Certification System for prepackages OIML R 87 Edition 2016

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Agenda

1. **Guidance for defining the system requirements for a certification system for prepackages**

2. **OIML R 87 Edition 2016: Quantity of product in prepackages**

Work of TC 6 under OIML

➢ OIML R 79 Edition 2015: Labelling requirements for prepackages
supersedes the edition of 1997

➢ OIML R 87 Edition 2016: Quantity of product in prepackages
supersedes the edition of 2004

➢ Guidance for defining the system requirements for a certification system for prepackages
this is a new guide

Guidance for defining the system requirements for a certification system for prepackages

➢ A draft has been submitted for CIML online ballot on June with date of 2017-06-27 and closing of vote September 27 2017.

➢ A final decision about the result of the vote is not known up to date.

➢ However, no major changes are to be expected anymore.

Guidance for defining the system requirements for a certification system for prepackages

Scope of the document:

This publication provides guidance to **national authorities** on the establishment and maintenance of **certification schemes** for the control of quantity of product in prepackages and labelling related to:

➢ the identity of the product,

➢ the declaration of responsibility for a prepackage,

➢ the quantity declaration and

➢ to the certification mark associated with the product.

General objectives of a certification system

➢ Harmonising requirements for labelling and indication of quantity of products.

➢ Same rules and efficiency of control of prepackages by authorities.

➢ Confidence in indication of quantity of prepackages.

➢ Enhances marketing of products among participating contries.

Objectives of certification of prepackages includes:

➤ Establishing rules and procedures for fostering confidence that labelling and quantity of prepackages comply with defined legal requirements,

➤ Promoting the efficiency of control of prepackages whilst maintaining confidence in products and facilitating trade of prepacked products,

➤ Promoting the harmonization and uniform interpretation of laid down legal metrology requirements.

General principles of a certification system (1)

➢ A certification system may include one or more certification schemes

➢ Generally, a **government authority** acts as the scheme owner and is the **designating authority**

➢ One ore more **public** or **private bodie**s may be **designated** under a certification scheme

Content of a certification scheme for prepackages

➢ The **scope of the scheme**, including the type of prepackages covered.

➢ The **requirements** against which the prepackages are evaluated: According **OIML R 79 and R 87** or other requirements, like minimum system etc.

➢ The conformity assessment activities.

➢ The requirements for the designated body.

Content of a certification scheme for prepackages

➢ The **methods and procedures** to be used **by the designated bodies** involved in the certification process.

➢ The **content of the certificate of conformity** (see Annex D).

➢ How to **deal with non-conformities** and how to resolve it. How to deal with **complaints**.

➢ Content, conditions and responsibility for publication of the **register of certificates**.

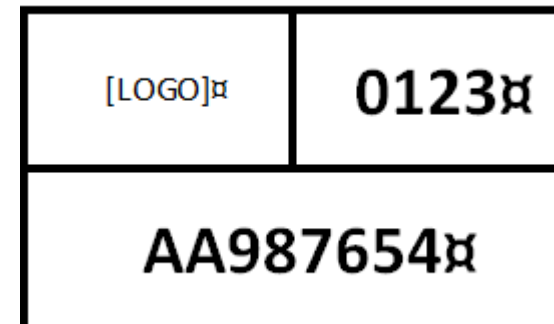# Elements for a certification scheme for prepackages

Scheme elements		Different types of certification schemes						
		A	B	C	D	E	F	N
4.4.1	**Production system assessment**	x	x	x	x	x	x	x
4.4.1.1	Statement of requirements							
4.4.1.2	Application for certification							
4.4.1.3	Initial assessment of production system							
4.4.1.4	Review the evidence of compliance							
4.4.2	**Certification of the production system**	x	x	x	x	x	x	x
4.4.2.1	Decision on certification							
4.4.2.2	Issuing of a certificate							
4.4.2.3	Registration of certificates							
4.4.3	**Licensing**			x	x	x	x	
4.4.3.1	Granting the right to use certificates							
4.4.3.2	Granting the right to use marks of conformity							
4.4.4	**Post certification conformity assessment activities**							
4.4.4.1	Inspection at point of production			x		x	x	
4.4.4.2	Inspection in market place				x	x	x	
4.4.4.3	Batch licensing		x				x	
4.4.4.4	Surveillance of the production system			x	x	x	x	
N – has been added to show an undefined number of possible other schemes which can be based on different activities								

Mark with Logo where packers name and address appears on prepackage

[LOGO]¤	0123¤
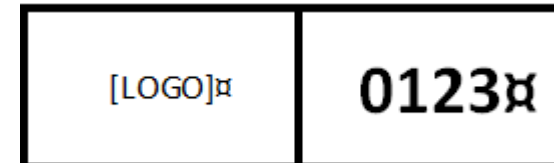
Mark with Logo where a code is used to identify the packer

[LOGO]¤	0123¤
AA987654¤	

Logo: Is either a **Logo of the designated body,** or the Logo is **defined by the designating body**

Agenda

1. **Guidance for defining the system requirements for a certification system for prepackages**

2. **OIML R 87 Edition 2016: Quantity of product in prepackages**

OIML R 87: Edition 2016

This Recommendation specifies requirements for the **quantity of product in prepackages**:

➢ which are labeled in predetermined <u>constant nominal quantities</u> of weight, volume, length, area and count;

➢ Specifies sampling plans and procedures for use by legal metrology officials in verifying the quantity of product in prepackages

Note: R 87 covers only prepackages of equal nominal content !

OIML R 87: Metrological requirements

Nominal quantity Q_{nom} in g or ml	Value of T in % of Q_{nom}	Value of T in g or ml
0 to 50	9	-
50 to 100	-	4.5
100 to 200	4.5	-
200 to 300	-	9
300 to 500	3	-
500 to 1'000	-	15
1'000 to 10'000	1.5	-
10'000 to 15'000	-	150
Above 15'000	1	-

(1) Average requirements: On average, the quantity in prepackages shall at least be equal to the nominal quantity Q_{nom}

(2) Individual requirements: Only a small percentage of the prepackages (typ. 2.5 %) are allowed to have a quantity between $(Q_{nom} - 2T)$ and $(Q_{nom} - T)$, called *T1* error.

(3) No prepackage shall have a quantity less than $Q_{nom} - 2T$ (referred to as *T2* error).

OIML R 87: Statistical approach

The tests are carried out by statistical means, based on random sampling of an hourly lot of production with lot size N and sample size n.

Average requirements for sampled lots:

- The probability of incorrectly rejecting an inspection lot satisfying equation $\mu \geq Q_{nom}$ shall be no more than 0.5 % (Producer's risk, PR).
- The probability of correctly rejection an inspection lot shall be at least 90 % (Consumer's risk, CR)

Individual requirements for sampled lots:

- The probability of incorrectly rejecting a lot with 2.5 % of the prepackages having *T1* or *T2* errors shall be smaller than 5 % (PR).
- The probability of correctly rejecting an inspection lot with 9 % of the prepackages having *T1* or *T2* errors shall be at least 90 % (CR).

Reject the lot if $\quad E_{ave}/s + SCF < 0 \quad$ with $\quad E_{ave} = \dfrac{1}{n}\sum_{i=1}^{n} E_i$

E_{ave} is the average of errors and E_i are the individual prepackage errors defined by $E_i = Q_i - Q_{nom}$, taking into account their signs, n is the number of prepackages of the sample size, s is the sample standard deviation of the individual errors, and SCF is the Sample Correction Factor.

Above formula is "equivalent" to the formula given in the European Directive 76/211/EEC (see 2.3.1 in Annex II):

$$Q_{mean} < Q_{nom} - \frac{s}{\sqrt{n}} \cdot t_{(1-\alpha)}$$

The SCF for the defined lot size N and sample size n is calculated using the formula:

$$SCF = -\frac{t_{0.005,n-1}}{\sqrt{\dfrac{n(N-1)}{N-n}}}.$$

$t_{0.005,n-1}$ is the quantile of the Student's t inverse cumulative function with probability p = 0.005 and degree of freedom f = n-1

student-t distribution: f(t)

area = 0.5%
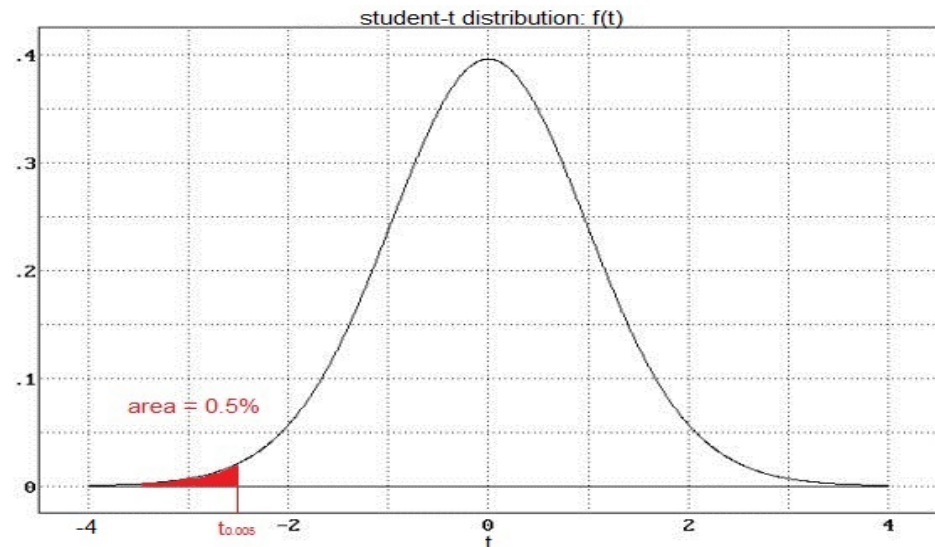
The test for the two individual requirements is realized by performing statistics for the values of n_{T1} and n_{T2}.

- The number n_{T1} is the maximum number of samples in the sample size n being allowed for accepting the lot under the assumption that only 2.5 % of prepackages of the lot with size N are allowed to have a T1 error.

- The lot has to be rejected for n_{T2} being larger than zero, this means no prepackage shall have a quantity less than $Q_{nom} - 2T$.

Sampling plan for lot sizes N based on the statistical requirements (average and individual requirements):

Inspection lot size N	Sample size n	SCF	Number of allowed $T1$ errors n_{T1}
N ≤ 20	100 % inspection	NA	0
40	32	0.22	1
60	35	0.30	1
80	47	0.25	2
100	49	0.28	2
200	64	0.27	3
300	67	0.29	3
400	81	0.26	4
500	81	0.27	4
600 – 30'000	98	0.24 – 0.26	5
> 30'000	98	0.27	5

OIML R 87: Multistep sampling plan

The stepwise sampling plan is a new feature in the OIML R 87 Edition 2016

Why a stepwiese sampling plan?

➢ Decreases the burden on packers by requiring fewer samples to be taken for control inspections.

➢ Saves time and costs for inspectors as well as packers since fewer prepackages have to be opened and destroyed for control purposes

➢ Particularly beneficial for inspectors in checking high volume production of prepacked goods

OIML R 87: Multistep sampling plan for lot size N = 50'000 and 7 steps

Step number	Cumulative sample size n	SCF	Number of allowed $T1$ errors n_{T1}
1	40	0.43	0
2	55	0.36	1
3	70	0.32	2
4	95	0.27	3
5	105	0.26	4
6	120	0.24	5
7	135	0.22	6

OIML R 87: Multistep sampling plan

Typical Application:

➢ For producers with high hourly production rate of prepackages (eg Chocolate manufacturer)

➢ Manufacturer with low risk of underfilling prepackages

➢ Checks of prepackages at stock or warehouses by legal metrology officials

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Institute of Metrology METAS

Thank you very much for your attention