



COMMITTEE DRAFT OIML CD2

Date: 18 June 2010

Reference number:

Supersedes document:
CD1 (2009.07.31)

OIML TC 6 *Prepackaged products*

TITLE OF THE CD (English):

International system for the certification of prepackages as complying with requirements for the quantity of product and associated labelling

TITLE OF THE CD (French):

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Original version in: English

Secretariat: South Africa

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

- discussion planned at a meeting
- Comments by: 31 October 2010
- vote (P-members only) and comments by 31 October 2010

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0 FOREWORD (to be added after completion of the basic publication)

1 SCOPE

This basic publication 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 1: This certification system is not binding on national authorities or prepackers.

Note 2: Importing countries are not bound by any requirements of this system but may take account of the mark in planning their inspection activities.

2 OBJECTIVES OF THE SYSTEM

2.1 To establish rules and procedures for fostering confidence that the content and labelling of prepackages comply with all the relevant requirements of OIML R 79 and OIML R 87.

2.2 To promote efficiency of the control of prepackages whilst maintaining confidence in 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 quantity control systems used by prepackers.

3 TERMINOLOGY

3.1 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]

3.2 Conformity assessment

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

3.3 Conformity assessment report

Report issued by the designated conformity assessment body after an assessment of a prepacker.

3.4 Designated body

Conformity Assessment Body designated by a designating authority to assess and register conforming prepackers in terms of the system.

3.5 Designating authority

A CIML member or OIML corresponding member who designates conformity assessment bodies in terms of the system.

3.6 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.

3.7 Management Committee

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

3.8 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]

3.9 Prepacker

A legal entity that physically places product in containers to produce prepackages and is registered by a designated body.

3.10 Registration certificate

Document issued to the prepacker by a designated conformity assessment body indicating that the prepacker complies with all applicable requirements of the system and that the quantity mark may be applied to prepackages.

4 PRINCIPLES OF THE SYSTEM

4.1 Eligibility for participation

Designated conformity assessment bodies 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 designating authority of the country in which they are established. Depending on national legislation more than one body may be designated per country.

4.2 Designation of conformity assessment bodies

Designating authorities shall be responsible for designating public or private conformity assessment bodies under the system. 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 a designating authority, the Management Committee shall satisfy itself as to the competence of a candidate conformity assessment body. Requirements for proving competency are given in clause 5.1.3.

4.4 Basic operation of system

An application for designation received from a conformity assessment body by a designating authority is evaluated by the designating authority for initial acceptability. This includes evaluation of an appropriate accreditation. If considered acceptable the designating authority 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 result of the peer assessment is positive the Management Committee issues a positive advice to the designating authority concerned. The designating authority 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 designating authority.

4.5 Establishment of the quantity mark

A mark shall be established to identify prepackages produced under and conforming to the requirements of the system. This mark shall be displayed in any position on the prepackage taking national requirements in the country of sale into consideration. This mark shall incorporate an identification of the designated body that registered the prepacker. This mark is described in annex B.

4.6 Registration of preparers

Prepackers shall be registered by a designated body in the country in which they are located, unless such a body does not exist in that country. Where there is no such body designated in a country a prepacker may use a body designated in another country.

5 ROLES AND RESPONSIBILITIES

5.1 Designated Bodies

5.1.1 Legal responsibility

The designated body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities. Where a designated body is part of another legal entity it shall clearly identify which legal entity has responsibility for each certification.

Note 1: A governmental designated body is deemed to be a legal entity on the basis of its governmental status.

Note 2: A designated body, along with other designated bodies, can be owned by (or under other contractual relationship with) a larger legal entity wherein all bodies work under a common management structure and management system. In such a situation each certification can only be the responsibility of one designated body/legal entity.

5.1.2 Impartiality and non-discriminatory conditions

5.1.2.1 Management of impartiality

5.1.2.1.1 The designated body shall have top management commitment to impartiality.

5.1.2.1.2 The designated body shall have, and make available on request, a statement that it understands the importance of impartiality in carrying out its certification activities, manages conflicts of interest and ensures the objectivity of its certification activities.

5.1.2.1.3 The designated body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a designated body with a risk to impartiality.

Note: A relationship that threatens the impartiality of the designated body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

5.1.2.1.4 If a risk to impartiality is identified, the designated body shall be able to demonstrate how it eliminates or minimizes such risk.

5.1.2.1.5 When a relationship poses an unacceptable threat to impartiality (such as a wholly owned subsidiary of the designated body requesting product certification from its parent, or when the designated body belongs to a corporation or holding company, or manufacturer, etc. which requests product certification from its related designated body), then certification shall not be provided.

5.1.2.1.6 Designated bodies shall document how they manage their certification business and any other activities so as to eliminate actual conflicts of interest and minimize any identified risk to impartiality. The documentation shall cover all potential sources of conflicts of interest that are identified, whether they arise from within the designated body or from the activities of other persons, bodies or organizations.

5.1.2.1.7 The designated body and any group within its organizational control or personnel, employed or contracted in an organization within its organizational control, shall not offer or provide consultancy on the product that it certifies. This also applies to that part of government identified as the designated body.

5.1.2.1.8 The designated body shall not give prescriptive advice or consultancy as part of an evaluation.

Note: This does not preclude normal exchange of information (including explaining its findings and/or clarifying the requirements) with clients and other interested parties.

5.1.2.1.9 The designated body (and any group within its organizational control or personnel, employed or contracted, in an organization within its organizational control) shall not offer or provide internal management system audits to the client (or other legal entities involved in the certification process), in those schemes that require the client (or other legal entities involved in the certification process), to perform internal management system audits. This also applies to that part of government identified as the designated body.

Note: See note to 5.1.2.1.3

5.1.2.1.10 The designated body shall not certify a product on which a client has received consultancy or internal evaluations, where the relationship between the consultancy organization and the designated body poses an unacceptable threat to the impartiality of the designated body.

Note: Allowing a minimum period of two years to elapse following the end of the product consultancy is one way of reducing the threat to impartiality to an acceptable level.

5.1.2.1.11 The designated body's activities shall not be marketed or offered as linked with the activities of an organization that provides product consultancy. The designated body shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the designated body were used. A designated body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

5.1.2.1.12 To ensure that there is no conflicts of interest, personnel who have provided consultancy for, or been employed by a client, including those acting in a managerial capacity, shall not be used by the designated body to make a certification decision nor resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

Note: This requirement does not apply to an individual participating in a group/committee.

5.1.2.1.13 The designated body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations.

5.1.2.1.14 All designated body personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.

5.1.2.1.15 The designated body shall manage the risk to impartiality arising from over-familiarity between its personnel and the client.

5.1.2.2 Management of non-discriminatory conditions

5.1.2.2.1 The policies and procedures under which the designated body operates and their administration shall be non-discriminatory and shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants.

5.1.2.2.2 Designated bodies shall not practice any form of discrimination such as hidden discrimination by speeding up or delaying the processing of applications.

5.1.2.2.3 The designated body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions.

5.1.2.2.4 Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued.

Note: A designated body may deny certification to a client when fundamental/demonstrated reasons exist, such as illegal activities, history of repeated non compliances with the certification/product requirements and similar issues.

5.1.2.2.5 The designated body shall confine its requirements, evaluation (if the designated body is responsible for evaluation), review, decision, and surveillance (if any) to those matters specifically related to the scope of the certification.

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 R 79 and OIML R 87, either:

(a) By being accredited by a recognised accreditation body that has signed the IAF MLA or applicable ILAC MRA. Ongoing competency shall be ensured by the applicable accreditation body according to its rules. The designated body shall submit to the designating authority 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 authority. Ongoing competency shall be ensured by submitting 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 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, as defined in annex B, to each prepacking plant requesting to apply a quantity mark to prepackages and that conforms to all applicable requirements. The registration certificate shall comply with the requirements of annex A.

5.1.6 Deregistration of prepacker or suspension of registration

The registration shall be withdrawn or suspended in the following cases according to the rules of the designated body:

- a) non resolution of non compliance with the requirements of this basic publication;
- b) repeated non compliance with the same element of the system or requirements for prepackages; or
- c) any major non-compliance that the designated body considers it necessary to withdraw or deregister the packer.

5.1.7 Information on prepackers and registration certificates

Designated bodies shall maintain an up to date register of all prepackers they have 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.

Note: National legislation may require a designated body to notify the national authority responsible for the control of prepackages about any change in the status of a prepacker's registration certificate.

5.1.8 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.

5.1.9 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 designated body or to cease forthwith the application of the quantity mark to prepackages.

5.1.10 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 designating authorities.

5.2 Designating authorities (CIML members and OIML corresponding members)

5.2.1 Applications for designation

Designating authorities 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 designating authority 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; and

- 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 BIML of the designation.

5.2.2 Resolution of complaints

Designating authorities 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 a designating authority are the responsibility of such authority and shall be separate from the fees charged by the Management Committee for the designation of conformity assessment bodies, if any.

5.3 Management Committee

5.3.1 Review of applications

The Management Committee shall:

- a) Receive and register all applications for designation from designating authorities.
- b) Request additional information from the relevant designating authority should this be necessary.
- c) Arrange for peer assessment where the applicant is not accredited.
- d) Evaluate evidence submitted by the designating authority or the peer assessment team as applicable and assess the applicant's competence and notify the designating authority 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) Approve the unique identification of the applicant for use with the conformity mark to identify the designated 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 authority.

Note: The unique identification is necessary to identify the designated body on the prepackage to prevent the BIML web-site from having to list all registered prepackers. Using the identification 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 designated bodies

Sanctions shall consist of either of the following:

- a) Notice of inadequacy
Should there be sufficient evidence that a designated body is not fulfilling its duties under the system or that packers under its 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 designating authority who is responsible for the designated body, requesting formal resolution of the problem. The designating authority shall request feedback from the designated body. 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 should 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 designated body may be suspended by the designating authority on the advice of the Management Committee from operating under the system. In order for the suspension to be lifted the designated body shall either arrange for a full reassessment of the quality system by its accrediting authority or, where not accredited, request the designating authority to have a peer assessment arranged by the Management Committee of the full quality system. A period of not longer than three months should be allowed for receipt of a successful assessment report as applicable and if this is not complied with the designation of the designated body may 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 designated body then the designating authority 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 designating authority 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 conformity assessment body applying for designation. All costs 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 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 R79 and OIML R87, 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 body according to the rules of such body. All costs for registration will be levied by the designated 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 OIML R 87 and the requirements of this basic publication 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 OIML R 87 and their assessed quantity system for as long as the quantity mark is applied to prepackages.

Note 1: Notwithstanding participation in the system the packer may also be subject to compliance with national requirements.

Note 2: Any complaints concerning registered prepackers should be lodged by the complainant directly with the designated body that has registered the prepacker concerned.

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 of the prepacker is withdrawn by the designated body; or
- b) The designation of the designated 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 OIML R 87 or requirements of its assessed quantity system.

Note 1: Application of the quantity mark will be subject to national legislation in the country in which the prepackages are sold.

Note 2: Products packed prior to the registration of the packer becoming invalid for the reasons mentioned in (a), (b) or (c) above may be found in the market for some time after such withdrawal.

5.5.7 Identification of packer

A prepackage that carries the quantity mark shall carry an identification of the prepacker, either:

- a) the packers full name and address, or
- b) an anonymous code assigned by the designated body.

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 shall seek the opinion of the Management Committee.

6.3 The designating authority concerned shall, 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 designating authority who shall inform the Management Committee.

Note: This does not imply that the designating authority and/ or Management Committee should be involved in legal proceedings.

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

6.6 Any disputes and complaints unresolved by the designating authority 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.

ISO/IEC CD 17065, Requirements for certification bodies certifying products, processes and services.

ANNEX A

Normative

Minimum requirements for registration certificates issued to prepackers by designated conformity assessment bodies

A.1 General requirements

Registration certificates issued to prepackers by designated bodies shall contain at least the information required in A.2 and A.3. Any changes to the scope of registration or product range shall be indicated by means of a revised registration certificate.

A.2 Registration certificates where the prepacker is identified on the certificate.

A.2.1 Full registered name of prepacker.

A.2.2 Full trading name(s) of prepacker if applicable.

A.2.3 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 relevant requirements in OIML R79).

A.2.4 Full postal address of the registered prepacker.

A.2.5 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 registration certificate (see clause 5.5.1).

A.2.6 Date of registration.

A.2.7 Specification of the mark including the unique identification of the designated body permitted to be applied to prepackages (see annex B).

A.2.8 Scope of registration.

A.2.8.1 The scope shall include a brief description of the products in such a way that it allows a prepackage carrying the mark to be identified as covered by the registration certificate. This shall include a reference to which packaging system is used i.e. average system, minimum system or both average and minimum systems.

A.2.8.2 To give a clear description of the product the following guidelines shall be used in the description of the products:

- a) Brand name or generic name describing the product in such a way that the products that the packer is registered to prepack are covered. This description shall be sufficiently complete to distinguish products that are all covered from those that are not covered under the registration certificate;

- b) Product description if necessary to distinguish from other products e.g. liquid, powder, granules, paste, gel, semi-solid, etc.;
- c) Measuring unit in which marked;
- d) Measuring range (smallest to largest quantity);
- e) Type of packaging material if only certain packing materials are included under the registration e.g. sachets, tins, packets, glass/ plastic bottles, flexible bags, boxes, etc.; and
- f) Other limitations if registration is restricted e.g. only high viscosity liquids, un-carbonated soft drinks.

A.2.8.3 If all products packed by prepacker are covered by the registration certificate then it is only necessary for a brief description covering measuring unit used e.g.:

- a) Powdered milk products between 250 g to 10 kg;
- b) Foodstuffs by mass 5 g to 1 kg;
- c) Cosmetics by mass and volume ranging from 5 g to 500 g and 9 ml to 350 ml;
- d) Aerosols by mass and volume up to 250 g or 250 ml;
- e) Toilet paper by length and pieces (count by number); or
- f) Carbonated and uncarbonated softdrinks and beer in nominal quantities between 500 ml and 1,5 L.

A.2.8.4 If only some of the products packed by the prepacker are covered by the registration certificate then it would be necessary to have a more specific description e.g.:

- a) Powdered milk products in flexible bags between 250 g to 1 kg bearing XYZ brand name;
- b) Fruit preserves in glass containers between 250 g to 10 kg when packed for XYZ company; or
- c) Aerosol perfumes in glass containers between 15 ml and 30 ml.

A.3 Registration certificates where the prepacker is not identified on the certificate.

A.3.1 Where a prepacker does not want to be identified on the registration certificate, such as a contract prepacker who packs on behalf of a third party whose name appears on the prepackages, the certificate may use a code to identify the prepacker provided that all of the information required by A.2.1 to A.2.5 shall be kept by the designated body and made available, on request, to a national body responsible for the regulation of prepackages or the responsible designating authority. The following minimum information will then be required on the certificate.

A.3.2 Unique code to identify the prepacker.

A.3.3 Date of registration.

A.3.4 Specification of the mark as in A.2.7.

A.3.5. Scope of registration as in A.2.8.

ANNEX B



Normative

Design and application of quantity mark

B.1. The quantity mark shall consist of:

- a) the OIML logo;
- b) an unique identification of the designated body, assigned by the Management Committee; and
- c) where the name and address of the prepacker does not appear on the prepackage the unique identification code (see 5.5.7) shall also appear within the mark.

B.2. The format of the marks shall be as defined in drawing B.1. and B.2.

	
Drawing B.1.- Mark where packers name and address appears on the prepackage	Drawing B.2.- Mark where a code is used to identify the prepacker

B.3. The minimum height of figures and characters in the mark shall be 3 mm.

Note from OIML TC6 secretariat: Should OIML R87 be revised to include a minimum packing system and this is covered in the scope of registration of preparers then this mark will need to be amended to indicate which packing system has been used in the packing process. To be discussed by TC6.

ANNEX C

Normative

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

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 complies with the requirements of annex D and has the necessary qualified personnel, facilities, measuring and test equipment, and control procedures to provide capability for ensuring compliance of prepackages to OIML R79 and OIML R87;
- 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; and
- 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.

ANNEX D

Normative

Minimum requirements for quantity control systems used by prepackers

D.1 System documentation

D.1.1 Quantity control system documentation shall include a description of the organisational structure, authorities and responsibilities of key personnel, procedures, work instructions, controls, records, forms and maintenance practices to permit consistent interpretation of the quantity control system.

D.1.2 Applicable documentation such as procedures and work instructions shall be available as controlled documents at the location where used e.g. where prepackage control measurements are carried out.

D.2 Implementation, maintenance and review of the system

D.2.1 A prepacker shall designate a person or persons to have the authority and responsibility for the implementation and maintenance of the quantity control system.

D.2.2 The quantity control system shall be audited and reviewed annually and updated as appropriate under the responsibility of the designated person.

D.2.3 Documented procedures shall be established for:

- a) recording non-conformances raised;
- b) recording corrective action taken to eliminate a recurrence;
- c) evaluating and recording the effectiveness of corrective actions taken; and
- d) closing out of non conformances.

D.3 Competent personnel

A prepacker shall ensure competent personnel through relevant training or instruction to a level that will ensure the effective and efficient manufacture and control of prepackages.

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 Retention of records

D.5.1 Records shall be maintained for a sufficient period decided on by the prepacker but at least until the relevant element of the quantity system 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.5.2 Records that are produced while controlling prepackages shall be traceable to the prepackages concerned, the person responsible for the control and measuring instruments used and be kept for at least the estimated shelf life of the applicable prepackages.

D.5.3 The records may be kept electronically.

D.6 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.

D.7 Basic quantity control requirements

D.7.1 Prepackages may 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 minimum requirements prescribed in this annex.

D.7.2 The control of prepackages by packers shall be carried out before the prepackages are released for sale.

D.7.3 As required in OIML R 87, the combined expanded uncertainty at a 95% confidence level of the measuring instruments and control test methods used for determining quantities shall not exceed 0,2 of the applicable tolerable deficiencies permitted on the prepackages being controlled. If larger than 0,2 of the tolerable deficiency, the expanded measuring uncertainty shall be compensated for by the prepacker.

Note: It is not the intention that packers should calculate an uncertainty of measurement each time prepackages are controlled. The combined measurement uncertainty of the control method including measurement uncertainties, density calculations, etc should be calculated when designing the method and selecting suitable measuring equipment for use with the method.

D.7.4 Precautions shall be taken to ensure that products that might reduce in quantity after prepacking (e.g. hygroscopic products in non moisture retaining containers) will continue to comply with the requirements of OIML R87 for at least the estimated shelf life of the applicable product.

D.8 Identification of packing lines

D.8.1 The quantity system shall contain at least the information regarding each packing line as required in D.8.2 to D.8.7.

Note: A packing line could be made up out of several filling machines, if they pack the same product.

D.8.2 Packers name for the filling line

D.8.3 Details of the prepackaged product

- a) name (generic name)
- b) main components of the product (example: fruit, yoghurt, nuts, etc.)
- c) physical properties (example: liquid, shrinking, deep frozen, etc.)

D.8.4 Packaging materials

- a) type of packaging material (glass, can, cardboard, PE foil, etc.)
- b) indication of the weight deviation of the packaging material in order to establish if an average tare weight may be used.

D.8.5 Quantities and target values for each product and pack size

- a) smallest acceptable quantity
- b) largest acceptable quantity
- c) target value

D.8.6 Filling process

- a) type of filling machine
- b) rate of filling and the number of prepackages per hour
- c) the number of filler heads
- d) smallest adjustment that is possible to be made to the quantity

D.8.7 Indication of the process standard deviation per product and pack size

D.9 Measuring instruments

D.9.1 The measurements of the content of prepackages, the density of liquid products, the weight of packaging materials and other relevant measurements shall be carried out by means of measuring instruments that are at least as accurate as the requirements prescribed in OIML R 87 for instruments used to control prepackages by legal metrology officials (inspector's reference test). The minimum requirements in D.9.2 to D.9.4 are applicable.

D.9.2. Measuring instruments shall be traceable to international standards.

Note: Traceability to international standards could be obtained via the national standards of the country in which the prepacker is located or via the national standards of another country.

D.9.3 Calibration frequencies for instruments that have the possibility of becoming inaccurate due to wear and tear shall be calibrated at intervals that will ensure their required accuracy at all times but calibration shall take place at least every 12 months.

Note: The frequency of calibration can be determined by considering the maintenance of accuracy of a certain instrument over time. For glass measuring instruments usually one calibration is sufficient.

D.9.4 In service validation shall be carried out by the prepacker as deemed necessary to ensure continued accuracy between calibrations.

D.10 Sampling and measuring methods

D.10.1 To ensure compliance of the production with the requirements OIML R 87 at all times, the prepacker shall conduct sufficient sampling of the running production to obtain data that enable the prepacker to decide if the production process is in control. Records of the sampling and the results of measurement shall be kept for a sufficient period to be evaluated by the designated body.

D.10.2 The requirements for sampling and the inspector's reference test given in OIML R 87 are not designed for production process control purposes and prepackers shall have a system suited to their own production process.

D.10.3 When determining the sample frequency consideration shall be taken of the standard deviation of the filling process. In the case of multiple filling heads e.g. bottle filling carousels, precautions shall be taken to ensure that each filling head complies. A sample shall be taken after each manual adjustment to correct a filling process.

D.10.4 Where products are measured together with the packaging material (i.e. complete prepackage), the weight of the packaging material shall be determined on a regular basis to determine if it is sufficiently consistent to allow an average tare weight to be used. The requirements given in OIML R 87 for determining the average tare weight and acceptability for use shall be used as a minimum. Where the use of the average tare weight is not suitable because of a large deviation in the weight of individual packaging materials, destructive testing shall be carried out and the product measured exclusive of the packaging material.

D.10.5 When the quantity of liquid is determined by gravimetric means the density of every batch of liquid product shall be determined by a method that is suitably accurate to ensure that the overall uncertainty of measurement of the test method is not exceeded (see D.7.3).

D.10.6 When calculating the volume from the mass of a liquid using the determined density, the requirements for air buoyancy and density corrections in OIML R 87 shall be used.

D.10.7 Control charts that are manually completed, automated systems connected to weighing instruments and automated systems in a network are accepted. Software in automated systems must be validated (see D.10.8).

D.10.8 Software and systems used in quantity control shall be secured and validated to ensure that they fulfil their intended purpose, are accessible to, and may be modified by, designated personnel only.

Note: Software is validated by comparing the readouts with manually calculated results.

D.11 Non conforming products

D.11.1 Where a production run is found to have deficiencies that could result in non compliance with the requirements of OIML R 87 all packages since the previous acceptable sample shall be segregated and prevented from being released for sale.

D.11.2 Where markings on prepackages are found not to conform to the requirements of OIML R 79 such prepackages shall be segregated and prevented from being released for sale.

D.11.3 When prepackages are found not to comply, notes relating to the cause and actions undertaken should be kept with production control records (see D.5.2).

D.11.4 It is left up to the preparer to decide on the method of rectification of non conforming prepackages to ensure compliance to the requirements of OIML R 79 or OIML R 87 as applicable.