

WELMEC 6.3

Issue 2

WELMEC

European cooperation in legal metrology

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



June 2009

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 of Guides published by WELMEC. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives.

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

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General

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. These directives deal with marking and quantity control of e-marked prepackages.

These directives have recently been amended by Directive 2007/45/EC of 5 September 2007, which revokes Directives 75/106/EEC and 80/232/EEC and amends Directive 76/211/EEC. The only prescribed quantities permitted without specified time limit relate to certain wines and spirits. Members States can retain prescribed quantities for milk, butter, dried pasta and coffee until 11 October 2012, and for sugar until 11 October 2013.

This document is part of a series of documents (to be) published by WELMEC:

6.0 Introduction to WELMEC documents on 'e' marked prepackages

6.1 Definitions of terms

6.2 Translations of terms

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

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 Controls on non-e-marked Prepackages

Some of these documents represent the opinion of WELMEC, others are under revision or preparation. Those that have been agreed by WELMEC are published on their website (www.welmec.org).

This series of documents primarily intends to provide guidance to all those concerned with the application of Directive 2007/45/EC laying down the rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (the Directives). They are intended to lead to a uniform interpretation and enforcement of these directives and assist in the removal of barriers to trade

Disclaimer

Please note that this series of documents does not deal with all the matters not covered by the above directives, such as requirements for certain products to be made up in prescribed quantities, and controls on non e-marked prepackages.

Format of Document

This document is divided into 5 parts:

Part 1: Introduction, methodology, and definitions

Part 2: Scope of the Directive

Part 3: Annex I to Council Directive 76/211/EEC

Part 4: Annex II to Council Directive 76/211/EEC

Part 5: Issues not specifically covered by the Directive.

In Parts 2 to 4 of the document, the numbering of the paragraphs is the same as that used in Directive 76/211/EEC.

PART 1: Introduction, methodology and definitions

- 1.1 At the meeting of WELMEC Working Group 6 held in May 2007, Resolution 172 required that the existing WELMEC document 6.3 be updated, specifying how signatories to the WELMEC Memorandum of Understanding have implemented Directive 76/211/EEC, (the Directive).
- 1.2 Members were asked to consider each part of the Directive and agree acceptable ways of implementing the requirements in a practical manner, but which would also give confidence to them that 'e' marked products, in quantities of 5 g to 10 kg or 5 ml to 10 l, would comply with the Directive.
- 1.3 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 OIML Recommendations be reflected in its work. Consequently OIML recommendations¹ 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 for harmonised implementation of the Directive based on the opinions of the experts in the Working Group.
- 1.4 With Directive 2007/45/EC coming into effect, the guidance has been reviewed to reflect the changes in requirements and references.
- 1.5 To assist in cross-referencing, the wording from the Directive is in italics and the paragraph numbers in Parts 2 to 4 relate 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 Directive's Annexes have been quoted; these parts contain non-contentious requirements or definitions accepted as written.

¹ OIML R 79, Labelling requirements for prepackaged products, and OIML R 87, Quantity of product in prepackages

1.6 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.

1.7 Definitions - see WELMEC document 6.1 and the International Vocabulary of Basic and General Terms in Metrology (VIM). Directive 2007/45/EC has not altered any definitions contained in the original Directives. Relevant OIML definitions are noted, but definitions in European legislation take precedent.

Actual contents of the prepackage are the quantity (weight or volume) of product which it in fact contains.²

This should be taken as the actual net content of the prepackage. Procedures for verifying the actual contents are set down in the Annex II to the Directive.

NOTE: R87 uses the term 'actual quantity' which is defined as 'Actual quantity of product that a prepackage in fact contains as determined by measurements made by legal metrology officials.'³

Importer

'importer' shall mean any natural or legal person established within the Community who places a product from a third country on the Community market⁴.

MCB –measuring container bottle

a bottle whose volume and labelling comply with the Council Directive 75/107/EEC.

NOTE: The OIML R138 defines an 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.'⁵

² 76/211/EEC Annex I para 2.2

³ OIML R87 para 2.1

⁴ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

⁵ OIML R138 paragraph 2.3

Nominal quantity (nominal weight or volume) of the contents of a prepackage is the weight or volume indicated on the packaging, i.e. the quantity of product which the prepackage is deemed to contain⁶.

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 OIML R 79.

Packer

the term 'packer' is not defined in the Directive, but is given the responsibility for ensuring that prepackages meet the requirements of the Directive⁷.

Packing material

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.

NOTE: Packing material is generally used to contain, protect, handle, deliver, preserve, transport, inform about and serve as an aid (e.g. food serving tray) while using the product it contains.⁸

Prepackage

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 being opened or undergoing a perceptible modification⁹

OIML R87: *Combination of a product and the packing material in which it is prepacked.¹⁰*

Prepackaged product 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.

OIML R87 2.11: Single item for presentation as such to a consumer, consisting of a product and the packing material into which it was put before being offered for sale and in which the quantity of product has a predetermined value, whether the

⁶ 76/211/EEC Annex I para 2.1, and also see OIML R87 2.8

⁷ 76/211/EEC Annex1 para 4

⁸ OIML R87 2.9 note

⁹ 76/211/EEC art. 2.2

¹⁰ OIML R87 2.10

packing material encloses the product completely or only partially, but in any case in such a way that the actual quantity of product cannot be altered without the packing material either being opened or undergoing a perceptible modification.

Principal display panel

the part of the package that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display¹¹.

Product

also referred to as identified product. The Working Group resolved that the Directive should define 'individual package'¹² as 'everything that is meant to be left after use of the product, except for items naturally present in the product. Use includes consumption or subjecting to a treatment'¹³,

Together with the definition of prepackage (prepackage = product + individual packaging) it clarifies what is the product and what is the packaging.

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

Examples of packaging include the stick in a lollypop, immediate wrappers around sweets and tea bags. Similarly the quantity of cheese shall be exclusive of any wax put on cheese after its manufacture. Following the above resolution the wax is left over after the cheese has been used, and as is not naturally present in the product (cheese) it is therefore part of the packaging.

Verified

means established to comply with the requirements of appropriate legislation . For equipment for which there is no relevant legislation it means testing and approval by a competent organisation.

Wrapping

a package of whatever nature which encloses the product.¹⁴ With regard to food if, the wrapping is intended to be eaten it is treated as part of the product, e.g. rice paper.

¹¹ OIML R79 para 2.4

¹² 76/211/EEC article 2.1

¹³ OIML R87 2.9

¹⁴ WELMEC 6.1 definition number 122

PART 2: Scope of the Directive

Article 1 *“This Directive relates to products intended for sale in constant unit nominal quantities which are:*

- *equal to values determined 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.”*

Products which this Directive does not control are:

- those products made up in variable quantities, sometimes referred to as ‘catchweight’ product,
- product that is sold in quantities of length, area and number, and
- product in constant unit nominal quantities less than 5 g or 5 ml or more than 10 kg or 10 L.

Article 3 *“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 (‘e’ mark) is not mandatory

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 rules.”*

There are no European contrary rules and no European-wide trade practices.

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 packages 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 consumers¹⁵ compare value.

¹⁵ See recitals (4) and (6) of Directive 2007/45/EC

PART 3: Annex I to Council Directive 76/211/EEC

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”

For ‘actual contents’ and ‘nominal quantity’ see the definitions above.

Packers and importers can decide for themselves what quantity control system they use, as long as the competent department is satisfied with it.

The prepackages shall be capable of passing a reference test whose effectiveness is comparable to the reference method¹⁶. The reference test shall be carried out by the competent department and shall be performed on a sample drawn from a batch which,

- a) when sampled after the packing line, consisting of 1 hour’s production, or a lesser time if the whole batch is packed in this period, or
- b) when sampled once the packages have left the packing line, consisting of up to 10,000 packages from the same batch.¹⁷

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 of 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 TU1 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 is also satisfied.

¹⁶ 76/211/EEC Annex II

¹⁷ 76/211/EEC Annex II, 2.1.2

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

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'.

Solely for the purposes of setting up a quantity control system, it will be considered acceptable if the probability of producing one prepackage below TU2 is not more than 1 in 10000.

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:

OIML R79 recommends that the declaration of the net quantity shall appear on the principal display panel¹⁸, in easily legible boldface type or print that contrasts conspicuously with the background and with other information on a package; however, when the value of the net quantity is blown, embossed or moulded on the surface of the package, then all other required label information shall be provided conspicuously elsewhere on the surface or on a label¹⁹.

3.1 "The nominal quantity (weight or volume).."

Prepackages containing liquid products shall be marked with their nominal volume and prepackages containing other products shall be marked with their nominal weight²⁰.

As laid down in Directive 2007/45/EC, aerosols have their own specific requirements:

¹⁸ OIML R79 para 5.1

¹⁹ OIML R 79 para 5.5.2

²⁰ 76/211/EEC article 4.2, also see OIML R79 para 5.3.1

- aerosol dispensers shall indicate the nominal total capacity of the container. The indication shall not be such as to create confusion with the nominal volume of the contents.
- By way of derogation from article 8(1)(e) of Directive 75/324/EEC, products which are sold in aerosol dispensers need not be marked with the nominal weight of their content.

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.

NOTE: For aerosols the OIML recommends that the quantity stated should be the “net quantity in mass that will be expelled when instructions for use are followed. The propellant is included in the net quantity statement”²¹.

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’.

The European Court case C-83/96²² ruled that for foodstuff an indication of the packer outside the EU would be enough, meaning that no identification of the importer is needed.

The OIML recommendation is that the label of a prepackaged product shall specify conspicuously the name and place of business of the person responsible for any of the following: manufacturing, packing, distributing, importing or retailing the product. When the product is not manufactured or packaged by the person whose name appears on the label, the name may be qualified by a phrase that reveals the connection such person has with the product, for example: “manufactured for ...”, “distributed by ...”, “marketed by ...”, “imported by ...” or “sold by ...”²³.

NOTE: In some cases, the identity of the manufacturer or packer may be added as a code if permitted by national regulations. The statement of the place of business, with complete mailing address, shall be in accordance with the national laws and postal usage or may be represented by an indicator (such as a code number) if permitted by national regulations.

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 on the label when the product is manufactured outside the EEA.

²¹ OIML R79 para 5.3.2

²² See 61996J0083

²³ OIML R79 para 4.2

3.3 “a small ‘e’, at least 3 mm high, placed in the same field of vision as the indication of the nominal quantity....”

Only one of the quantity declarations is considered to be 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’.

In addition to the metric quantity other quantity markings, not in the metric system, are permitted on the label as long as they are not misleading.

4. RESPONSIBILITY OF THE PACKER AND IMPORTER.

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

For packages produced in the EEA, the packer is responsible for meeting this requirement.

For packages produced outside the EEA, the first importer based in the EEA is responsible for meeting this requirement.

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

4.2 “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.”

An importer may contract with another person to carry out the necessary checks on his behalf. The checks must be carried out before the prepackages leave his possession. The importer remains responsible for meeting this requirement and needs to ensure that the checks and records made are adequate.

For aerosol dispensers there is an industry standard²⁴ which describes a method providing a direct means of measuring the density of a complete aerosol formulation.

²⁴ FEA 605 Filled aerosol packs – Measurement of the density of aerosol formulations, available from www.aerosol.org

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

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.

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.

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.

4.4 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..."

This paragraph does **not** apply to prepackages where each one is made up using legal and suitable equipment where the packer ensures that the actual contents of each prepackage is equal to, or greater than, the nominal quantity (minimum system). In this instance no records are required to be made and a packer can affix an 'e' mark without approval²⁵.

²⁵ Case C - 96/84,

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 limits,
- c) contain a procedure to be followed when limits are breached,
- d) require records to show that it is being followed, and
- c) ensure staff are adequately trained.

Suitable measuring equipment is listed in appendix 1.

4.5 "...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 records 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 required to be kept are listed in appendix 2.

The records must be kept for at least 1 year, and general data shall be kept for one year after the expiration of the lifetime of the product (unless otherwise specified by legislation or certification of the system).

4.6 "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.

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 3 Packers Rules have been met..

NOTE: 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: See WELMEC 6.4, 2.4.3 import from third countries

4.7 "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 at used at 20 °C, the reference temperature and co-efficient 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 ± 1 mm.

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.

The importer & 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 & systems review

Generally checks on 'e' marked products should be carried out at packers' and importers' 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 accepted methods of quality acceptance inspection. Its effectiveness shall be comparable to that of the reference method specified in Annex II.

Other effective sampling plans are in use, see appendix 3 for some of these. Also see appendix C of WELMEC 6.7 where equivalence is considered in detail.

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 net 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 document 6.7

'Desiccating' products is discussed in Part 5 of this document.

PART 4: Annex II to Council Directive 76/211/EEC

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.”

‘actual content’ refers to ‘actual quantity’.

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.

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 is only for inspectors carrying out reference tests. Tests can be applied as soon as prepackages are available, after all normal packer’s checks.

If the product is not labelled at the time of packing then the packer will be able to show what the intended nominal quantity will be.

NOTE: OIML R87 defines a batch in a warehouse as being equivalent in size to one hour’s production, where the production rate exceeds 10,000 an hour.²⁶

²⁶ OIML R87 para 4.2.1.i)

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 document gives guidance on those 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 R79 & 87 & 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.

At the time a prepackage has left the packing line and not been quarantined, whether or not it has been labelled, it shall comply with the requirements of the Directive.

When a packer fills product with no nominal quantity on the label, some domestic legislation requires him to declare the future nominal quantity in his records. At the time such future prepackage has left the packing line and has not been quarantined by the packer, it shall comply with the requirements of the Directive.

Thereafter it depends on the national regulations as to what is acceptable. There are generally two different views:

1. The product must meet the rules in any stage of the distribution chain, and
2. The product must meet the rules at the moment of packing, and any reasonable loss of weight is allowed.

This generally leads to this pragmatic solution for inspection purposes (not to be 'used' by packers!):

The quantity of a 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.

Ideally the labelling should make it clear to the consumer that the product desiccates. When the Directive is updated the time at which the 'packer's rules' apply needs to be clarified. OIML recommendations²⁷ implies the product have to be correct at any point in the distribution chain.

²⁷ OIML R 87 paragraph 3

2. Product contained in a liquid medium

The drained weight of the product must comply with Directive 2000/13/EC.

The Working Group resolved that the Directive should:

- define 'individual package'²⁸ as 'everything that is meant to be left after use of the product, except for items naturally present in the product. Use includes consumption or subjecting to a treatment'²⁹, and
- regard the net drained weight required by Directive 2000/13/EC as the nominal quantity and should be 'e' marked as such. This cannot occur until article 2.1 is amended as this defines 'product' as everything within the 'individual package'. Therefore the quantity of 'product' for a food in a liquid medium includes the quantity of liquid medium.

Where food has been glazed, the drained weight of the food shall be exclusive of the glaze. The European Commission requested that WELMEC WG6 give guidance on a suitable test method, this has been published as WELMEC 6.8.

3. 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 package is excessive in anyway.

Recent research has shown that consumers pay more heed to the size of the packaging than the declared nominal quantity³⁰. The Unfair Commercial Practice Directive, Directive 2005/29/EC, covers all false and misleading claims and omissions. This had to be implemented by Member States by December 2007.

Section 6 of OIML R79 and annex E of OIML R87 endeavours to ensure consumers are not misled and that packers have fair competition by setting out the following recommendations. WELMEC document 6.11 – Avoidance Deceptive Prepackages addresses these issues.

²⁸ 76/211/EEC article 2.1

²⁹ OIML R87 2.9

³⁰ National Consumer Council "Weights and Measures through the eye of the consumer"

Appendix 1: Equipment permitted to be used by packers and importers

1. For all equipment

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 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.

2. Equipment used for making up prepackages

(that is where the quantity of product in each prepackage is measured)

It must be verified as complying with the legislation or, where not under legislative control, it must be approved or certificated by the competent department for that purpose. This point shall be applied, when this equipment is the only one used for checking batches.

3. Equipment used for checking prepackages

(where only a sample of packages is tested)

It shall comply with the domestic legislation for the Member State where the packer or importer is situated.

Appendix 2: Records required to be made and kept by the packer.

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.

3 System including corrective action & 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 when ever 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.

4 Storage

Sample data shall be stored for at least one year; cumulated and general data shall be kept for one year after the expiration of the lifetime of the product (unless otherwise specified by legislation or certification of the system).

Appendix 3: Tests comparable to the reference tests and other checks.

1. Tests comparable to the reference tests

WELMEC document 6.7 clarifies the statistical requirements for the reference test and demonstrates that the single sampling plan for defective units (non-standards packages) introduced by UK and Germany is acceptable.

The criteria being:

Number in group	Number in sample	Acceptance criteria	Rejection criteria
100 to 500	50	3	4
501 to 3200	80	5	6
over 3200	125	7	8

The German & Bulgarian sampling plan also has different acceptance criteria for the average quantity based on the weights of all the items in the sample (using the appropriate k value), and not just a sub-sample of 50.

2. Other checks on groups less than 100 packages

The Directive also applies to batches of less than 100 prepackages , but does not specify a sampling plan, nor criteria, for batches less than 100 prepackages. Document 6.7 shows that there are no practical sampling plans that meet the reference test criteria for batches containing less than 100 prepackages.

WELMEC 6.7 “Guidance for Market Control on Prepackages for Competent Departments” gives guidance on appropriate screening tests in Appendix B1.of that document.