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OIML TC 6

Project p1

Title:
International system for the certification of prepackages as complying with requirements for the quantity of product and associated labeling

Secretariat:
South Africa

Circulated to P- and O-members and liaison international bodies and external organizations for:

☐ discussion at meeting (*date and place*)

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TITLE OF THE CD (English)

New OIML Basic Publication

International system for the certification of prepackages as complying with requirements for the quantity of product and associated labeling (Provisional title)

TITLE OF THE CD (French)

Nouvelle Publication OIML de Base

Système international de certification des préemballages conforme aux exigences de quantité de produit et d'étiquetage associé (titre provisoire)

Original version in: English

Contents

0 FOREWORD (to be added after completion of the document)

1 SCOPE

This document describes the framework for a voluntary certification system for the quantity of product in prepackages and associated labelling.
The system may be applied to prepackages that are in conformance with the requirements of OIML R 79 and OIML R 87 and for which conformity assessment test procedures for determining the actual quantity of product are available in OIML publications.

Note: This certification system shall not be binding on national authorities.

Note to be deleted: An additional document for the minimum packaging system will need to be referenced throughout this document as applicable, when completed.

2 OBJECTIVES OF THE SYSTEM

2.1 To establish rules and procedures for fostering confidence that the content and labelling of prepackages are correct.

2.2 To promote efficiency of the control of prepackages whilst maintaining confidence and facilitating global trade of prepackaged products.

2.3 To promote the global harmonization, uniform interpretation, and implementation of legal metrology requirements for the quantity of product in prepackages including labelling requirements and packaging system requirements for packers' quantity control systems.

3 TERMINOLOGY

3.1 Registration certificate

Document issued to the prepacker by a designated conformity assessment body indicating that the requirements of the system have been complied with.

3.2 Conformity assessment report

Report issued by the designated conformity assessment body after an assessment of a prepacker and which may accompany a Registration certificate.

3.3 Correct

Means that prepackages comply with all the relevant requirements of OIML R79 and R87.

3.4 Participant

Conformity Assessment Body designated by a CIML member to participate in the system by assessing prepackers and registering them. In this Basic publication these bodies are also referred to as “designated bodies”.

3.5 Management Committee

Committee consisting of CIML members who have designated bodies or their appointed expert representatives which is chaired by a CIML member.

3.6 Prepacker

A legal entity producing prepackages and registered by a designated body.

3.7 Conformity assessment

Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. [ISO 17000:2004, 2.1]

3.8 Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific tasks. [ISO 17000:2004, 5.6]

3.9 Peer assessment

Assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group. [ISO 17000:2004, 4.5]

3.10 Internal audit

Systematic examination against specified requirements by personnel, not being directly responsible for the activity, to determine whether the implemented quality system, required by this system, is suitable and effective.

4 PRINCIPLES OF THE SYSTEM

4.1 Eligibility for participation

Participants may be public or private bodies that meet the requirements for being designated as conformity assessment bodies under the system. They shall apply for designation to the CIML Member of the country in which they are established.
Depending on national legislation more than one body may be designated per county.
Registered prepackers may be located in any country irrespective of whether or not such country is an OIML Member State.

Note: OIML Corresponding Members are not eligible to designate conformity assessment bodies.

4.2 Designation by CIML members

CIML members shall be responsible for designating public or private conformity assessment bodies under the system if they are satisfied as to their competence. They shall take

responsibility according to the requirements of clause 5.2 for the actions of such bodies as long as they remain designated.

4.3 Competency of Designated Bodies

Before designation by the CIML Member, the Management Committee shall satisfy itself as to the competence of a candidate participant. Requirements for proving competency are given in clause 5.1.2.

4.4 Basic operation of scheme

An application for designation received from a conformity assessment body by a CIML member is evaluated by the CIML member for initial acceptability. This includes evaluation of an appropriate accreditation. If considered acceptable the CIML member informs the Management Committee of the application. This information includes documentation providing evidence of the applicant's competence. The Management Committee evaluates the evidence and issues an opinion as to the competence of the conformity assessment body as a designated body under the system. In the case where the scope of the applicant's accreditation is not considered acceptable or in the absence of accreditation the Management Committee arranges for a peer assessment of the applicant. Once the applicant is found to be acceptable the Management Committee issues a positive advice to the CIML Member concerned. The CIML Member formally notifies the BIML of the designation of the applicant. The BIML then registers the applicant as a designated body and notifies the applicant and the CIML member.

4.5 Establishment and legal protection of the quantity mark

Marks shall be established to identify prepackages produced under and conforming to the requirements of the system. Separate marks will be used to identify prepackages packed according to the requirements of an average packaging system and a minimum packaging system. These marks shall be displayed in any position on the prepackage taking national requirements in the country of sale into consideration. These marks shall be accompanied in close proximity by a number issued by the BIML to identify the participant that registered the prepacker. These marks are described in Annex B.
CIML members who have designated participants shall ensure that the quantity marks are protected by legislation in their country from being used by any person not registered with and supervised by a designated body.

5 ROLES AND RESPONSIBILITIES

5.1 Designated Bodies (Participants)

5.1.1 Legal responsibility
Designated bodies shall be entities that can be held legally responsible.

5.1.2 Independence
The Designated Body and its staff shall be independent of the packers it has registered and shall not engage in any activity that may conflict with their independence of judgement and integrity in relation to their certification and inspection activities.

5.1.3 Competency

Designated bodies shall demonstrate their competency for the certification of a packer's quantity control system in accordance with the provisions of this Basic Publication and for the inspection of prepackages for compliance with OIML Recommendations R 79 and R 87, either:

(a) By being accredited by a recognised ILAC affiliated accreditation body. Ongoing competency shall be ensured by the applicable accreditation body according to its rules. The designated body shall, upon request, submit to the CIML Member who designated the body and to the Management Committee all assessment reports received from the accreditation body; or

(b) By having an entrenched quality system and by being peer assessed by an assessment team, nominated by the Management Committee, consisting of members independent of the designating CIML member. Ongoing competency shall be ensured by submitting, upon request, copies of an annual internal audit and management review done on it's own quality system and being subjected to peer assessments arranged by the Management Committee at least every five years or more often at it's discretion, should doubt concerning the competency exist.

5.1.4 Assessment of compliance

Designated bodies shall ensure that registered prepackers fulfil the requirements of clause 5.5 by carrying out conformity assessment inspections of prepackers as required and issuing conformity assessment reports after each visit. Specific requirements for assessing of compliance are given in annex C.

5.1.5 Registration of packers

Designated bodies shall register conforming prepackers by issuing a registration certificate to each prepacking plant requesting to apply a quantity mark to prepackages and conforming to all applicable requirements. The registration certificate shall contain an annex identifying all products (brand, descriptive name of the product, nominal quantity, etc) to be marked with the quantity mark. Changes to the conforming product range shall be indicated by means of an amended annex to the registration certificate issued to the relevant prepacker. Specific requirements for registration certificates are given in annex A.

5.1.6 Information on prepackers and registration certificates

Designated bodies shall maintain an up to date register of all prepackers it found competent and who apply the quantity mark under their authority. Such records shall be publicly available on their website, the address of which shall be registered with the BIML. Designated bodies shall also make available on their web sites the registration certificates and information about their validity.

5.1.7 Procedures for registration

Designated bodies shall have documented procedures for registration as follows:

(a) application to apply the quantity-mark and period of validity of registration;
(b) the means by which a registered prepacker may request permission to withdraw from participation in the system;
(c) the procedure to withdraw registration if a prepacker fails to meet the requirements of the system;
(d) the establishment of a fair and equitable appeals mechanism by which a prepacker may request resolution of any disputes that arise in an assessment of the implementation and maintenance of its quality system and applying a quantity-mark; and

(e) rules for investigating complaints received from third parties concerning the correctness of prepackages packed by a registered prepacker.

5.1.8 Notification of change in designation status
A designated body shall without delay inform all registered prepackers of suspension or withdrawal of its designation and provide them with adequate instructions to seek registration with another participant or to cease forthwith the application of the quantity mark to prepackages.

5.1.9 Collaboration with other designated conformity assessment bodies

Designated bodies shall collaborate, as applicable, in the following efforts:
(a) To monitor the capability and competence of their registered prepackers;
(b) To achieve and maintain competence for determining conformity to requirements; and
(c) To provide active participation in any technical revisions of relevant OIML Recommendations through their proposing CIML members.

5.2 CIML members

5.2.1 Applications for designation
CIML members shall:
(a) Receive applications from prospective conformity assessment bodies wishing to become designated in terms of the system.
(b) Evaluate the application and if found to be acceptable forward it together with supporting documents to the Management Committee. Should any aspects of the application be unacceptable the CIML member shall communicate this to the applicant to resolve the matter.
(c) Obtain any additional information from the applicant should this be requested by the Management Committee.
(d) Designate the applicant after having received notification from the Management Committee that the applicant's competency is satisfactory and notify the applicant and the BIMLof the designation.

5.2.2 Resolution of complaints
CIML Members shall be responsible for assisting the Management Committee in resolving any complaints concerning the conformity assessment body that has been designated under their responsibility as contemplated in clause 6.5 and if necessary assist in disputes or appeals as contemplated in clause 6.3.

5.2.3 Fees to be charged
Any fees charged for administration by the CIML Member are the responsibility of such Member and shall be separate from the fees charged by the Management Committee for the designation of conformity assessment bodies, if any.

5.2.4 Sanctions against prepackers
Notwithstanding registration under the system, packers who are found to transgress national or local requirements may be sanctioned by the CIML member or other bodies responsible for regulating prepackages.

Note: Any complaints concerning registered prepackers should be lodged by the complainant directly with the designated body that has registered the prepacker concerned.

5.3 Management Committee

5.3.1 Review of applications
The Management Committee shall:

(a) Receive and register all applications for designation from CIML members.
(b) Request additional information from the relevant CIML Member should this be necessary.
(c) Arrange for peer assessment where the applicant is not accredited.
(d) Evaluate evidence submitted by the CIML member or the peer assessment team as applicable and assess the applicant's competence and notify the CIML Member of the conclusions of the evaluation.
(e) If it is considered that the applicant's competence is not satisfactorily demonstrated, request additional information or evidence as deemed necessary.
(f) Allocate a unique identification number or code to the applicant for use with the conformity mark to identify the responsible body on prepackages.
(g) Record actions and prepare an entry suitable for publication on the BIML web-site established for the system and consisting of the unique identification number or code, name and web-site address of the applicant and the designating CIML member.

Note to be removed when document is completed: The unique identification number or code is necessary to identify the designated body on the prepackage to prevent the BIML web-site from having to list all registered prepackers. Using unique number an interested person can access the BIML web-site to determine the address of the designated body and can then visit the website of the designated body to establish if the prepacker is registered.

5.3.2 Sanctions against participants
Sanctions shall consist of either of the following:

(a) Notice of inadequacy
Should there be sufficient evidence that a participant is not fulfilling it’s duties under the system or that packers under it’s supervision are consistently failing to meet the requirements for the correctness or marking of packages the Management Committee may issue a notice of inadequacy to the CIML Member who has designated the participant requesting formal resolution of the problem. The CIML Member shall request feedback from the participant. Requested feedback shall include evidence of registration of a complaint, internal audit of the affected area of the quality system including the result of findings and the corrective action taken where necessary. The period allowed for receipt of feedback shall be not longer than 30 days.
(b) Suspension
Should feedback to a notice of inadequacy not be received by due date or should it be unacceptable or should similar complaints continue, the participant may be suspended by the CIML Member on the advice of the Management Committee from operating under the system. . In order for the suspension to be lifted the designated conformity assessment body shall either arrange for a full reassessment of the quality system by its accrediting authority or, where not accredited, request the CIML Member to have a peer assessment arranged by the Management Committee of the full quality system. A period

of not longer than three months shall be allowed for receipt of a successful assessment report as applicable and if this is not complied with the designation of the participant shall be withdrawn.

(c) Withdrawal of designation
Should the requirements for lifting a suspension not be complied with or should the Management Committee have sufficient evidence of a complete breakdown in the quality system or suspension of the accreditation of a participant then the CIML Member on the request of the Management Committee shall withdraw the designation. Once the designation has been withdrawn the conformity assessment body may re-apply for designation through a CIML member as in clause 5.2.1.

5.3.3 Fees
The Management Committee may levy fees for its work and the work of the BIML as decided by the CIML and according to OIML policies. All costs of peer assessments shall be for the account of the participant applying for designation. All cost incurred by members of the Management Committee to attend meetings etc. shall be for the member's own account. All income shall accrue to the BIML.

5.3.4 Review of system requirements
The Management Committee shall continuously evaluate the requirements of this system and report any recommended amendments to OIML TC 6 for consideration.

5.4 BIML

The BIML shall:

(a) Supply the secretariat for the management committee.
(b) Establish a website for the system and maintain a list of designated bodies and their unique identification numbers or codes, as supplied by the Management Committee.
(c) Invoice and dispose of the fees decided on by the CIML according to OIML policies.
(d) Receive complaints and appeals and give interpretations as required in clauses 6.1 and 6.2.

5.5 Prepackers

5.5.1 Individual registration of packing plants
Each packing plant operated by a prepacker shall be registered as a separate entity and be subject to the required conformity assessments by a designated conformity assessment body.

5.5.2 Requirements for a prepacker's quantity control system
Prepackers shall implement and maintain a documented quantity control system either integrated with an overall quality system or a stand alone system, to ensure that prepackages comply with the requirements of OIML R87 and R79, including any tests for quantity of product in packages. Minimum requirements for the quantity control systems are prescribed in Annex D.

5.5.3 Application for registration
A prepacker shall submit an application for registration to any designated conformity assessment body according to the rules of such body. All costs for registration will be levied by the designated conformity assessment body according to its own rules and shall be for the account of the prepacker.

5.5.4 Equipment

A prepacker shall use suitable equipment and associated software to ensure compliance of prepackages with OIML R 87. Minimum requirements for equipment and calibration or verification thereof are prescribed in Annex D.

5.5.5 Responsibility for compliance

Compliance with requirements of OIML R 79 and R 87 and the requirements of this document pertaining to the system will be assessed by the designated body. Prepackers shall continue to manufacture prepackages according to the requirements of OIML R 79 and R 87 and their assessed quantity system for as long as the quantity mark is applied to prepackages. Notwithstanding participation in the system the packer shall also be subject to compliance with national requirements in the country in which the packages are sold and the resultant inspection and sanctions, if applicable.

5.5.6. Application of the quantity mark

Once a prepacker is registered by a designated body it may apply the applicable quantity mark, together with the unique identification number or code allocated to the designated body, according to the rules of the designated body. Should any of the following occur a prepacker shall immediately cease to apply the mark to prepackages:

(a) The registration certificate is withdrawn by the designated body; or
(b) The designation of the conformity assessment body is suspended or withdrawn by the management committee; or
(c) The prepacker no longer manufactures prepackages or a specific range of prepackages according to the requirements of OIML R 79 or R 87 or requirements of its assessed quantity system.

Note: Application of the quantity mark will be subject to national legislation in the country in which the prepackages are sold.

6. RESOLUTION OF COMPLAINTS AND DISPUTES

6.1 The BIML may be contacted in the event of a dispute regarding the operational procedures of the system or any other matter concerning the system. The BIML will also provide, if requested, an interpretation or clarification of the intent of the system. In cases where the dispute appears to be based on an inconsistency or mistake in the text of this Basic Publication, the BIML will seek the opinion of the Management Committee.

6.2 An applicant conformity assessment body that has been refused designation by the management committee may appeal that decision to the BIML. The BIML will seek the opinion of the Management Committee.

6.3 The CIML Members concerned should, upon request, assist in resolving a dispute in 6.1 or an appeal in 6.2.

6.4 Complaints concerning prepackages shall be forwarded with documented and substantiated evidence to the responsible designated body for resolution in terms of its own procedures. Should complaints not be satisfactorily resolved, the matter may be brought to the attention of the relevant CIML Member who shall inform the Management Committee.

6.5 Complaints concerning designated bodies shall be forwarded to the CIML Member concerned who shall inform the Management Committee.

6.6 Any disputes and complaints unresolved by the CIML Member may be referred to the CIML Presidium (consisting of the CIML President and two Vice-Presidents). The Presidium would consider the matter or refer it for resolution to an independent ad hoc task group of CIML members.

7. REVISION

Revision of this Basic Publication shall be the responsibility of OIML TC 6, and shall be approved by the CIML.

8. REFERENCES

OIML V 1 (2000), International Vocabulary of Terms in Legal Metrology (VIML)

WELMEC 6.6(2003), Guide for recognition of procedures.

ANNEX A

Minimum requirements for registration certificates issued by designated conformity assessment bodies

Registration certificates issued to prepackers by designated bodies shall contain at least the following:

A.1 Full registered name of prepacker.

A.2 Full trading name(s) of prepacker if applicable.

A.3 In the case of contract prepackers, the names and addresses of companies for which goods are packed and which will appear on prepackages as taking responsibility for the prepackages (see OIML R79 clause 4).

A.4 Full postal address of the registered prepacker.

A.5 Full physical address of the registered packaging plant.

Note: In the case of more than one packing plant owned by the same prepacker each packing plant shall be registered separately on an individual certificate.

A.6 Date of registration.

A.7 Identification of applicable mark including the unique identification number of the designated body permitted to be applied to prepackages.

A.8 Scope of registration including a brief description of the products that will be prepacked e.g. foodstuffs, cleaning materials or solvents and whether they are packed by mass or volume etc.

A.9 In the case where not all products manufactured at the packing plant are covered by a registration certificate an annexure identifying all products (brand, descriptive name, quantity etc.) to which the mark(s) may be applied, shall be attached to the certificate.

Annex B

Design and application of quantity marks

To be developed later possibly with a space within the mark to contain the identification mark of the designated body.

Annex C

Minimum requirements for conformity assessment of prepackers by designated conformity assessment bodies

(Note: These clauses were taken from clause 10 in the previous draft.)

C.1 In the case of initial assessment by a designated body, prepackers shall be subjected to at least the following:

a) a determination that the prepacker has the necessary qualified personnel, facilities, measuring and test equipment, and control procedures to provide capability for ensuring compliance of prepackages to OIML R87 and R79,
b) a determination of the suitability of the prepacker's quantity control system, and
c) a determination of the conformity of prepackages produced by the prepacker by means of reference testing.

C.2 In order to maintain registration the prepacker shall be subject to the following:

a) an assessment of the continued suitability and effectiveness of the prepacker's quantity control system at specified intervals not exceeding twelve months through conformity assessment inspection (including review of required process control records), testing of prepackages and, where applicable, witnessing the procedures required by the system;
b) unannounced inspections, surveillance, and testing if necessary; or
c) the implementation of more frequent or detailed inspections, surveillance, and testing when a need is indicated. (UK comment – do we need further guidance on this?)

Annex D

Minimum requirements for the quantity systems of prepackers

(Note: The following clauses were taken from clause 10 of the previous draft and are subject to change by a work group formed to look into these requirements and align them with WELMEC 6.1. Proposals from this workgroup follow clause D.11 hereafter.)

D.1 System documentation

System documentation shall include a description of the management methods, organisational structure, procedures, controls, records, and maintenance practices to permit consistent interpretation of the quantity control system.

D.2 Authority and responsibility

A prepacker shall designate a person to have the authority and responsibility for the implementation and maintenance of the quantity control system. The quantity control system shall be audited and reviewed annually and updated as appropriate under the responsibility of this designated person.

D.3 Competent personnel

A prepacker shall ensure competent personnel through relevant training or instruction.

D.4 Inspection of packaging material

A procedure shall be established for inspecting, accepting, and rejecting packaging containers and materials. These checks shall include assessing conformance to marking requirements in OIML R 79.

D.5 Production process

A prepacker's packaging practices should be documented and appropriate for the specific category of products and relevant measurement procedures.
Prepackers shall select, maintain, adjust and test filling equipment to ensure proper filling of prepackages. Records shall be maintained.

Note: prepacker should take cognisance of national requirements.

D.6 Measuring instruments and test equipment

The prepacker shall establish and document procedures and maintain records for the performance criteria, maintenance, verification or calibration or both, for all measuring instruments and test equipment used in determining the quantity of prepackages to ensure compliance with requirements of R87.

D.7 Sampling and testing

To ensure compliance of the production the prepacker shall conduct sampling and tests to obtain data that enable the packer to decide if the production process is in control and keep records thereof.
Where the quantity of product in each package is measured at the time of packing or thereafter by a suitable instrument as required in D.6 there is no need for further sampling and control measures. (need more guidance on suitability)

Note: The requirements for sampling and the inspector's reference test given in OIML R 87 are not designed for production process control purposes and packers should have a system suited to their production process as covered in the guidance document.

D.8 Production records

Records shall be maintained that provide information on the checks of quantities of packaged products at least until the element of the quality system dealing with records has been assessed by the designated body.

Note: Cognisance should be taken of other legal requirements pertaining to the retention of records in the country of packaging.

D.9 Software and automated data systems

Such software and systems used in quantity control shall be controlled and validated to ensure that they fulfil their intended purpose, are accessible to, and may be modified by, designated personnel only.

D.10 Non-conformances, corrective and preventative actions

The prepacker shall establish documented procedures for recording non-conformances raised and corrective actions taken in order to eliminate reoccurrence.

The prepacker shall establish documented procedures for evaluation and recording of the effectiveness of corrective actions taken and the closing out of the non-conformances.

D.11 Identification of product

The prepacker shall establish documented procedures to clearly identify product batches and relate them to their production control records. Identification may include but not be limited to production location or plant, production time and date, and production line.

(Note: The following are proposals from the work group established to investigate minimum requirements for prepackers quantity systems. They need to be discussed by TC 6.)

"Basic Packaging System Requirements for Packers Quantity Control Systems"

1.1 Introduction

This chapter describes the subjects that must be addressed by an International Quantity Mark (IQ) packer before they can be considered to be 'recognized procedures'. In this document the chapters describe these subjects. The 'procedures' must be documented before they can be recognized.

Prepackages can only be assumed to comply with the provisions of OIML R 87 (Quantity of Product in Prepackages) when the prepackages have been produced in accordance with the recognised procedures. In other cases the packer must update his procedures and re-apply for recognition of them.

As an alternative to having his procedures recognized, a packer may also measure the contents of every prepackage. Packers applying the IQ mark may only do so if they meet the requirements of R 87, such as labelling. This recommendation also provides for checks to be performed by the Competent Departments.

Different scenarios are suggested for different situations. Combining the alternatives might result in insufficient guarantees that prepackages meet the requirements of the R 87.

In the document notes give more guidance to the text. The notes are written in smaller text (or font) and shaded in grey, and are not requirements.

1.2 General Information

legal name of packer	:	...
address of head office	:	…
postal address	:	...
		...
place of packing	:	...
		...
contact person	:	...
his/her function	:	...
phone	:	...
fax	:	...
e-mail address	:	…
Competent Department	:	...
date of first recognition	:	...

1.3 Packing lines

The following information is required per packing line:

- packers name for the filling line
- details of the prepacked product
  - name (generic name)
  - main components of the product (example: fruit, yoghurt, nuts, etc.)
  - physical properties (example: liquid, shrinking, deep frozen, etc.)
- packaging materials
  - type of packaging (glass, can, cardboard, PE foil, etc.)
  - indication of the deviation of the packaging material
- nominal quantity and the target value
  - smallest quantity
  - largest quantity
  - target value
- filling process
  - type of filling machine
  - rate of filling and the number of prepackages per hour
  - the number of filler heads
  - smallest adjustment facility
- indication of the process deviation

Remark: a packing line can be made up out of several filling machines, if they pack the same product.

1.4 Measuring instruments

The measurements of the content of prepackages, the density of liquid product, the weight of packaging materials and other relevant measurements must be carried out by means of a legal and suitable measuring instrument.

Some measuring instruments are not subject to legal metrology. Depending on national situations equipment like for temperature measurement will not be controlled by legal metrology institutes. For those measuring instruments a different maintenance and calibration regime is necessary. The packer shall organize this regime in line with the conditions of use and behaviour.

The word "suitable" includes a number of conditions of use that arise from the need to limit the uncertainty of measurement.

Measuring instruments must be checked on a regular basis by an accepted method to verify that they meet specifications.

The frequency of calibration can be determined in accordance with international standards on measurement uncertainty.

For checkweighers and multiheads separate procedures are available. For glass measuring instruments usually one calibration is sufficient. Non-automatic weighing instruments usually are calibrated 2 to 6 times per year.

1.5 The recognized procedures

1.5.1 Definitions

All definitions are listed in WELMEC Publication 6.1.

batch

All the prepackages of the same nominal quantity, the same type and the same production run, packed in the same place, which are to be inspected.

lot

A lot consist of the number of the same prepackages with the same nominal quantity one filling line produces in one hour.

A lot that has been stored consists of the maximum of 10.000 of the same prepackages with the same nominal quantity.

sample

A number of prepackages drawn at random from the batch.

individual package

Individual package is everything that is meant to be left after use of the prepackage, except for items naturally in the product. Use includes consumption or subjecting to a treatment.

A prepackage is the combination of product and packaging materials. The definition of "individual package" is here to distinguish between product and packaging materials.

1.5.2 The measuring and sampling methods

An employee of the packer must draw a sample of enough items of the running production on a regular basis. The content of each item in the sample is determined. Parts of this may be automated (for instance by using a checkweigher). The measuring instrument used is specified under the chapter "measuring instruments".

Sampling Frequency

The sampling frequency depends on the deviation of the filling process and the number of adjustments, but it should be at least once an hour and after adjustment. In certain situations (for instance bottle filling carousels that can not be adjusted) a lower frequency might be possible.

Checks must be carried out before the prepackages are distributed.

Sample size

The sample size can be calculated with this formula:

$$n \geq \frac{(t_{n-1}0{,}995)^2 \times S^2}{(\text{nominal quantity} + \text{overfill} - \text{rejection limit of Competent Department})^2}$$

where:

sample size Competent Department	$t_{n-1}0{,}995$	rejection limit Competent Department (where S = estimation of the standard deviation and Qn is nominal quantity
20	2,862	$Q_n - 0{,}640 \times S$
30	2,757	$Q_n - 0{,}503 \times S$
50	2,680	$Q_n - 0{,}379 \times S$
80	2,640	$Q_n - 0{,}296 \times S$

This calculation does not take into account subjective aspects like the packers experience and knowledge of the filling process. When this is taken

into account a lower sample size might be possible.

example:

(nominal quantity = 1.000, standard deviation = 3, overfill = 1):

$$\text{sample size} \geq \frac{2{,}640^2 \times 3^2}{(1000 + 1 - [1000 - 0{,}296 \times 3])^2} \Rightarrow \text{sample size} \geq \frac{62{,}73}{3{,}56} \Rightarrow \text{sample size} \geq 17{,}6$$

Overfill

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

- the nominal quantity
- $TU_1 + 2 \times S$
- $TU_2 + 3{,}72 \times S$

Where 'S' is the estimation of the standard deviation of the production process, which might also Include allowances for measurement uncertainty. If the standard deviation is larger than (target quantity – TU_1) the standard deviation must be monitored.

When packaging materials are used the weight of the packaging materials is determined on a regular basis by weighing a sufficient number of packages using a weighing instrument specified at the chapter "measuring instruments".

Determination of the weight of the packaging materials is not necessary when the quantity of product is measured without packaging materials, for example when fluids are poured in a measuring glass, a product has no packaging material, when a template is used together with a measuring container bottle or when product is weighed without package.

When the standard deviation of the weight of the packaging materials are small, the average weight of the packaging materials may be used when determining the content of the prepackage ('average tare'). Sometimes a higher sample frequency is necessary: determination per pallet or preceding the measuring of the content of the prepackage ('average momentary tare').

When the standard deviation of the weight of the packaging materials is too large, the content of each repackage must be determined by subtracting the weight of the package from the weight of the prepackage the package is part of ('individual tare').

The density of every batch of liquid products must be determined by a suitable method.

When the 'apparent density' is measured, the 'density in vacuum' is calculated by adding 0,0012 g/ml.

For some fluids the density can be derived from the brix number. The packer must provide a conversion table. The accuracy of the table must be calibrated on a regular basis.

When the density of carbonated product is determined without carbon dioxide, the measured density must be corrected.

When the density of every batch is not measured, its contribution to the measurement uncertainty will increase.

The processing of measuring results

The content of every measured prepackage must be determined. When relevant, the weight of the packaging materials and the density must be included.

This is the relationship:

weight of the contents = weight of the prepackage – weight of the packaging materials

$$\text{volume of prepackage} = 0{,}99985 \times \frac{\text{weight of the contents}}{\text{apparent density}}$$

This is a formula frequently used in e-marking software.

Control charts that are manually completed, automated systems connected to weighing instruments and automated systems in a network are accepted. A Competent Department does not have any preference.

Automated systems must be equipped with validated software.

Software is validated by comparing the readouts with manually calculated results. The approval does not include any statement of functionality of the software. Software can be approved at the request of the packer or the manufacturer of the software. If the automated system is subject to legal metrological control, then according to WELMEC 7.1, the legally relevant parts of the software should be approved, as well as validated.

Of the contents of the measured prepackages, the average or the median must be determined and presented. Also the number or percentage of the prepackages with a content below TU_1 and TU_2 must be established and presented.

The expanded measuring uncertainty of the combined measurements must not be larger than one fifth of the specified permissible error. If bigger than one fifth of the specified permissible error, the expanded measuring uncertainty must be compensated for by the packer.

1.5.4 The utilisation of measuring and sampling results and/or possible actions

When the average of the measuring results that relate to an hour's production is less than the nominal quantity, the hour's production must be quarantined.

To quarantine means: identify as such so that the prepackages will not be put onto the market (this can be by labelling the pallet or placing the prepackages in a suitably marked area).

When sampling is used there are several methods of decisions possible:

1. When the average (or median) of a sample falls below a warning limit (often 'nominal quantity'), then packers often undertake corrective action to bring the average back on target by adjusting the filling machine. A follow up sample must be taken to ensure the action was appropriate.
2. When the average (or median) of a sample lies in a (statistically determined) range around the nominal quantity, another sample is drawn without adjustments of the filling machine. When the average of all prepackages measured in the two samples is below the nominal quantity, the filling machine is adjusted upwards. These adjustments are usually checked by a test sample. This method is less suitable when automated systems are used to calculate and present the average of an hour's production.

For the statistical background, see annex D of WELMEC Publication 6.5.

The production level to which the samples relate varies. Below are some examples:

1. The hour's production is divided into parts that are "closed" with a sample taken at the end. If the average of the averages (or medians) of the production parts is below the nominal quantity, the production parts that cause the average of the hour's production to be too low are quarantined.

2. The hour's production is divided into parts that are "enclosed" with samples taken from each end. The average of a production part is calculated by calculating the average of the two enclosing average (or median) of the enclosing samples. When the average of the averages (or medians) of the production parts in an hours production is below the nominal quantity, the parts that cause the too low average of the hours production is quarantined.

3. When the average of the samples fall below an action limit, all the prepackages since the last acceptable sample result must be isolated from delivery.

When more than a small number of prepackages in a sample has contents below the TU_1 limit, the prepackages that have been produced since the previous sample must be quarantined.

Depending on the standard deviation of the filling process and the company policy:

1. When in a sample one or more prepackages is found to have contents below the TU_1- and/or TU_2-limit the production that is produced since the last sample is blocked from delivery.

2. When in a sample one prepackage is found to have contents below the TU_1-limit (but above the TU_2-limit), another sample is drawn without adjusting the filling machine. When this or the next regular sample has one or more prepackages with a contents below the TU_1-limit, the prepackages that have been produced since the last satisfactory sample must be quarantined.

3. When checkweighers of multiheads are used, more than 'a small number of prepackages' below the TU_1-limit cannot be produced. In that case 'small number 'is defined as '2,5%' of all produced prepackages. The correct functioning of the machines must be checked on a regular basis.

Some machines monitor the percentage of prepackages. The rejection mechanism is usually set at the TU_2-limit. When the percentage of prepackages with a contents below the TU_1-limit exceeds 2½, the rejection mechanism is automatically set to the TU_1-limit. When it can be set lower 'safely', it will revert to the TU_2 limit.

When one or more prepackages in a sample has a contents below the TU_2-limit, the prepackages that have been produced since the previous sample are quarantined.

When checkweighers of multiheads are used, when functioning normally, prepackages with a contents below the TU_2-limit do not occur. The functioning of the machine must be checked on a regular basis.

When the packer samples in the same way as outlined in R 87, he may use the same acceptance and rejection criteria.

Prepackages that are quarantined because the average content is too low must be rectified by an acceptable method such as:

- destroyed by repacking the prepackages
- removing deficient prepackages
- mixing with another batch with an enhanced average to ensure the overall average is not below the nominal quantity
- re-labelled
- divided into lots of (maximum) 10 000 prepackages and are checked by sampling in accordance with the method that would be used in conjunction with R 87. The lots that are acceptable can then be released, rejected lots must be rectified.

Prepackages that are quarantined because too many prepackages have contents which fall below the TU_1-limit, must be rectified by an acceptable method:

- destroyed by repacking the prepackages
- removing deficient prepackages
- mixing with another batch with an enhanced average to ensure the overall average is not below the nominal quantity
- re-labelled
- divided into lots of (maximum) 10.000 prepackages and are checked by sampling in accordance with the method that would be used in R 87. The lots that are acceptable can then be released, rejected lots must be rectified.

Prepackages that are quarantined because too many prepackages have contents below the TU_2-limit, must be rectified by an acceptable method:

- destroyed by repacking the prepackages
- re-labelled
- removing deficient prepackages

In some Member States it is also allowed to sell defective prepackages to the packer's staff, the government and educational establishments or giving them away for free, BUT only if the recipients are informed that the prepackages do not comply with the Recommendation and they cannot be re-sold.

1.6 Instructions to staff

The practical execution of the above must be laid down in working instructions that form part of the description of the recognized procedures and which are available at the location at which the results of the measurements are examined.

When the working instructions are part of a certified quality system the recognized procedures will refer to them. The work instructions must be validated and controlled. Employees must be trained.

Work instructions must be written in the language that the worker understands.

Sometimes (particularly with small packers) employees involved with e-marking have detailed knowledge of the recognized procedures. In such cases the work instructions do not have to cover all parts of the recognised procedure.

1.7 The records

The records that are produced while carrying out the recognized procedures should be kept for a specified period.

The specified period varies between Member States and may be for one year, during the shelf life of prepackages, until they have been checked by an inspector or until subject to market surveillance.

Usually these are the results of the samples, the determination of the weight of the packaging, density measurements, training records and calibration records. They must be traceable to (respectively) prepackages, personnel and measuring instruments. In some countries they also contain inspection, audit and surveillance reports from the Competent Department.

An example of the records should be included in the description of the recognized procedures.

The records may be kept electronically.

When prepackages are quarantined, notes relating to the cause and actions undertaken should be kept with the records.

1.8 The IQ Mark

The IQ mark of the prescribed shape and size must be printed on the prepackage in the same field of vision of the nominal quantity. The minimum height is 3 mm and it must be indelible, easily legible and visible on the prepackage under normal conditions of presentation.

1.9 The annexes

With the description of the recognized procedures these are the annexes required:

- working instructions
- samples of the records
- setting target quantities, set points and other relevant parameters