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WELMEC Guide 6.3

Guidance for the Harmonised Implementation of Council Directive 76/211/EEC as amended

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WELMEC e.V. is a cooperation between the legal metrology authorities of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC e.V. 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 EU Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC e.V as to the best practice to be followed.

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General

It is mandatory for Member States to implement Directives 76/211/EEC (*hereafter referred to as* ***the Directive***) and 2007/45/EC. The Directive introduces the ℮-mark, a mark which is a declaration by the packer or importer that the prepacked products (*hereafter called* ***prepackages***) in the batch comply with the labelling and quantity requirements of the Directive. It is up to the packer or importer to apply the ℮-mark or not. Directive 2007/45/EC, requires certain wines and spirit drinks to be prepacked in specific quantities.

Regulation (EU) 1169/2011 on the provision of food information to consumers (*hereafter referred to as* ***the Food Regulation***), is Mandatory for Member States and the requirements must be met by the food business operators. The Directive must still be applied for prepacked foods.

An non-exhaustive overview of additional requirements on the expression of nominal quantity for particular products, resulting from other European Legislative Acts, can be found in Annex 2 of this Guide.

Documents agreed by WELMEC are published on their website at: https://www.welmec.org/guides-and-publications/guides/

Introduction

The Working Group 6 recognised the importance of international trade and at their meeting of 15 May 1998, agreed that the World Trade Organisation acceptance of OIML Recommendations has to be reflected in its work. Consequently, OIML Recommendations have been noted in this document for guidance. It has also been recognised that domestic legislation may differ from these Recommendations.

With the Food Regulation coming into effect, the guidance has been reviewed to reflect its impact to the Directive.

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 for harmonised implementation of the Directive based on the opinions of the experts in the Working Group.

To assist in cross-referencing:

i. The wording from the ***Directive*** is in both bold and in italics. The paragraph numbers in Parts 2 to 4 are related to the paragraph reference in the appropriate text and Annexes of the Directive 76/211/EEC. It will be evident that not all of the paragraphs of the Directive have been quoted; these parts contain non-contentious requirements or definitions which are accepted as written.
ii. The wording from OIML R 79[1], OIML R 87[2] and the Food Regulation, begin with: ***OIML R 79, OIML R 87*** and ***R 1169/2011*** respectively.

Scope

The aims of this document are:

a) To clarify the Directive where it is vague, to lay down guidelines for the EU when the Directive is reviewed, and to assist in removing any problem areas.
b) In due course, to assist WELMEC countries in aligning their legislation to remove any barriers to trade.
c) To assist other Countries wishing to implement quantity controls that will enable packages to comply with the Directive.
d) To identify the interaction between the Directive and other European legislative acts that have specific requirements on the labelling of certain prepackages.

[1] OIML R 79 (2015). *Labelling requirements for prepackages*.
[2] OIML R 87 (2016). *Quantity of product in prepackages*.

PART 1: DEFINITIONS

This Guide uses a set of definitions that is laid down in WELMEC Guide 6.1 Part 2, as well as definitions from other WELMEC Guides presented in Part 4 of WELMEC Guide 6.1. These definitions are noted in Table 1, as well as the corresponding chapter and paragraph.

Table 1: Definitions laid down in Guide 6.1

Term	Paragraph of Guide 6.1
Prepackage	2.1
Packing Material	2.2
Medium	2.3
Importer	4.39

For more details on definitions, see WELMEC Guide 6.1 and the International Vocabulary of Basic and General Terms in Metrology (VIM).

In this Guide, relevant Food Regulation definitions are noted. Relevant definitions from OIML documents are also noted, but definitions in European legislation take precedent.

1.1 *The actual contents of the prepackage are the quantity (weight or volume) of product which it in fact contains*[3]*.*

This should be taken as the actual quantity of product the prepackage in fact contains as determined by measurement. Procedures for verifying the actual quantity are set down in the Annex II to the Directive.

OIML R 87 *uses the term 'actual quantity' which is defined as* 'amount of product that a prepackage contains as determined by measurement.'[4]

1.2 *Measuring Container Bottle (MCB)*

A bottle whose volume and labelling comply with the Council Directive 75/107/EEC, which defines[5] a 'measuring container bottle' as a bottle:

- made of glass or other rigid and stable substance,
- designed to be stoppered, and intended for storage, transport or delivery of liquids,

[3] Directive 76/211/EEC, Annex I, Paragraph 2.2.
[4] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 2.1.1.
[5] Council Directive 75/107/EEC, article 1.

− having a nominal capacity between 0.05 l and 5 l inclusive,
− that can be measured with sufficient accuracy, when filled to a specified level or specified percentage of their Brim Capacity.[6]

Note: The OIML R138[7] defines a MCB as 'Bottles intended to be filled either at constant level or at constant ullage with sufficient accuracy without the need to use an independent measuring instrument.'

1.3 *The nominal quantity (nominal weight or volume) of the contents of a prepackage is the weight or volume indicated on the prepackage, i.e. the quantity of product which the prepackage is deemed to contain[8].*

Nominal quantity shall mean the quantity of product in a prepackage declared on the label by the packer.

Note 1: The symbol 'Q_n' is used to designate the nominal quantity.

Note 2: The nominal quantity must be declared in accordance with Annex 1 of this Guide.

Note 3: The Food Regulation specifies that the 'nominal quantity' required by the Directive, shall be regarded as the 'net quantity' required by the Food Regulation[9].

OIML R 87[10] nominal quantity: Quantity of product in a prepackage declared on the label.

1.4 Packer

The term 'packer' is not defined in the Directive, but is given the responsibility for ensuring that prepackages meet the requirements of the Directive[11].

A packer places product in packing material that bears a nominal quantity, an ℮-mark constituting a guarantee by the packer or the importer that the prepackage meets the requirements of this Directive and an identification of the importer or the person arranging for the packing to be done.

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[6] WELMEC Guide 6.12, Issue 1 (2013) 'Guide on Directive 75/107/EEC Measuring Container Bottles', Paragraph 2.1.
[7] OIML R138 (2007). *Vessels for commercial transactions*. Paragraph 2.3.
[8] Directive 76/211/EEC, Annex I, Paragraph 2.1.
[9] Regulation (EU) 1169/2011 Annex IX, Paragraph 2.
[10] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 2.1.7.
[11] Directive 76/211/EEC, Annex I, Paragraph 4.

1.5 Principal display panel

OIML R 79[12]: *"*Part of a prepackage that is designed to be visible under normal conditions of display for sale.

Note: This is normally the main or front panel of the prepackage and there could be more than one."

1.6 Product

Product – All of the prepackage that is not packing material.[13]

Examples of product, even though left over after use, include a banana skin, tea leaves and coffee grounds.

1.7 Verified

Means established to comply with the requirements of appropriate legislation. For equipment for which there is no relevant legislation the equipment still needs to be 'suitable' and acceptable for the competent organisation.

[12] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 2.10.
[13] WELMEC Guide 6.1, Issue 2 (2019) 'Definitions of Terms', Paragraph 2.4.

PART 2: SCOPE OF THE DIRECTIVE

Article 1 "This Directive relates to 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,***
- ***not less than 5 g or 5 ml and not more than 10 kg or 10 L."***

The above 3 criteria, must be met at the same time.

Products which the Directive does not control are:

- Products made up in variable quantities, sometimes referred to as "catchweight" products,
- Products that are sold in quantities of length, area or number.
- Products in constant unit nominal quantities, less than 5 g or 5 ml or more than 10 kg or 10 L.

All the above, are summarized on the Table 2.

Table 2: Products related or not related to the Directive

	Products related to the Directive	**Products not related to the Directive**
1	Products made up in constant unit nominal quantities (Q_n), predetermined by the packer	Products made up in variable nominal quantities (catchweight products)
2	Products whose nominal quantity is expressed in units of weight or volume	Products whose nominal quantity is expressed in units of length or area or number
3	Products whose nominal quantity is in the range: 5 g or 5 ml ≤ Q_n ≤10 kg or 10 L	Products whose nominal quantity is: 5 g or 5 ml > Q_n >10 kg or 10 L

Article 3.1 "The prepackages which may bear the EEC sign specified in section 3.3 of Annex I are those which comply with this Directive and with Annex I thereto."

The EEC sign (℮-mark) is not mandatory. It is entirely optional for the packer or the importer, but once the packer or the importer chooses to apply it, then the provisions of the Directive have to be followed.

Article 4.2 "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."

OIML R 79[14]: "The quantity declaration shall generally be expressed as follows:

a) In units of volume, if the product is liquid;
b) In units of mass if the product is a solid, a gas or a liquefied gas;
c) In units of mass, volume or both mass and volume, if the product is semi-solid or viscous;…."

Note 1: Requirements on the expression of nominal quantity for particular products, resulting from other European Legislative Acts, can be found in Annex 2 of this Guide.

Note 2: Regardless of any other legislation that might be applied, when the e-mark applies, the quantitative and labelling requirements of the Directive have to be met.

Note 3: The term 'other products' refers to any product other than liquid e.g. solid products, solid products in a liquid medium.

Note 4: There is no definition given in European legislation for 'a liquid' or 'a liquid product' and this leads to some fundamental differences for some products between Member States. If the products are viscous (e.g. pastes, mustard, etc), their nominal quantity is expressed in units of mass in some Member States and in units of volume in others. Dual quantity expression (in nominal weight and in nominal volume) is not prohibited from the Directive, nor from the Food Regulation. Thus, if national legislation does not prohibit dual quantity expression, the packers of these products are allowed to mark them with nominal weight **and** nominal volume. In that case, both nominal quantities have to comply with the requirements of the Directive.

Note 5: WELMEC Guide 6.14, gives a definition for liquid (4.1.2) and Annex III of it, illustrates a practical way of assessing whether a product is a liquid.

Note 6: Information regarding quantity declaration for products contained in a liquid medium, can be found in Part 1, "Definitions" of WELMEC Guide 6.8.

Note 7: WELMEC Guide 6.8[15] provides guidance regarding the determination of drained net weight.

[14] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraphs 5.5 (a, b, c).
[15] WELMEC Guide 6.8 (2020) 'Drained Weight, Guide on the Verification of Drained Weight, Drained Washed Weight and Deglazed Weight', Part 3.

Article 4.3 "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."

This requirement is to ensure that unit pricing is indicated in the same unit of measurement for each type of product, so enabling the consumer to make informed decisions as to value for money. With the abolition of the majority of specified nominal quantities in Directive 2007/45/EC there is reliance on unit pricing to assist consumers[16] compare value.

[16] Directive 2007/45/EC, Recitals (4) and (6).

PART 3: ANNEX I TO THE DIRECTIVE

1. OBJECTIVES

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

The requirements below (Paragraphs 1.1-1.3) are sometimes referred to as 'the 3 Packer's Rules'.

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

For 'actual contents' and 'nominal quantity' see the definitions in Part 1, of this Guide.

OIML R 87[17]: "The average actual quantity of product in prepackages shall be at least equal to 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."*

The 'tolerable negative error' (TNE) for each nominal quantity is specified in Paragraph 2.4, Annex 1 of the Directive.

The quantity, which is one tolerable negative error below the nominal quantity, is sometimes referred to as 'TU1' or 'T1'.

A 'defective' prepackage is one whose quantity of product is below TU1 or T1.

"Sufficiently small" is not defined in the Directive although the reference test is based on an AQL (acceptable quality level) of 2.5 %. Because statistical methods of testing are used, there is still a risk of failing a batch even if the amount of defective prepackages is less than 2.5 %. For these purposes 'sufficiently small' is generally taken to mean that not more than 2.5 % of the prepackages in the batch may be defective **and** the reference test in 2.2 of Annex II of the Directive is also satisfied.

Note: Reference tests are only for the Competent Department to be used, they are not intended to be used by Packers or Importers to show compliance with the

[17] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 3.2.

Directive. The sampling allowance should only be used by Inspectors; it is for the packer to ensure the requirements are met using appropriate quantity control methods.

OIML R 87[18]: "The actual quantity of product in a prepackage shall accurately reflect the nominal quantity but tolerable deficiencies (T) shall be allowed.
A homogenous group of prepackages shall contain no more than 2.5 % of packages having T1 errors."

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"*

The quantity which is two tolerable negative errors below the nominal quantity is sometimes referred to as 'TU2' or 'T2'.

The packer must not pack quantities below the value of TU2, appropriate to the nominal quantity, and system design must ensure that no more than 1 in 10 000 prepackages violate TU2 by chance. More information can be found in WELMEC Guide 6.5[19].

OIML R 87[20]: "No prepackage shall have a T2 error."

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:

R 1169/2011: "…mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material'[21]."

OIML R 79: "A prepackage shall bear a declaration of the nominal quantity of the product on the principal display panel[22], in easily legible boldface type or print that:

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[18] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraphs 3.3.1 - 3.3.2.
[19] WELMEC Guide 6.5, (2012), Guidance on Controls by Competent Departments on e-marked Prepackages, Annex E, *E2 – Principles for estimating the target quantity, Qt.*
[20] OIML R 87(2016). *Quantity of product in prepackages*. Paragraph 3.3.3.
[21] Regulation (EU) 1169/2011, article 13.1.
[22] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 5.1.

a) contrasts conspicuously with the background and with other information on a prepackage and
b) are so positioned on the principal display panel as to make them conspicuous and easy to read and understand[23].

When the quantity declaration is blown, embossed or molded on the surface of the package, then all other required label information shall be provided elsewhere on the surface or on a label so as to be conspicuous and easy to read and understand[24]."

3.1 "*The nominal quantity (nominal weight or nominal volume) expressed in kilograms, grams, litres, centilitres or millilitres..."*

It is important to have consistent units of measurement for a product so that unit pricing can be used by consumers to judge value for money.

The nominal quantity must be declared using the units of measurement stated. The full names of units of measurement and their symbols can be found in Table 4, Annex 1 of this Guide.

In addition to the metric system units and their symbols, other units (and symbols) which are not in the metric system (SI), are permitted on the label[25] as long as they are being accompanied and not misleading[26] and be no more prominent than the nominal quantity.

R 1169/2011[27]: "The net quantity of a food shall be expressed using litres, centilitres, millilitres, kilograms or grams, as appropriate…."

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 minimum requirement would be the name or mark (which could be a trade mark), together with the post code or a geographical code. This marking must be 'easily legible and visible on the prepackage in normal conditions of presentation'.

Other vertical Directives may require extra information such as the full address, or address of the Registered Office to be supplied, or the country of origin to be stated

[23] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 5.6.1.
[24] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 5.6.2.
[25] Directive (EU) 80/181/EEC, article 3.
[26] Directive (EU) 2005/29/EC, article 6.
[27] Regulation (EU) 1169/2011, article 23.1.

on the label when the product is manufactured outside the EEA (European Economic Area).

R 1169/2011[28]: "The name or business name and address of the food business operator."

OIML R 79: "The name and complete physical address of the manufacturer, packer, distributor, importer, exporter or vendor responsible for the prepackage shall be declared on any surface....[29] When the product is not manufactured or packaged by the person who takes responsibility for the product, the name may be qualified by a phrase that reveals the connection such person has with the product, e.g.: "manufactured for…", "imported by…", or "packed for…" and the person responsible for supplying the name and address of the packer to a regulator requiring this information for official purposes.[30] The name and address of the manufacturer or packer may be indicated as a code if permitted by national legislation.[31]**"**

3.3 *"a small 'e', at least 3 mm high, placed in the same field of vision as the indication of the nominal weight or nominal volume..."*

The 'nominal quantity' and the e-mark should be in the same field of vision. This combination must be 'easily legible and visible on the prepackage in normal conditions of presentation'.
Where there are two nominal quantities (nominal weight and nominal volume) and they are in the same field of vision only one e-mark is required, although there is no restriction on applying an e-mark next to each declaration.
If there is a declaration of the nominal quantity in more than one field of vision on the prepackage, the e-mark should be applied next to each declaration and then the requirement applies for each of these declarations.[32]

Note: Other legal acts may require the nominal quantity to be indicated on the immediate packaging* and at the same time on the outer packaging**. Once the e-mark is applied, it has to bear at least on the outer packaging. Obviously, when there is no outer packaging, the e-mark is applied on the immediate packaging.

*immediate packaging (or container or primary packaging): contains and is in contact with the product
**outer packaging (or packaging or secondary packaging): contains the immediate packaging

[28] Regulation (EU) 1169/2011, article 9.h.
[29] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 4.1.
[30] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 4.2.
[31] OIML R 79 (2015). *Labelling requirements for prepackages*. Paragraph 4.3.
[32] WELMEC Guide 6.4 (2015) 'Guide for packers and importers of e-marked prepacked products', Paragraph 4.7.

4. RESPONSIBILITY OF THE PACKER OR IMPORTER

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

For packages produced in the EEA the packer is responsible for ensuring that the prepackages meet the requirements of the Directive.

For packages produced outside the EEA, the first importer based in the EEA is responsible for ensuring that the prepackages meet the requirements of the Directive.

Domestic legislation may specify whether the company or individual employee is held responsible.

R 1169/2011[33]: "The food business operator responsible for the food information shall be the operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market."

Note 1[34]: a) Where the food business operator is the packer or importer in Europe, he is responsible for all the food information, including for ensuring that the quantity requirements in the Directive are met.
b) Where the food business operator is not the packer or importer in Europe, then he is responsible for all the food information provided and he must be able to identify the packer or importer established in Europe who is responsible for ensuring that the quantity requirements are met.

Note 2[35]: "Importers of ℮-marked prepackages need to fulfil the same requirements as packers of ℮-marked prepackages in Europe. In practice, it is much harder for the Competent Departments to control these importers, because it is more difficult to trace them. Consequently, there is a risk of imported ℮-marked prepackages, to be placed on the European market without complying with the requirements of the Directive".

[33] Regulation (EU) 1169/2011 article 8.1.
[34] WELMEC, Informative Document – Overview of the food Information Regulation impact in Prepackages, 2016, Issue 8, *Impact*.
[35] COMMISSION STAFF WORKING DOCUMENT, REFIT, SWD(2016) 219 final, Annex 4, 3rd Paragraph.

The quantity of product contained in a prepackage (or packing quantity), known as the 'actual contents', shall be measured or checked by weight or volume on the responsibility of the packer and/or importer."

By the term "measured", it is meant that the packer measures the actual quantity of product in every prepackage in the batch using a legal and suitable measuring instrument. This is (e.g.) the case where the packer fills manually the packing material with product until the actual quantity of product at least equals to the nominal quantity.

By the term "checked", it is meant that the packer or importer performs checks in accordance with procedures recognized by the competent departments in the Member State, as to effectively guarantee that the prepackages in the batch meet the quantitative requirements of the Directive.

An importer may contract with another person to carry out the necessary checks on his behalf. The checks must be carried out before prepackages leave his possession. The importer remains responsible for checking the actual quantity of product and needs to ensure that the checks and records made are adequate. More information can be found in WELMEC Guide 6.13[36].

Packers and importers can decide for themselves what quantity control system they wish to use, as long as their procedures are recognized by the Member State. They should be aware that the recognition of procedures may be different in each Member State. It is advised that packers and importers check the requirements of the Competent Department in the corresponding Member State.

Note 1: In some Member States checkweighers and automatic gravimetric filling instruments could be part of packer's procedures, recognized by the Competent Department.

Note 2: For aerosol dispensers there is an industry standard[37] which describes a method providing a direct means of measuring the density of a complete aerosol formulation.

"The measurement or check shall be carried out by means of a legal measuring instrument suitable for effecting the necessary operations."

Where the type of equipment used is controlled by legislation, then it must be verified and checked thereafter to ensure that it continues to comply with those legislative requirements.

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[36] WELMEC Guide 6.13, 2017, Compliance of Imported e-marked Prepackages, Part 6.
[37] FEA 605 Filled aerosol packs – Measurement of the density of aerosol formulations.

Other equipment shall only be used if permitted by the competent department and shall be:

a) calibrated by an agreed method, or
b) certificated by an approved body

in both cases demonstrating traceability and uncertainty of measurement.

The value and uncertainty obtained shall be taken into account. The total uncertainty of measurement (at the 95 % confidence level) for the measurement being made shall ideally not exceed one-fifth of the tolerable negative error of the prepackage. The requirements on measurement uncertainty can be reduced if the packer compensates by overfilling.

The measurement equipment must be selected in a way that takes into consideration the total measuring uncertainty. When considering the measurement uncertainty all components and circumstances that can influence the measurement result, such as equipment, environment and tare, should be included. More information can be found in WELMEC Guide 6.4[38].

It is recognised that the errors on measuring container bottles complying with Directive 75/107/EEC exceed one-fifth of the tolerable negative error. This will necessitate the target quantity being enhanced to take into account the large errors permitted on the MCB.

Tolerances shall not be exploited.

"Where the actual contents are not measured, the check carried out by the packer shall be so organized that the quantity of the contents is effectively ensured.
This condition is fulfilled if the packer carries out production checks in accordance with procedures recognized by the competent departments in the Member State…"

An adequate documented quantity control system is needed; which domestic legislation may require to be recognised by a competent department.

For the system to be adequate it must:

a) specify the system from setting up, to monitoring and regular reviewing,
b) justify the targets and quantity control limits,
c) contain a procedure to be followed when limits are breached,
d) require records to show that it is being followed, and
e) ensure staff are adequately trained.

[38] WELMEC Guide 6.4, 2015, Guide for packers and importers of e-marked prepacked products, Paragraph 5.3.

Suitable measuring equipment is listed in Annex 3 of this Guide.

Note 1: More information on the recognition of procedures and on the requirements of packer's e-mark control system can be found in WELMEC Guide 6.6[39].

Note 2: For prepackages whose actual content are measured, checks carried out by the packer are not mandatory.[40]

"*...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 to be necessary, have been properly and accurately carried out."*

The records that are produced while carrying out the recognized procedures, must be made available on demand from an Inspector. They may be held on any type of media as long as their security is guaranteed and they are accessible in a readable and easy to understand state.

The records must contain process capability data, the monitoring data and any corrective actions taken for each batch of product. The records that should be maintained are listed in Annex 4 of this Guide.

It is recommended that the records should be kept for at least the lifetime of the product, and general data should be kept for one year after the expiration of the lifetime of the product, unless otherwise specified by national legislation or certification of the system.

"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"

Some of the acceptable evidence includes:
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.

[39] WELMEC Guide 6.6, 2013, Guide for Recognition of Procedures, Part 4 and Part 5.
[40] Case C - 96/84.

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.

In the case of checking prepackages (and not measuring the quantity going into each package) the importer, when requested by the competent department, shall present the same kind of records to show that the requirements of the Directive have been met.

Note 1: Regardless of which alternative is used, this does not prevent the competent department in the importing country from performing tests in accordance with Annex 1 point 5 of the Directive at the premises of the importer.

Note 2: Information for the packer / importer and their responsibilities can be found in WELMEC Guide 6.4[41] and in WELMEC Guide 6.13[42].

"In the case of products in quantities expressed in units of volume, one of several methods of meeting the measuring and checking requirements is to use, when making up the prepackage, a measuring container of the type defined in the Directive relating thereto, filled under the conditions prescribed in that Directive and herein"

The verification, or certification, of the templets must include the indications of nominal volume, the tolerance marks TU1 and TU2, the unit of measurement, the identification of the bottle type, where appropriate the type of enclosure to be used and, if it is not used at 20 ^{o}C, the reference temperature and coefficient of cubical expansion of the liquid. The templet should be used only for the bottle for which it was designed.

For the templets to be suitable they should be graduated in millilitres or if in millimetres there must be a calibration curve to give the corresponding volume.

For the MCB to be suitable for testing with templets the dimensions of the neck between TU2 and the nominal quantity should be such as to move the meniscus at least 1 mm when a volume of liquid equal to one fifth TNE is added. There should be no distortion of the meniscus in this range so that the meniscus is visible and can be measured to $\pm$ 1 mm.

[41] WELMEC Guide 6.4, 2015, 'Guide for Packers and Importers of e-marked prepacked Products', Paragraph 2.4.3.
[42] WELMEC Guide 6.13, 2017, Compliance of Imported e-marked Prepackages, Part 6.

5. CHECKS TO BE CARRIED OUT BY THE COMPETENT DEPARTMENTS ON THE PREMISES OF THE PACKER OR OF THE IMPORTER OR OF HIS AGENT ESTABLISHED IN THE COMMUNITY

Checks to ensure that prepackages comply with the provisions of this Directive shall be carried out by the competent departments of the Member States by sampling on the packer's premises or, if this is not practicable, on the premises of the importer or of his agent established in the Community.

The importer and packer 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:

a) the accuracy and suitability of the equipment and whether it was adequately maintained,
b) the adequacy of the records, and their accuracy by checking prepackages from that batch,
c) the labelling of the product,
d) the quantity of product in prepackages,
e) staff training and systems review.

Generally, checks on ℮-marked products should be carried out at packer's and importer's premises at least once a year where the Inspector is aware that the product has international distribution.

***This statistical sampling check shall be 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 II*.**

The batch of prepackages should be capable of passing a reference test whose effectiveness is comparable to the reference method described in Annex II of the Directive.
In Appendix C of WELMEC Guide 6.7[43] equivalence of checks (in accordance with the Directive) is considered in detail.

Note 1: The effectiveness of OIML R 87 sampling plan is not comparable to the reference method described in Annex II of the Directive.

Note 2: General information on the "statistical sampling test" referred to as "reference test", is given in Annex 5 of this Guide.

[43] WELMEC Guide 6.7 (2008), 'Guidance for Market Control on Prepackages for Competent Departments'.

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.

Checks on the quantity in prepackages need to bear in mind the statistical significance of the results. Checks may also be made on the compliance with other requirements such as labelling.
These other checks are considered in WELMEC Guide 6.7.

PART 4: ANNEX II TO THE DIRECTIVE

This Annex lays down the procedures of the reference method 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.

1. REQUIREMENTS FOR 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 in the prepackage."

For consistency the error should be taken to refer to the uncertainty of measurement. Consequently, the expanded combined standard uncertainties (k=2) for the measurement should not exceed one-fifth of the TNE.

More information and examples can be found in WELMEC Guide 6.9[44].

2. REQUIREMENTS FOR CHECKING BATCHES OF PREPACKAGES

2.1 Prepackage batches
2.1.2 When prepackages are checked at the end of the packing line, the number in each batch shall be equal to the maximum hourly output of the packing line, without any restriction as to the batch size.
***In other cases the batch size shall be limited to 10 000*.**

This definition for batch size, is only for inspectors carrying out reference tests.

a) When sampled at the end of the packing line, the batch size equals to the maximum hourly output of the packing line, or a lesser time if the whole batch is packed in this period.
b) When sampled after the prepackages have left the packing line, the batch size should not exceed 10 000 prepackages.

Note 1: OIML R 87 defines the size of the inspection lot (batch) as it is described in Table 3.[45]

[44] WELMEC Guide 6.9[44], 2009, 'Prepackages – Uncertainty of measurement'.
[45] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 4.4.

Table 3: Definition of the size of the inspection lot according OIML R 87

	When sample prepackages are collected...	**The size of the inspection lot shall be...**
1	...from the production line	...equal to the maximum hourly output of the production line.
2	...at the premises of the packer but not from the production line	...equal to the maximum hourly output of the production or 100 000, whichever is the lesser.
3	...outside the packer's premises	...defined by the legal metrology official, but shall not exceed 100 000. Generally, the legal metrology official should take number of prepackages available as the batch size.

2.2 Checking of the actual contents of a prepackage

The reference method in Annex II of the Directive does not give any directions or acceptance/rejection criteria in case of the detection of a prepackage with actual quantity below T2. This package counts as a defective package and should be eliminated for any further use. The Directive states that such a package may not bear the ℮-mark[46].

Packers should be aware that Competent Departments (and customers) may reject batches after finding one or more prepackages with quantity less than T2 and to further investigate the filling and checking procedures of the packer.[47]

[46] Directive 76/211/EEC, Annex 1, 1.3.
[47] WELMEC Guide 6.8 (2020) 'Drained Weight, Guide on the Verification of Drained Weight, Drained Washed Weight and Deglazed Weight', Paragraph 2.3.2.3.

PART 5: Issues not specifically covered by the Directive

Introduction

The delegates of the Working Group have experienced various problems when enforcing the provisions of the Directive and other issues not addressed by the Directive. This part of the Guide gives guidance on some of these issues and is mutually accepted by the delegates. It is envisaged that these issues could be resolved when the Directive is next updated, and that the terminology should be in line with OIML R 79, OIML R 87 and VIM, the international vocabulary of metrology, where appropriate.

1. Desiccating Products

Product which, even though in packing material, can diminish in quantity by evaporation, whether of the product or of an ingredient, are referred to as desiccating product. Examples are: soap, cheese, sausages, bread, white spirit, etc.

National legislations have different requirements regarding desiccating products. There are generally two different views:

1. The product must meet the requirements of the Directive in any stage of the distribution chain.

2. The product must meet the requirements of the Directive at the moment of packing and thereafter any reasonable loss of weight is allowed.

Ideally the labelling should make it clear to the consumer that the product desiccates.

WELMEC Guide 6.11[48], Paragraph 5.1 has considered this issue and recommends the following: The actual quantity in the package shall not reduce below TU2 at any time while being offered for sale. The packer should be able to substantiate that the product, as packaged, is a desiccating product and that the Directive's requirements were met at time of packing as defined above.

OIML R 87[49]: "Prepackages shall meet the requirements …. at any level of distribution including at the point-of-pack, import, distribution and wholesale transactions, and sale."

[48] WELMEC Guide 6.11 (2013) 'Guide for Prepackages whose Quantity Changes after Packing'.
[49] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 3.1.

OIML R 87[50]: "National legislation may permit allowances in addition to tolerable deficiencies for the loss of quantity of product after packaging caused by ordinary and customary exposure to environmental conditions that occur in storage and distribution in the evaluation of both the average and individual prepackage requirements. These additional allowances would typically not apply to products packed in hermetically sealed (airtight) packing material."

2. Deceptive Packaging

The size of the prepackage shall not mislead consumers. This may be the case when the size of the packaging increases without the nominal quantity, the nominal quantity decreases without the packaging or when the packaging is excessive in any way.

The Unfair Commercial Practice Directive, Directive 2005/29/EC, covers all false and misleading claims and omissions.

Article 7 of the Food Regulation, Section 6 of OIML R 79 and Annex E of OIML R 87, endeavours to ensure consumers are not misled and that packers have fair competition.

WELMEC informative document 6-002 'Deceptive Packaging' 2017, provides more information on Deceptive Packaging.

3. Checks to be carried out by the Competent Departments for batches less than 100 prepackages

While the Directive also applies to batches of less than 100 prepackages, it does not provide any sampling plan.

Note: WELMEC Guide 6.7[51] gives guidance on appropriate screening tests.

4. Batch Size

The Directive was drafted in the 1970s, when the maximum hourly output of the packing line, approached 10 000 prepackages.

[50] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 4.1.4, Note.
[51] WELMEC Guide 6.7 (2008), Guidance for Market Control on Prepackages for Competent Departments, Appendix B.

Nowadays, packing machines are able to produce more than 100 000 prepackages per hour. Therefore, the maximum batch size of 10 000 should be replaced by a new and more representative number of the current times.[52]

Until then, for a batch containing more than 10 000 prepackages, the batch may be divided into batches of 10 000 prepackages and the reference test performed into one of those batches.

[52] COMMISSION STAFF WORKING DOCUMENT, REFIT, SWD(2016) 219 final, Annex 7,*speed of production.*

Annex 1: Information about inscription and markings

Units of Measurement

The full names of units of measurement and their symbols that are used for the expression of nominal quantity (nominal weight or nominal volume) are shown in Table 4[53].

Table 4: Units of Measurements

	Full Name of Unit of Measurement	Symbol
Weight	grams kilograms	g kg
Volume	millilitres centilitres litres	ml or mL cl or cL l or L

Height of Nominal Quantity Figures

The minimum height of nominal quantity figures must be in accordance with Table 5[54].

Table 5: Minimum Height of Nominal Quantity Figures

Q_n of the product (g or ml)	Minimum height of Q_n figures (mm)
$Q_n \leq 50$	2
$50 < Q_n \leq 200$	3
$200 < Q_n \leq 1\,000$	4
$1\,000 < Q_n$	6

Note: The Food Regulation requires the mandatory food information, including the net quantity, to be in characters using a font size where the x-height, as defined in Annex IV, is equal to or greater than 1,2 mm[55]. In the case of small packages or containers where the largest surface has an area of less than 80 cm², the x-height of the font size, shall be equal or greater than 0,9 mm[56].

Consequently, for ℮-marked prepackages of food, when the minimum height of nominal quantity figures complies with the requirements of the Directive, it also complies with the corresponding requirements of the Food Regulation. On the other hand, packers and business operators should be aware that if the height of

[53] Directive 76/211/EEC Annex 1, Paragraph 3.1, OIML R 79 (2015) Annex A, A.1, Table A.1.
[54] Directive 76/211/EEC Annex 1, Paragraph 3.1.
[55] Regulation (EU) 1169/2011, article 13.2.
[56] Regulation (EU) 1169/2011, article 13.3.

the characters of the nominal quantity complies with the requirement of the Food Regulation, it could possibly not comply with the requirement of the Directive.

The height of nominal quantity figures is covered at “Issue 7” WELMEC Informative document 6-001[57], “Issue 7”.

[57] WELMEC Informative document 6-001 ‘Overview of the Food Information Regulation impact on Prepackages’ 2016

Annex 2: Requirements on the expression of nominal quantity for particular products, resulting from other European Legislative Acts – Non-exhaustive list

Category of prepackaged product / Corresponding European Act	Referred to and covered in other WELMEC Guides	Additional requirements not covered in other WELMEC Guides
Foodstuff / Regulation (EU) No 1169/2011	WELMEC Guide 6.14, Paragraph 2.1.2 (***general requirement***) WELMEC Guide 6.6, Paragraph 5.14 (***multipacks***) WELMEC Guide 6.8, Paragraph 1 (***foods in a liquid medium***)	• Regulation 1169/2011, article 2.2 (e): Definition of “prepackaged food”: ... ‘prepacked food’ does not cover foods packed on the sales premises at the consumer’s request or prepacked for direct sale • Regulation 1169/2011, Annex IX, Paragraph 1: The net quantity declaration shall not be mandatory in the case of foods: (a) which are subject to considerable losses in their volume or mass and which are sold by number or weighed in the presence of the purchaser; (b) the net quantity of which is less than 5 g or 5 ml; however, this provision shall not apply to spices and herbs; or (c) normally sold by number, provided that the number of items can clearly be seen and easily

		counted from the outside or, if not, is indicated on the labelling.
Wines and spirits / Directive 2007/45/EC	WELMEC Guide 6.10, Paragraph 7.1 WELMEC Guide 6.14, Paragraph 2.2.1	• *There is no restriction on the application of any nominal quantity that is outside the ranges specified in the Directive 2007/45/EC, Annex 1, Table1.* • Regulation (EU) 2019/787, article 48: By way of derogation from Article 3 of Directive 2007/45/EC, single distilled **shochu**, may be placed on the Union market in nominal quantities of 720 ml and 1 800 ml that correspond to traditional Japanese bottle sizes.
Aerosol Dispensers / Directive 75/324/EEC and Directive 2007/45/EC	WELMEC Guide 6.14, Paragraph 2.2.2	
Feed Material / Regulation (EC) No 767/2009	WELMEC Guide 6.14, Paragraph 2.2.3	
Detergents / Regulation (EC) No 648/2004	WELMEC Guide 6.14, Paragraph 2.2.4	

Soil Improvers and Growing Media / European standards EN12579, EN12580 and EN15238	WELMEC Guide 6.14, Paragraph 2.2.5	
Cosmetic Products / Regulation (EC) No 1223/2009	WELMEC Guide 6.14, Paragraph 2.2.6	
Fertilising Products / Regulation EU No 2019/1009		• Regulation EU No 2019/1009, Annex III, Part I: 1. The following information shall be provided: ... (c) the quantity of the EU fertilising product, indicated by mass or volume;
Medicinal Products for Human Use / Directive 2001/83/EC		• Directive 2001/83/EC: Article 54: The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging: …

		(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the product; … Article 55: 1. The particulars laid down in Article 54 shall appear on immediate packagings other than those referred to in paragraphs 2 and 3. 2. The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 54 and 62. … 3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 54 and 62 cannot be displayed: … — the contents by weight, by volume or by unit.
Veterinary Medicinal products / Regulation (EU) No 2019/6		• Regulation (EU) No 2019/6, Article 11: The outer packaging of a veterinary medicinal product shall contain the following information and shall contain no information other than: …

		(b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product;
Eggs / Regulation (EU) No 2023/2465*		• Regulation (EU) No 2023/2465, article 5: Grading of Class A eggs by weight 1. Class A eggs shall be graded by weight as follows: (a) XL — very large: weight ≥ 73 g; (b) L — large: weight ≥ 63 g and < 73 g; (c) M — medium: weight ≥ 53 g and < 63 g; (d) S — small: weight < 53 g. 2. The weight-grading shall be indicated by the corresponding letters or terms as defined in paragraph 1 or by a combination of both, which may be supplemented by the corresponding weight ranges. 3. By way of derogation from paragraph 1, where Class A eggs of different sizes are packed together in the same pack, the minimum net weight of the eggs shall be given in grams and the indication 'Eggs of different sizes' or equivalent terms shall appear on the outer surface of the pack.[58]
		• Regulation (EC) No 543/2008, article 9:

[58] It is unclear to what 'minimum net weight of the eggs' refers to. Contact your national authority on eggs.

Poultrymeat / Regulation (EC) No 543/2008**		... 2. All pre-packages shall in accordance with paragraphs 3 and 4 bear an indication of the weight of the product, known as 'nominal weight', which they are required to contain. 3. Pre-packages of frozen or quick-frozen poultrymeat may be classified by categories of nominal weights as follows: (a) carcases: — < 1 100 g: classes of 50 g (1 050 — 1 000 — 950, etc.), — 1 100 — < 2 400 g: classes of 100 g (1 100 — 1 200 — 1 300, etc.), — ≥ 2 400 g: classes of 200 g (2 400 — 2 600 — 2 800, etc.); (b) cuts: — < 1 100 g: classes of 50 g (1 050 — 1 000 — 950, etc.), — ≥ 1 100 g: classes of 100 g (1 100 — 1 200 — 1 300, etc.).

***** The Eggs Regulation (EC) No 2023/2465, article 19, provides tolerance for egg weight.
******The Poultrymeat Regulation (EC) No 543/2008, provides quantity requirements for Pre-packages of frozen or quick-frozen poultrymeats (article 9(4)) and a statistical test to be carried out by the competent authorities (article 9(6)-9(11)).

Note: Regardless of any other labelling requirement and/or quantitative that may result from other legislative acts, when the e-mark applies the requirements of the Directive have to be met.

Annex 3: Equipment permitted to be used by packers and importers

Measuring instruments, have to fulfil the requirements of Directive 2014/31/EU (NAWI) or 2014/32/EU (MID), when they are put into service.

Other types of measurement equipment outside the scope of these two Directives, have to follow national legislation and, if there is none, international Recommendations have to be followed. In case there are no international Recommendations, the measurement equipment should be accompanied by a calibration certificate, issued by an accredited laboratory or a national metrological institute.

All calibrations shall be traceable to national or international standards, and certificates shall specify the measurements and the uncertainty of measurement.
The equipment shall be deemed suitable if the **total** expanded uncertainty of measurement (k=2) in the system does not exceed one-fifth of the TNE, unless the quantity control system targets guarantee an appropriate overfill.

All equipment shall be maintained to ensure accuracy, and be periodically calibrated, or re-verified if required by domestic legislation. The calibration period should not exceed the period over which the user can prove (from previous records) that the equipment will not exceed any permitted error range or agreed tolerance.

Note: The equipment used by the packers/importers for “checking” the actual content of the prepackages in the batch, is part of the packers/importers procedure recognized by the Competent Department in the Member State, aimed to ensure that the prepackages meet the quantitative requirements of the Directive.

Annex 4: Records required to be made and kept by the packer

The packer must record all relevant factors that affect the recognised procedures. The records should provide evidence that the packer has followed the recognised procedures. More information on how to fulfil can be found in WELMEC Guide 6.4[59] and WELMEC Guide 6.5[60].

The records should include:

1 Identification and specification of product

1.1 product identity
Batch data:
1.2 batch identity
1.3 batch size
1.4 density, if applicable
1.5 nominal quantity, and where checks are carried out on finished product
1.6 target value, or set points for checkweighers
1.7 average quantity control limits
1.8 process variation limits
1.9 tare variability and other allowances
1.10 for checkweighers, the classification or zone of indecision, checks on data collection and calculations

2 In production checks

2.1 identification of checkpoint / packing line
2.2 reference to product identity
2.3 batch identity
2.4 time of sampling
2.5 number of packages in a sample
2.6 tare if applicable
2.7 average and variance of actual quantity of product (sample data)
2.8 average and variance of actual quantity of product (batch data)
2.9 number or percentage (%) of packages below TU1, and corrective action taken when necessary
2.10 number or percentage (%) of packages below TU2, and corrective action taken
2.11 for checkweighers, checks on set points, to ensure no drift

[59] WELMEC Guide 6.4 (2015), 'Guide for packers and importers of e-marked prepacked products', Paragraph 5.7.
[60] WELMEC Guide 6.5 (2012), 'Guidance on Controls by Competent Departments on "e" marked Prepackages', Paragraph F.3.1.

3 System including corrective action and review

3.1 Records showing isolation of non-conforming prepackages; rectification or disposal

3.2 Review of the quantity control system at least annually or whenever the production line or product changes

3.3 Staff should be appropriately trained to perform their duties, with sufficient stand-by staff to deal with absences for leave or illness

Annex 5: Reference test

- **What is it?** The reference test is statistical sampling check, carried out in accordance with the accepted methods of quality acceptance inspection. It could be the test described in Annex II of the Directive or a test with comparable effectiveness, which meets the criteria described in 3rd and 4th subparagraphs of Paragraph 5, Annex 1 of the Directive.

- **What is the aim of the reference test?** The reference test aims to ensure that batches of prepackages comply with the quantitative requirements[61] of the Directive.

- **By whom is it carried out?** It is carried out by Competent Departments of EEA countries.

- **Where is it carried out?** It is carried out on the packer's or importer's premises. If the importer is not established in the Community, then the reference test must be carried out on the premises of the importer's agent, established in the Community.
  Note: The Competent Departments of EEA countries, can perform other checks 'at any stage in the marketing process, in particular for the purpose of verifying that prepackages meet the requirements of the Directive'. When the test described in Annex II of the Directive (or a test with comparable effectiveness) is carried out in places other than at the premises of the packer's or importer's (or importer's agent), then the test can be considered as an 'other check'. More information on this can be found in WELMEC Guide 6.7[62], Paragraph 5.2.

- **When is it carried out?** The reference test can be carried out as soon as the prepackages are available, all quantity checks have been carried out by the packer as well as any corrective actions necessary. If the product is not labelled at the time of packing, then the packer must be able to justify what the intended nominal quantity will be.

- **Where must the sample be drawn from?** The sample must be drawn from the same batch. For more details about batches, see Paragraph 2 of Part 4 of this Guide.

OIML R 87[63]: "Legal metrology officials shall conduct tests to determine whether prepackages comply with the requirements of this Recommendation."

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[61] Directive 76/211/EEC, Annex I, Paragraph 1.
[62] WELMEC Guide 6.7[62], (2008), Guidance for Market Control on Prepackages for Competent Departments.
[63] OIML R 87 (2016). *Quantity of product in prepackages*. Paragraph 4.1.1.

Note: The quantitative requirements of the Directive and OIML R 87 are the same (for more information see Paragraphs 1.1-1.3 of Part 3 of this Guide), but the effectiveness of the reference test provided by the OIML R 87, is not comparable to the reference method specified in Annex II of the Directive.