, DK, EE, FI, GR, IE <sup>6</sup> , IS, IT, LT, LU, LV, MT, NO, PL, PT, RO, RS, SE, SI, SK	No guidance

7.7 The Directive states that “prepackages containing liquid products shall be marked with their nominal volume and prepackages containing other products shall be marked with their nominal weight, except in the case of trade practice or national regulations which provide otherwise and which are identical in all Member States, or in the case of contrary Community rules.”

7.8 The Directive goes on in saying “If trade practice or national regulations are not the same in all Member States for a category of products or for a type of prepackage, those prepackages must at least show the metrological information corresponding to the trade practice or national regulations prevailing in the country of destination”.

In general articles 28 to 30 of the Treaty have to be respected; however the same articles specify reasons for restrictions.

7.9 Regulation 764/2008/EC and Decision 768/2008/EC lay down procedures that Competent Departments need to follow when they want to stop product being sold in their Member State which do not comply with national technical rules (for instance the unit of measurement used for the marking of the nominal quantity, whether or not marked with an ‘e’).

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<sup>6</sup> Oral advice given to use mass when in doubt as it is easier to monitor quantity gravimetrically.

- 7.10 An example of when this procedure needs to be followed is where a packer marks the weight on a prepackage of ice cream, to comply with domestic requirements. If the prepackage is sent to another Member State where the domestic legislation requires ice-cream to be marked with the quantity by volume and the latter country insists that the package needed to be marked with the volume of the ice cream then the Competent Department would have to follow the procedure in Chapter II of Regulation (EC) 764/2008.
- 7.11 It is recognized that it is essential that the same products have the quantity expressed in the same units of measurement so that consumers can make use of unit pricing<sup>7</sup> as envisaged by Directive 2007/45/EC.
- 7.12 Also it has been recognized that if product contains air as an ingredient then the nominal volume may not assist consumers to make an informed decision as to value for money, as extra air will cause an increase in volume with no benefit for the consumer.
- 7.13 Likewise non-liquid product with water as an ingredient bearing a nominal quantity in weight may not assist consumers as extra water may be added with no benefit to the consumer. This may be overcome by declaring the water content so that the consumer is not misled, for example as provided for on processed meats or for growing media in EN 12580.
- 7.14 Looking at the exemption, it applies to either:
- trade practice or national regulations which provide otherwise and which are **identical in all Member States**, or
  - in the case of **contrary** Community rules.
- 7.15 No trade practices that are identical in all Member States have been identified, with the possible exception of the use of the EN 12580 on the determination of quantity of growing media and soil improvers, which stipulates a means of determining the volume of this solid product.
- 7.16 There are no known Community rules that require the quantity of a non-liquid product to have a quantity expressed by volume.

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<sup>7</sup> Directive 98/6/EC of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers.

## 8 Requirements for 'e'-marked prepackages

### Annex I to Council Directive 76/211/EEC

#### 8.1 "1. OBJECTIVES

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

***1.1 the actual contents shall not be less, on average, than the nominal quantity***

***1.2 the proportion of prepackages having a negative error greater than the tolerable negative error laid down in 2.4 shall be sufficiently small for batches of prepackages to satisfy the requirements of the tests specified in Annex II."***

Guidance given in Member States on what proportion is 'sufficiently small' is given in the Table 3.

**Table 3: Guidance on 'sufficiently small'**

<b>Proportion</b>	<b>Member State</b>	<b>Comments</b>
No greater than 2%	AT <sup>8</sup> , DE, PL, RS <sup>9</sup>	
No greater than 2.5%	AL, BG, DK, FI, GB, GR, IE, LT, LV, NL, NO, RO, SE, SI	
No guidance given	BE <sup>8</sup> , CH, CY, CZ, EE, FR <sup>8</sup> , IS, IT, LU, MT, PT, SK	

<sup>8</sup> Explain that sampling plan based on an AQL of 2.5% and explain risks

<sup>9</sup> Explain that sampling plan based on an AQL of 2% and explain risks.

**8.2 “1.3 no package having a negative error greater than twice the tolerable negative error given in the table in 2.4 may bear the EEC sign provided for in 3.3”**

In order to set up statistical process control a possibility has to be assigned to the term ‘no package’. Guidance in Member States on this point is given in Table 4.

**Table 4: Probability of ‘no package’**

<b>Possibility</b>	<b>Member State</b>	<b>Comments</b>
No greater than 1 in 10,000 <sup>10</sup>	AL, AT, DE, DK, EE, FI, GB, IE, NO, PT, SE, SI	AT, DE, EE, GB, IE, PT: e-marked prepackages below TU2 are illegal
No guidance	BE, BG, CH, CY, CZ, FR, GR, IS, IT, LT, LU, LV, MT, NL, PL, RO, RS, SK	

**8.3 “3. INSCRIPTIONS AND MARKINGS**

***All prepackages made up in accordance with this Directive shall bear on the package the following markings affixed in such a manner as to be indelible, easily legible and visible on the prepackage in normal conditions of presentation:”***

Guidance given by Member States on the legibility and visibility requirements are given in Table 5

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<sup>10</sup> No package having a negative error greater than twice the tolerable negative error given in the table in 2.4 may bear the e-mark



**Table 5: Legibility and visibility guidance.**

Guidance	Member State
<p>Legibility requires use of an appropriate font, and that the colour of print of the marking is in good contrast to the background. Where the container is transparent the marking must be in good contrast to the colour of the product forming the visible background. The RNIB has produced helpful 'clear print guidelines', which recommend fonts such as Arial, Univers and New Century Schoolbook, the use of a minimum point size of 12 or 14, and selective use only of block capitals and italics. Use of these guidelines will be helpful in ensuring legibility of the text. As regards the marking of the nominal quantity, however, note the minimum height of figures required by the Regulations. One way to ensure that markings are visible in normal conditions of presentation is to place the markings on the front, or possibly the top, of the container. However, there may also be other ways to comply. The size and shape of individual containers will influence the position of the quantity mark and the means by which legibility is best achieved in accordance with the regulations</p>	GB
<p>Legibility requires use of an appropriate font, and that the colour of print of the marking is in good contrast to the background. Where markings are blown, formed or shaped on glass or plastic surface on a pre-package colour contrast is not demanded</p>	CY
<p>Legibility requires use of indelible, visible and easily legible fonts</p>	AL, GR, PT
<p>Only the point size is regulated, not contrast or colour of print</p>	DE, RO
<p>If the nominal quantity is impressed or embossed on the packaging, no other markings may be made in the same place</p>	EE
<p>Use of indelible, visible and easily legible markings is required. Height of letters and numbers is regulated</p>	SE
<p>No Guidance</p>	AT, BE, BG, CH, CZ, DK, FI, FR, IE, IS, IT, LT, LU, LV, MT, NL, NO, PL, RS, SI, SK

8.4 ***“3.2 a mark or inscription enabling the competent departments to identify the packer or the person arranging for the packing to be done or the importer established in the Community.”***

The requirements in the Member States are as given in Table 6.

**Table 6: Packers’ and importers’ identity requirements.**

<b>Requirements</b>	<b>Member State</b>
Name & address in the UK or IE (except for cosmetic products) of the packer, or importer, or of the person who arranged for the packing or importing, or a mark which enables the name or address to be readily ascertained of one of these. Exemption if made up on & sold from retailer’s premises	GB, IE
Registered company name & postcode preceded by B, or full address	BE <sup>11</sup>
The name (or trademark) and the address of the manufacturer, or the packer, or the seller, established in Greece or in a Member state of the EEC	GR
Mark or inscription identifying the packer or importer	AT, BG, CH, DE, DK, EE, FI, FR, IS, IT, LT, LU, LV, MT, NL, NO, PT, RO, RS, SE, SI, SK
Designation identifying packer or importer	PL
Full name and address of the packer, or importer, or of the person who arranged for the packing or importing, or a mark which ascertains the identity of the packer or importer	AL, CY
No guidance	CZ, IT

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<sup>11</sup> Exceptions are possible

## 9 Responsibilities of the Packer and Importer

### Annex I to Council Directive 76/211/EEC

#### 9.1 "4. RESPONSIBILITY OF THE PACKER AND IMPORTER"

***"The packer or importer shall be responsible for ensuring that the prepackages meet the requirements of this Directive."***

This requirement depends on the definition of 'packer' and 'importer'. Member States define these as given in Table 7 and 8.

**Table 7: Definition of a packer**

<b>Packer definition</b>	<b>Member State</b>
Person who placed the product in the prepackage	BE, BG, FR, GB, LT, NL, NO, PL
Person whose name appears on the packing material	AT, CH, CZ, DE, FI <sup>12</sup> , LU, LV, PT, SE, SI,
Person who placed the product in the prepackage for trade purposes and includes the person who placed or contributed to place any name or mark on any prepackage not packed by him	CY
Person who placed the product, or caused it to be placed, in the prepackage	IE
A packer is the person, who produce prepackages released for sale	AL, DK, MT
No definition	EE, GR, IS, IT, RO, RS, SK

<sup>12</sup> In market surveillance the responsible body would in general be considered to be the company claiming responsibility for the product. Recognition of procedures is always performed at the actual packer who holds the permission to use the e-mark.

**Table 8: Definition of an importer.**

<b>Importer definition</b>	<b>Member State</b>
Person by whom, or on whose behalf, the package is brought into the country, except when it is e-marked and from another Member State	AT, DE, FR, GB, LT
Person whose name appears on the packaging	CZ, FI, NO, PL, PT, SE, SI,
Importer: he, who while practicing a business, brings on the market or tries to bring on the market prepackages that entered the Member State	BE, BG, NL,
Person by whom, or on whose behalf, the package is brought into the Republic of Cyprus from a third country	CY
Person by whom the prepackages are placed on the LU (EU) market from a third country	LU
Person by whom, or on whose behalf, the package is entered for customs purposes on importation. e-marked products coming from another EU Member State are not considered to be imported	IE
An importer is the person, who imports prepackages released for sale	AL, DK
An importer is the person, who imports prepackages released for sale from third countries.	MT
No definition	CH, EE <sup>13</sup> , GR, IS, IT, LV, RO <sup>13</sup> , RS, SK,

**9.2 “The measurement or check shall be carried out by means of a legal measuring instrument suitable for effecting the necessary operation.”**

The meaning of suitable legal measuring instrument differs between Member States as domestic legislation specifies the equipment that is legally controlled (see Table 9). Guidance may also be given on what is suitable (see Table 10).

<sup>13</sup> The definition of importer is laid down in the Regulation no 765/2008 of the European Parliament and of the Council and the regulation is directly applicable in all Member States.

**Table 9: Legal measuring instrument.**

<b>Legal measuring instrument</b>	<b>Member State</b>
Where equipment is controlled by law it must be verified and where equipment is not controlled by law, it can be used, however the suitability requirement includes accuracy and traceability	BG, CY, CZ, FI, GB, IS, LV, NL, NO, PL, PT, RO, RS, SE, SI, SK
Only verified equipment is permitted	AL, AT, CH, DE, EE, FR, IT, LT, LU, MT
Verified or calibrated equipment is permitted	BE, DK
The instrument used for making up or checking must be a verified controlled instrument or one which has been certified for accuracy if legislation does not provide for verification	IE
No guidance	GR

**Table 10: Suitability of equipment**

<b>Suitability</b>	<b>Member State</b>
There must be traceability and either, measurement error must be less than 0.2 TNE, or if more an allowance must be made when setting the target quantity	AL, AT, BG, CH (only for NAWI), CY, DE, FI, FR (only for NAWI), GB, IE <sup>14</sup> , IS, IT (only for NAWI), LU, PL, RO <sup>15</sup> , RS, SI
Guide 6.4	DK, NO
For all instruments: regular calibration, traceability, accuracy (table), functionality (in relation to the packers procedures), this includes overfilling if needed	NL
For all instruments: verification or regular calibration, traceability, accuracy, functionality (in relation to the packers procedures)	CZ, SK
Measurements must be carried out by applying metrologically valid measurement instruments with valid verification marks or certificates and suitable for the intended operations	LT, LV, PT
When NAWI is used the verification unit has to be in proportion to the nominal quantity	BE
Instruments have to be calibrated	MT
No guidance	EE, GR, SE

<sup>14</sup> Applies to NAWI with total exclusion of Class III NAWI.

<sup>15</sup> If NAWI is used, the verification scale interval is established against the nominal quantity.

9.3 ***“Where the actual contents are not measured, the checks carried out by the packer shall be so organised that the quantity of goods is effectively ensured. This condition is fulfilled if the packer carries out production checks in accordance with procedures recognised by the competent departments in the Member State...”***

How procedures are ‘recognised’ varies; the present systems are given in Table 11.

**Table 11: Means of recognising systems.**

<b>Method of recognition</b>	<b>Member State</b>
Certificate issued by accredited certification body	EE, NL, SE
Notification to & approval by national metrology body	DK, FI, LT, NO, RO, PT
Implicit recognition by Inspector	AT, BG, CH, CY, DE, FR, GB, GR, IE, IS, IT, LU, LV, MT, PL, SI
Procedures are recognized during the first visit within the scope of packing system assessment	CZ
Specified in legislation	AL, BE, IT, SK

9.4 ***“...he holds at the disposal of those departments the documents containing the results of such checks, in order to certify that these checks, together with any corrections and adjustments which they have shown as necessary, have been properly and accurately carried out.”***

The retention period for records varies, and is at present as given in Table 12.

**Table 12: Record retention periods.**

<b>Period</b>	<b>Member State</b>
1 year, or until ‘Best Before’ date if that occurs first	BG, GB
1 year or until ‘Best Before’ date, whichever is later	DK
Until next Inspector’s visit	CZ, DE, MT, RS, SI
1 year	AL, CY, IE, LT, NL
1-2 years	NO
2 years	BE, EE, FR, SK
From 1 month to 3 years	IT
Dependent on shelf life (tenability)	FI, LV, PL, PT, SE,
5 years	AT
None specified	CH, GR, IS, IT, LU, RO

9.5 ***“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”***

The acceptable evidence differs, but at present is as given in Table 13.

**Table 13: Acceptable importer’s evidence.**

<b>Evidence</b>	<b>Member State</b>
Evidence that gives reasonable grounds for believing the prepackages meet requirements. For example: check records, certificate from metrology service, self declaration that the packer is packing to the minimum	AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, GB, IE, IS, IT, LU, MT, NO, RO, RS, SI, SK
As above plus certificate from accredited certification body	NL
Competent Body checks	CH, LT, PT
Self declaration by importer	PL
None specified	AL, GR, LV, SE

## 10 Responsibilities of Competent Department

### Annex I to Council Directive 76/211/EEC

#### 10.1 “5. CHECKS TO BE CARRIED OUT BY THE COMPETENT DEPARTMENT ON THE PREMISES OF THE PACKER OR IMPORTER

*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.”*

There are several variables, the type of checks and the frequency of them. Table 14 indicates the present status:

**Table 14: Frequency of Competent Department checks**

Type of checks	Frequency	Member State
System and, if needed, a reference test	Based on risk	BG, EE, FR, GB, IE, LV <sup>16</sup> , NL <sup>17</sup> ,
System and reference test	Annually	AL, AT, CH, CZ, DE, DK, FI, LT NO, RO, RS, SI
System and reference test if needed	Annually	PT, SE,
System and reference test	Every 2 years	BE, MT, SK
System and reference test	Every 3 years	LU
Reference test	Every 2 years	PL
No guidance		CY, GR, IS, IT

<sup>16</sup> Frequencies range from 1 to 3 years.

<sup>17</sup> Dependent on government priority (read: funding)



10.2 Packers' premises, being fixed, are easy to identify and monitor. To ensure these packers operate in a fair market place it is important for importers to be subject to the same degree of monitoring. Importers may reside in an office remote from where the goods are being imported and stored, so it is more difficult to identify and monitor them. How Member States identify importers is given in Table 15.

**Table 15: Methods of Identifying Importers.**

<b>Method</b>	<b>Member State</b>
Use customs records	GB, RS
Trace back from shop checks	AT, BE, BG, CH, CY, CZ, DE, EE, FR, GR, IE, IS, IT, LT, LU, LV ,MT, NL
Chamber of commerce	RO
Declaration by importer	AT, BG, DE, DK, FI, IS, LT, NL (in theory), NO, PT, RO, RS, SE, SI
Registration by the Competent Department	AL, PL, RS, SK

10.3 ***“This statistical sampling checks shall be carried out in accordance with accepted methods of quality acceptance inspection. Its effectiveness shall be comparable to that of the reference method specified in Annex II.”***

The methods are generally those specified in Annex II to the Directive, but some Member States have other equivalent schemes (see Table 16)

**Table 16: Equivalent reference tests**

<b>Scheme</b>	<b>Member State</b>
Single sampling plan for defectives	DE, GB, IE, MT
Larger sample size for average requirement	BG, DE, NL
No equivalent tests	AL, AT, CH, CZ, DK, FI, FR, GR, IS, IT, LU, LV, NO, PL, RO, RS, SK, SI

10.4 " 6. OTHER CHECKS CARRIED OUT BY THE COMPETENT DEPARTMENTS

*This Directive shall not preclude any checks which may be carried out by the competent departments of the Member States at any stage in the marketing process, in particular for the purpose of verifying that prepackages meet the requirements of the Directive,"*

An indication of 'other checks' carried out are given in Table 17.

**Table 17: Other Competent Department checks.**

<b>Type of checks</b>	<b>Member State</b>
Occasional checks at wholesalers & retailers	AL, AT, CH, CY, FI, FR, GR, IT, NL, PL, PT, RO, SE,
At retailers, only if there is a reason, e.g. as part of a project to detect imported packages or inspect labelling	BE, CZ, DE, DK, GB, LT, LU
Checks at wholesalers & retailers, WELMEC 6.7 is used as a Guide for the Competent Department	BG
No guidance	EE, IE, IS, LV, MT, NO, RS, SI, SK

## 11 The Reference Test

### Annex II to Council Directive 76/211/EEC

11.1 ***"This Annex lays down the procedure of the reference method (reference test) for statistical checking of batches of prepackages in order to meet the requirements of Article 3 of the Directive and of Section 5, Annex I thereto."***

11.2 Measuring the actual contents of prepackages

***"The error made in measuring the actual contents of a prepackage shall not exceed one-fifth of the tolerable negative error for the nominal quantity of the prepackage."***

The 'error' is taken as the uncertainty of measurement at the 95% confidence level. See WELMEC document 6.9 Prepackages – uncertainty of measurement .

11.3 ***"For economic and practical reasons, destructive testing shall be limited to the absolute essential minimum, it is less effective than the non destructive test."***

In practice destructive testing is carried out where:

- warehouse tests are carried out on nominal weights with variable tares ( $s_t > 0.2 \text{ TNE}$ )
- warehouse tests on nominal volumes with:
  - variable tares where
    - liquid levels cannot be seen, or
    - liquid levels can be seen but the cross sectional area is too large,
  - inhomogeneous or immiscible liquids, and
  - products in aerosols.

11.4 For the average test, the necessary sample shall be drawn at random from the sample used for actual quantity of product and marked.

***"This marking operation shall be completed before the start of measuring operations."***

In some cases a computer program selects the average sample at random without the need for marking. Some Member States use the same sample size for the average test as for the actual contents (defectives) test, avoiding the need for sub-sampling.

11.5 The reference test can be carried out at any time, and for desiccating product, or products that change quantity after packing, Member States have different requirements. These requirements are indicated in Table 18.

**Table 18: Requirements for desiccating products**

<b>Requirement</b>	<b>Member State</b>
That the quantity requirements have to be met at time of packing or import	AT, CH, CY, CZ, DE, DK, EE, FI, FR, GB, IT, LU, MT, NL, RS, SE, SI, SK,
That the quantity requirements have to be met at time of purchase by the ultimate consumer	BE, BG, GR, IS, LV, RO
That the quantity requirements have to be met at time of packing, and that no prepackage shall ever have a deficiency of greater than twice the tolerable negative error anywhere in the distribution chain	IE, LT, PL
That the quantity requirements have to be met at time of packing or import, and that no prepackage shall ever have a deficiency of greater than twice the tolerable negative error anywhere in the distribution chain	NO
Nothing specified in legislation	AL

11.6 The WELMEC Committee has agreed requirements for prepackages whose quantity changes after packing. These are

- the prepackages shall meet the three quantity requirements at time the prepackages have passed the quantity checks specified in the packer's or importer's<sup>18</sup> quantity control system, and so are ready for placing on the market,
- the packer or importer is able to demonstrate this from records, and
- no prepackages shall have a deficiency greater than twice the tolerable negative error anywhere in the distribution chain,

It is recommended that, in order to preserve the quality of the product, the packer or importer should provides organisations in the distribution chain with the necessary information as to the storage and handling that needs to be observed.

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<sup>18</sup> 'importer' shall mean any natural or legal person established within the Community who places a product from a third country on the Community market; Decision 768/2008/EC, article R1.5

## 12 Other Issues

### 12.1 Non-e-marked Prepackages Requirements

At present Member States have the following general requirements for non-'e'-marked prepackages (there may be exceptions and exemptions)

The meaning of the terminology used in Table 19 is:

- Minimum without tolerance – the quantity of product in each prepackage must be equal to or more than the nominal (marked) quantity
- Minimum with a negative tolerance – the quantity of product in each prepackage must be within a specified tolerance, but there is no average requirement
- Average – the 3 requirements in OIML R87<sup>19</sup>, and
- None – there are no legislative requirements.

12.2 Prepackages made up to within a tolerance can, on average contain less than the marked quantity. Whereas prepackages made up to the minimum will on average contain more than the marked quantity. The differences in average content may lead to a competitive advantage.

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<sup>19</sup> OIML R87 (2004) 4.1.1 Criteria

**Table 19: Requirements for non-‘e’-marked prepackages**

	<b>Minimum without tolerance</b>	<b>Minimum with a negative tolerance</b>	<b>Average</b>	<b>None</b>
<b>Weight</b>	GB (>25 kg), GR, IE (Qn>55 kg), IS, NL <sup>20</sup>	CZ (foodstuffs) <sup>21</sup> , SK (foodstuffs) <sup>21</sup>	AL, AT, BE (Qn>10 kg) <sup>22</sup> , BG, CH, CY (Qn≥5 g), DE, EE, FI, FR, GB, IE (Qn ≤55 kg), IS, IT, LT, LU, LV, MT, NO, PL, RO, RS (Qn>10 kg), SI, SE	BG (Qn>10 kg), SI (Qn>10 kg)
<b>Volume</b>	GB (>25 L), GR, IE (Qn>55 L), NL	CZ (foodstuffs) <sup>21</sup> , SK (foodstuffs) <sup>21</sup>	AL, AT, BE (Qn>10 L) <sup>22</sup> , BG, CH, CY (Qn≥5 mL), DE, EE, FI, FR, GB, IE (Qn ≤55 L), IS, IT, LT, LU, LV, MT, NO, PL, RO, RS (Qn>10 kg), SI, SE	BG(Qn>10 L), SI(Qn>10 L)
<b>Length</b>	GB, GR, IE, LT (Qn≤ 5 m)	CH	BE <sup>22</sup> , DE, CY, FR <sup>22</sup> , LT (Qn > 5 m), LU <sup>22</sup> ,	AT, BG, CZ, EE, FI, IS, IT, LV, MT, NO, PL, RO, SE, SI, SK
<b>Area</b>	GB, GR, IE	CH	BE <sup>22</sup> , DE, CY, FR <sup>22</sup> , LT, LU <sup>22</sup> ,	AT, BG, CZ, EE, FI, IS, IT, LV, MT, NO, PL, RO, SE, SI, SK
<b>Number</b>	GB, CH(Qn<101), DE (Qn<31), IE, IS, LT (Qn≤ 50)	CH(Qn>100)	BE <sup>22</sup> , CY, DE (Qn>30), FR <sup>22</sup> , LT (Qn> 50), LU <sup>22</sup> , MT	AT, BG, CZ, EE, FI, GR, IT, LV, NO, PL, RO, SE, SI, SK
<b>&lt;5 g or &lt;5 ml</b>	GB, IE, NL	CZ (for some products) <sup>21</sup> , SK (for some foodstuffs) <sup>21</sup>	AT, BE <sup>22</sup> , FR <sup>22</sup> , DE, PL, LT, LU <sup>22</sup> , RS	BG, EE, FI, GR, IS, IT, LV, NO, SE, SI, RO
<b>Catchweight product</b>	BE <sup>23</sup> , GB, GR, IE, IS, RS, SE	BG, CH, DE, PL,	FR <sup>22</sup> , LT, LU <sup>22</sup> , MT	AT, CZ, EE, FI <sup>24</sup> , IT, LV, NO <sup>24</sup> , SI, SK

<sup>20</sup> All prepackages without e-mark have to comply with minimum principle

<sup>21</sup> Minimum with a negative tolerance specified by regulation or by the packer. When specified by the packer the tolerance must be indicated on the package. The quantity in each prepackage must be within a given tolerance, but there is no average requirement.

<sup>22</sup> The minimum is legally required but in practice the OIML R87 (2004) average requirements are accepted, for all prepackages outside of the scope of e-mark prepackages

<sup>23</sup> Minimum requirement is legal but because of the mandatory use of verified catchweighers we accept the MPE from annex MI 006 MID.

<sup>24</sup> Catchweight products have to be measured with legal and suitable measuring instruments.

### 12.3 Drained Weight

For some foodstuffs in certain liquid mediums there is a requirement<sup>25</sup> to mark the packaging with a declaration of drained weight. The metrological requirements for the drained weight indication are not specified and guidance has been produced in WELMEC document 6.8. At present the tolerances applied by domestic legislation varies, and Table 20 indicates the present requirements.

**Table 20: Drained weight requirements**

<b>Requirements</b>	<b>Countries</b>
WELMEC document 6.8 (equivalent to OIML R87 tolerances)	CH, CY, NO, PT
Other tolerances, $T_{abs} = 3 \times TU1$	DE
No TU1 requirement, only TU2, and no “e” marked package permitted below TU2	FR
Nothing specified in legislation	AL, AT, BE <sup>26</sup> , BG, CZ <sup>27</sup> , DK <sup>28</sup> , EE, FI, GB <sup>28</sup> , GR, IE, IS, IT <sup>29</sup> , LT, LU, LV, MT, PL, RO, RS, , SE, SK, SI

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<sup>25</sup> Directive 2000/13/EC, section 8.4

<sup>26</sup> Minimum requirement is legal - in practice OIML R87 (2004) is considered as the reference

<sup>27</sup> WELMEC document 6.8 is used for best practice although there are also different technical standards used

<sup>28</sup> But reference to WELMEC document 6.8

<sup>29</sup> Except pre-packaged fish products

#### 12.4 Specified Quantities

Directive 2007/45/EC requires that only certain wines and spirits must be sold in mandatory prescribed nominal quantities, and that countries must accept all other prepackages, regardless of the quantity in each prepackage.

Member States can continue with their national mandatory prescribed nominal quantities for butter, milk, coffee and dried pasta until 11<sup>th</sup> October, 2012, and for white sugar until 11<sup>th</sup> October 2013. Table 21 indicates whether countries are going to make use of these derogations.

**Table 21: Mandatory national prescribed nominal quantity requirements:**

<b>Requirement for mandatory prescribed nominal quantities</b>	<b>Member State</b>
Making full use of derogation for national mandatory prescribed nominal quantities for all 5 products until the dates stated above	EE
Derogation only for pasta	FR, GR
Derogation for milk and dried pasta	IT
Not making use of the derogation at all for these products	AT, BE, BG, CH, CY, CZ, DE, DK, FI, GB, IE, IS, LU, LV, MT, NO, PL, RO, RS, SE, SK, SI



## Annex 1 Competent Departments for metrological aspects of non-‘e’-marked packages

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