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REPORT

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The statistical principles of the metrological surveillance of the net content of prepackages as laid down by the CEE 76/211 Directive

Les principes statistiques du contrôle métrologique du contenu net des préemballages fixé par la directive CEE 76/211

OIML E 4 Edition 2004 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
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Foreword

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1. THE PRINCIPLES OF THE CONTROL

The metrological control of the content of prepackages laid down in the CEE directive 76/211 has the aim to check that the mean value of the actual content of the batch is at least equal to the value declared on the label and, at the same time, that the dispersion of the actual content of the single packages around the mean value is kept as small as possible.

Two types of control statistical tests are used. They are based on the evaluation of samples taken at random from the batch to be controlled.

a) the control of the actual content of individual packages is done with a statistical test by attributes, the principles of which are described in the ISO 2859 standard.
b) the mean value of the content is checked by measuring the mean value of the contents of a sample taken from the batch to be controlled; the statistical principle of this test is presented in the ISO standards 2854-1976 and 3494-1976

The batch to be controlled is defined as an homogenous batch of prepackages, i.e. produced or manufactured under conditions which may be presumed uniform and numbering between 100 and 10000 pieces.

* If the batch numbers more than 10000 pieces, it must be divided in partial batches numbering each between 100 and 10000 pieces. The whole batch is accepted if each partial batch is accepted.

* For batches numbering less than 100 pieces, the statistical test applicable to batches numbering 100 to 10000 pieces is not appropriate[1]. The control of such a batch is only foreseen in the case of non-destructive tests and in that case the directive recommends a 100 % check in paragraph 2.1.3[2].

In order to compare the statistical tests used by the competent authorities of the member states, paragraph 5 of annex I refers to their operating characteristics. This paragraph prescribes that this control be comparably efficient to the reference tests of annex II ; it defines under what conditions the efficiency of the controls can be considered as equivalent.

[1] Because in that case drawing out the sample will affect the characteristics of the batch and, as consequence, the rules of decision on the batch.

[2] The content of every package is controlled, but the criteria of the controls are not given.

2 THE CONTROL OF THE ACTUAL CONTENT

One of the tests by attribute described in ISO standard 2859 is used.

The number of defective units in the sample or samples taken from the batch must be determined and compared to a maximum number C; the values of C are laid down in paragraphs 2.2.1 and 2.2.2 of annex II.

A defective package is a package whose actual content is less than the nominal quantity minus the maximum permissible error (MPE) defined in paragraph 2.4 of annex I.

2.1 Maximum Permissible Error (MPE)

Nominal content in grams or millilitres	**Maximum permissible error MPE**	
	% of nominal content	Grams or millilitres
0 to 50	9	
50 to 100		4,5
100 to 200	4,5	
200 to 300		9
300 to 500	3	
500 to 1000		15
1000 to 10000	1,5	

2.2 Decision on the batch

<u>2.2.1 Case of a destructive test</u>

- the sample size is 20 prepackages,
- if the number c of defective packages does not exceed 1, the batch is accepted for the control of actual content. Otherwise it is rejected for this control.

2.2.2 Case of a non-destructive test

We have a double sampling test,

- if the number of defective packages in the first sample does not exceed the acceptance criterion, the batch is accepted;
- if on the other hand the number of defective packages in the first sample equals or surpasses the reject criterion, the batch is rejected;
- if the number of defective packages lies between the accept and the reject criteria (principle of the double sampling test) the case is undetermined and the second sample must be used in order to reach a decision on the defective packages. The number of defective units in the second sample is determined and added to the number in the first sample. The sum thus obtained is compared to new accept-reject criteria. If the number of defective units is inferior or equal to the accept criterion, the batch is accepted for this criterion, if the sum equals or surpasses the reject criterion, the batch is rejected (see diagram 7).

the following diagram gives the accept and reject criteria for the different sample sizes.

DIAGRAM Evaluation of the results of the first sample

Batch size	Size of the first sample	Number of defective units in the first sample	Decision on the batch for the control of defective packages
From 100 to 500	30	1 or 0	Accepted
		2	Use of the second sample
		3 or more	Rejected
From 501 to 3200	50	2 or less	Accepted
		3 or 4	Use of the second sample
		5 or more	Rejected
More than 3200	80	3 or less	Accepted
		Between 4 and 6	Use of the second sample
		7 or more	Rejected

DIAGRAM Evaluation of the results of both the first and the second sample

Batch size	Total size of the first and the second sample	Total number of defective units in the first and second sample	Decision on the batch for the control of defective packages
from. 100 to 500	60	4 or less 5 and more	Accepted Rejected
From 501 to 3200	100	6 or less 7 and more	Accepted Rejected
More than 3200	160	8 or less 9 and more	Accepted Rejected

3 CONTROL OF THE MEAN VALUE OF THE CONTENT

The object is to make a one-sided comparison test between the unknown mean value of the net content of a batch and the nominal value printed on the label. The comparison is based on the measured values of a sample of n prepackages taken at random from the batch. The variance of the net contents is also unknown.

3.1 The characteristics of the test

Those are defined in paragraph 2.3 of annex II of the directive :

- **QN** is the nominal quantity printed on the label;
- **n** is the number of units in the sample;
- $\mathbf{t_{0,995}}$ = 0.995 confidence level of a Student distribution with (n-1) degree of freedom;
- **0.995** is the confidence level of the results of the test; this confidence level is 99,5% ; it means that the probability not to reject the hypothesis that the true mean value of the nominal quantity be at least equal to the nominal quantity is 99,5% for a batch just fulfilling the requirements;
- $\bar{x}$ is the arithmetical mean value of the individual actual contents x_i of each of the n prepackages of the sample ; it is also an estimator of the unknown mean value of the contents of the prepackages of the batch

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{i=n} x_i$$

- s is the estimator of the unknown standard deviation of the actual contents of the batch

$$s = \sqrt{\sum_{i=1}^{i=n} \frac{\left(x_i - \bar{x}\right)^2}{n-1}}$$

$\bar{x}$ is then compared to the term QN - $[s * \frac{t_{0.995}}{\sqrt{n}}]$

n = size of the sample	**value of the term** $\frac{t_{0.995}}{\sqrt{n}}$ **= g**
20 prepackages	0,640
30 prepackages	0,503
50 prepackages	0,379

3.2 Acceptance of the batch for checking the mean

The batch is accepted for checking the mean when

a) Batch size at least 100 and maximum 10000 prepackages.

$$\bar{x} \geq \text{Q.N} - [\frac{t_{0.995}}{\sqrt{n}}]$$

b) Batches of fewer than 100 prepackages in case of non-destructive test.

In that case the net contents of each prepackage of the batch are measured,

$\bar{x}$ is then the arithmetical mean value of the contents of the whole batch.

The batch is accepted for checking the mean value when

$$\bar{x} \geq \text{Q.N}$$

3.3 Rejection of the batch for checking the mean value

The batch is rejected for checking the mean value when

Batch size at least 100 and maximum 10000 prepackages,

$$\bar{x} < \text{Q.N} - [\frac{t_{0.995}}{\sqrt{n}}]$$

Batches of fewer than 100 prepackages in case of non-destructive test,

$$\bar{x} < Q.N$$

4 ACCEPTANCE OF THE BATCHES FOR THE METROLOGICAL CONTROL

The batch is accepted for the metrological control if it is accepted both for checking of the actual contents of a prepackage and for checking of the average actual contents of the prepackages making up the batch.

5 EFFICIENCY OF THE CONTROLS

5.1 Efficiency of a statistical test

5.1.1 Operating characteristic of a statistical test

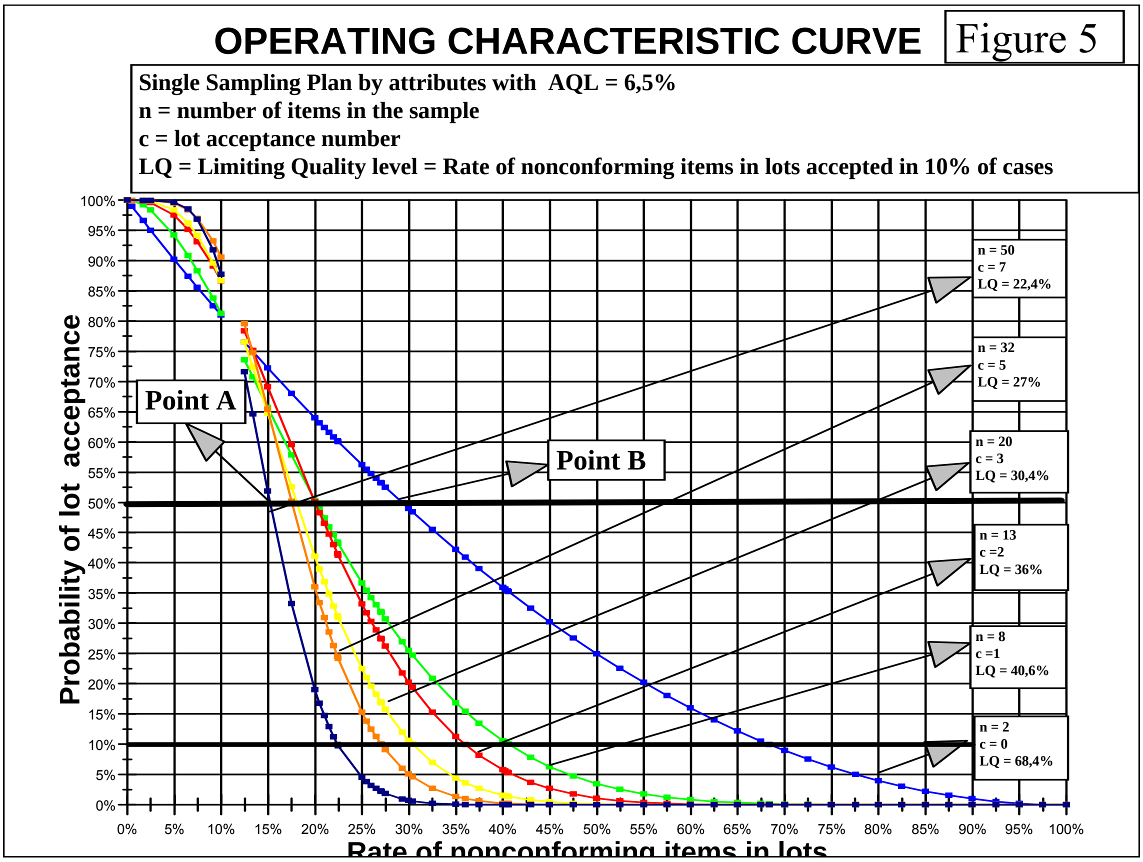
For a given statistical test, its operating characteristic curve depicts the acceptance probability of a batch in function of its real quality. It links the proportion of defective units of a batch to the probability of acceptance of these batches for the control. The following graph 1 illustrates this notion for a sampling plan by attributes.

Graph 1

Operating characteristic curve of single sampling tests by attributes at AQL = 6,5%
n = number of elementary units in the sample
c = acceptance criterion for the batch
LQ = limit acceptable quality = proportion of defective units in batches accepted in 10% of the occurrences

Acceptance probability
of these batches

Proportion of defective units in these batches



The curve running through point A corresponds to a batch controlled by way of a 50 units sample. This batch will be accepted if not more than 7 defective units are found in the sample. The abscissa of point A (15%) corresponds to a batch with 15% defective units, the ordinate of point A (50%) depicts the probability to accept this batch containing 15% of defective units.

The curve running through point B corresponds to a batch controlled by a sample of 2 units. The batch is accepted if no defective unit is found in the sample. The abscissa of point B (30%) corresponds to a batch with 30% defective units, the ordinate of point B (50%) depicts the probability to accept this batch containing 30% of defective units.

This graph shows that the bigger the sample size is, the smaller the consumer's risk is[3] of accepting batches with a high proportion of defective units.

5.1.2 Manufacturer's and consumer's risks

[3] The consumer's risk usually corresponds to the LQ, percentage of defective units in batches accepted in 10% of the cases.

Manufacturer's risk (PR)

On the operating characteristic curve of a sampling plan, the manufacturer's risk corresponds to the probability to reject a batch containing a percentage P_1 of defective units lower than the limit (usually low) fixed for the sampling test. According to the manufacturer such a batch should not be rejected.

In other words it is the probability to wrongly reject a batch.

The PR is usually expressed by a percentage, denoted P_{95} , depicting the proportion of defective units in batches accepted in 95% of the cases (i.e. rejected in 5% of the cases).

Consumer's risk (CR)

On the operating characteristic curve of a sampling plan the consumer's risk corresponds to the probability to accept a batch containing a percentage P_2 of defective units larger than the limit (usually low) fixed for the sampling test. According to the consumer such a batch should be rejected.

In other words it is the probability to wrongly accept a batch.
The CR is usually expressed by a percentage, denoted P_{10} depicting the proportion of defective units in batches accepted in 10% of the cases (i.e. rejected in 90% of the cases).

5.1.3 Acceptable Quality Level of a batch (AQL)

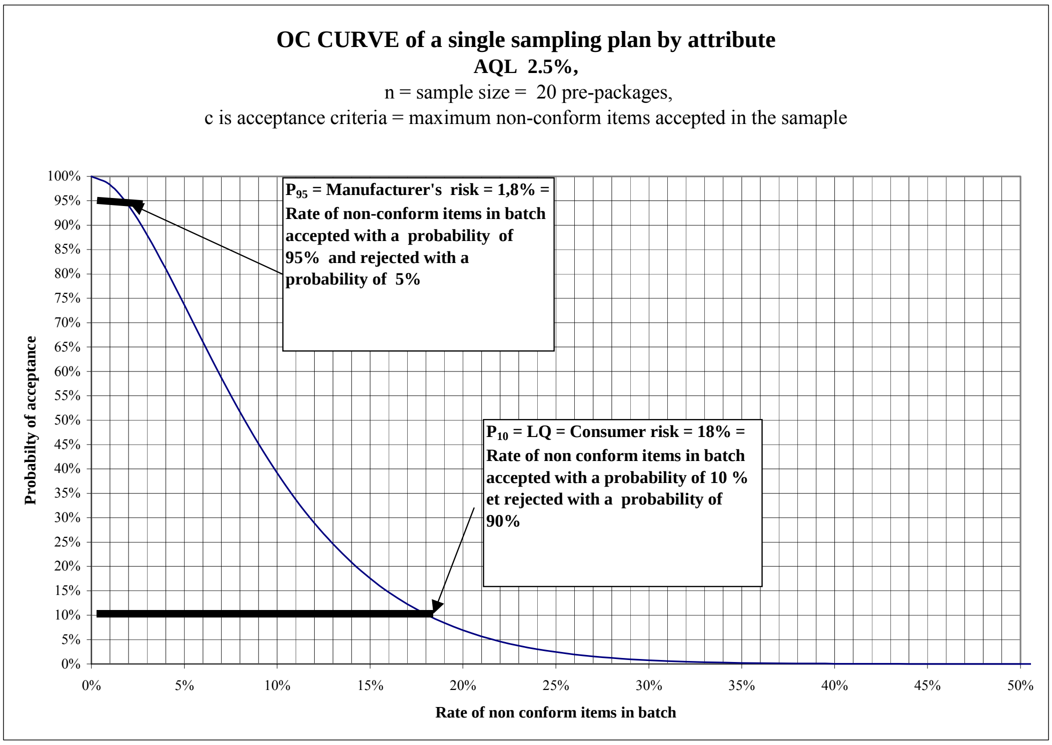
The acceptable quality level (AQL) of a batch is a quality level characterised by an acceptable percentage of defective units giving a high probability of control acceptance.

The acceptable quality level (AQL) is an indexation criterion applied to a continuous series of batches which corresponds to a maximum admissible percentage of defective units in a batch. It is a quality objective a professional strains to achieve. It does not mean that every batch with a higher percentage of defective units than the AQL will be rejected at the control, but that the higher the percentage surpasses the AQL the higher the rejection probability will be. For a given sample size, the lower the AQL of the test is, the better the consumer's protection will be against batches with defective elements and the harder it will be for the manufacturer to conform to sufficiently demanding quality prescriptions.

The AQL of the statistical tests laid down in the 76/211 directive is 2,5%. It does not mean that every batch with a percentage of defective units higher than 2,5% is going to be rejected but that, as shown in the following graph 2, the reject probability increases as the percentage of defective units rises above 2,5%.[4]

Graph 2

Operating characteristic curve of a sampling test by attributes with a 2,5% AQL
n = size of the sample 20 prepackages,
the batch is accepted if not more than one defective package is found in the sample



Acceptance probability of these batches

Percentage of defective packages in the controlled batches

[4] In order to limit the risk of rejection, it is advisable to recommend to the manufacturers to adopt for their internal controls sampling plans with a lower AQL than the 2,5% laid down in the directive.

P_{95} = manufacturer's risk
1,8% = percentage of defective packages in batches with an acceptance probability of 95% and a rejection probability of 5%

P_{10} = LQ = consumer's risk
18% = percentage of defective packages in batches with an acceptance probability of 10% and a rejection probability of 90%

5.2 Efficiency of the control of the actual quantity

The directive has two different tests

5.2.1 Efficiency of single statistical tests by attributes

The equation of the operating characteristic curve of the single statistical test

$$P_A = \sum_{i=0}^{i=c} C_n^i p^c (1-p)^{n-i}$$

n is the size of the sample

P_A is the acceptance probability for the controlled batch
c is the maximum admissible number of defective units for the sampling plan in order to accept the conformity of the batch
p is the percentage of defective units in the controlled batch

5.2.2 Double statistical test by attributes

The equation of the operating characteristic curve of the sampling test by attributes

$$P_A = \sum_{i=0}^{i=c1} C_{n1}^i p^i (1-p)^{n1-i} + \left[\left(\sum_{i=c1+1}^{i=r1-1} C_{n1}^i p^i (1-p^i) * \sum_{i=0}^{i=n2} C_{n1+n2}^i \; p^i (1-p)^{(n1+n2)-i} \right) \; . \right]$$

P_A is the acceptance probability of the batch
p is the percentage of defective units in the controlled batch
c1 is the maximum admissible number of defective units in the first sample
r1 is the number of defective units in the first sample above which the batch is rejected
c2 is the maximum admissible number of defective units cumulated from both samples with $c1 \leq r1 \leq c2$

5.2.3 Operating characteristic curves of tests of the actual content

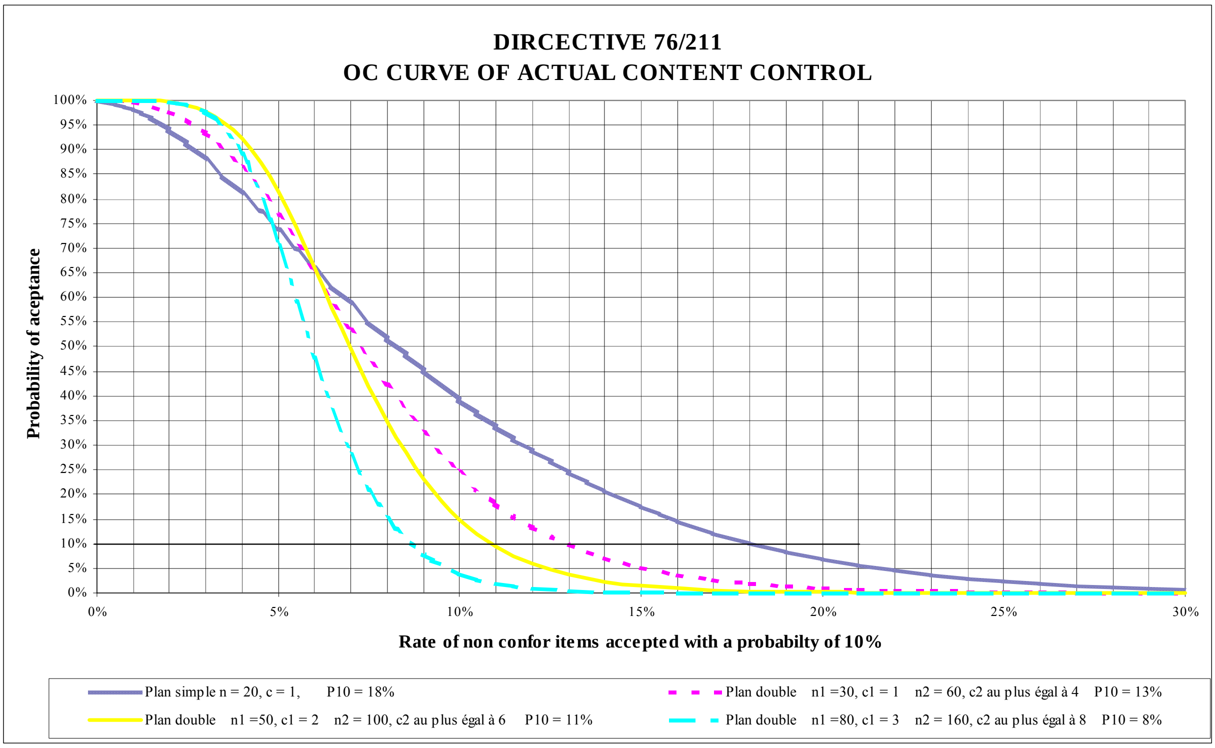
The following graph 3 presents the operating characteristic curves of the sampling plans laid down by the directive for checking the actual content.

Graph 3

DIRECTIVE 76/211
OPERATING CHARACTERISTIC CURVE OF THE CONTROLS OF THE ACTUAL CONTENT

Probability to accept these batches

Percentage of defective units in the controlled batches



single test
double test ... at most equal to 6 ....

double test .... at most equal to 14 ...
double test .... at most equal to 8 ...

5.2.4. Comparable sampling tests to the reference sample test for checking the actual content laid down in Annex II

According to paragraph 5 of annex I of the directive, a sampling test for checking the actual content is deemed comparable to the reference test of the directive when :

The abscissa of the 0.10 ordinate point of the operating characteristic curve of the first plan (probability of acceptance of the batch = 0.10) deviates by less than 15% from the abscissa of the corresponding point of the operating characteristic curve of the sampling plan recommended in Annex II.

It means that the difference between the percentage of defective units P_{10i} accepted by another control test and the percentage of defective units P_{10r} accepted by the reference test may not exceed 15% of P_{10r}.

$$I P_{10i} - P_{10r} I < 15\% P_{10r}$$

5.2.5 Numerical example : sampling test comparable to the control test for checking the actual content

A member state uses a sampling test for checking the actual content of a batch of prepackages which has the following characteristics :

single sampling test by attributes n = 32, c=2

ISO standard 2859-1 states that P10 of this test is 15, 8%. Graph 3 indicates that P_{10r} of the corresponding reference test is 18%

As

$$I P_{10i} - P_{10r} I = 18\% - 15.8\% = 2.2\%$$

$$15\% P_{10r} = 0.15 * 18\% = 2.7\%$$

$$I P_{10i} - P_{10r} I < 15\% P_{10r}$$

The test of the member state is accepted since, in accordance with paragraph 5 of Annex I of the directive, its efficiency is comparable to that of the reference test of Annex II of this directive.

5.3 Efficiency of the control of the mean quantity

5.3.1 Operating characteristic curve of the test for checking the mean quantity

The operating characteristic curve of the test for checking the mean quantity depicts the acceptance probability in function of a given underfilling expressed as a percentage of the estimated standard deviation conventionally called λ.

$$\lambda = -\left[\frac{\mu_s - Qn}{s}\right]$$

- μ_s *:* mean of the underfilled batch,
- *QN* : nominal quantity and
- $\bar{x}$ is the arithmetical mean value of the actual contents x_i of each of n prepackages making up the sample; it is also an estimator of the unknown mean value of the contents of the prepackages of the batch

$$\bar{x} = \frac{\sum_{i=1}^{i=n} x_i}{n}$$

- *s* : estimated standard deviation of the batch based on the measurements made on the prepackages of the sample

$$s = \sqrt{\sum_{i=1}^{i=n} \frac{\left(x_i - \bar{x}\right)^2}{n-1}}$$

The equation of the operating characteristic curve is

$$\mathbf{P_A} = F\left[t_{1-\alpha/2} - (\lambda.\sqrt{n})\right]$$

- *F* : cumulative distribution function of the Student distribution
- P_A : acceptance probability of the batch
- α is the level of the risk
- $t_{1-\alpha/2}$ is the confidence level (1-α/2) of a student distribution with (n-1) degree of freedom

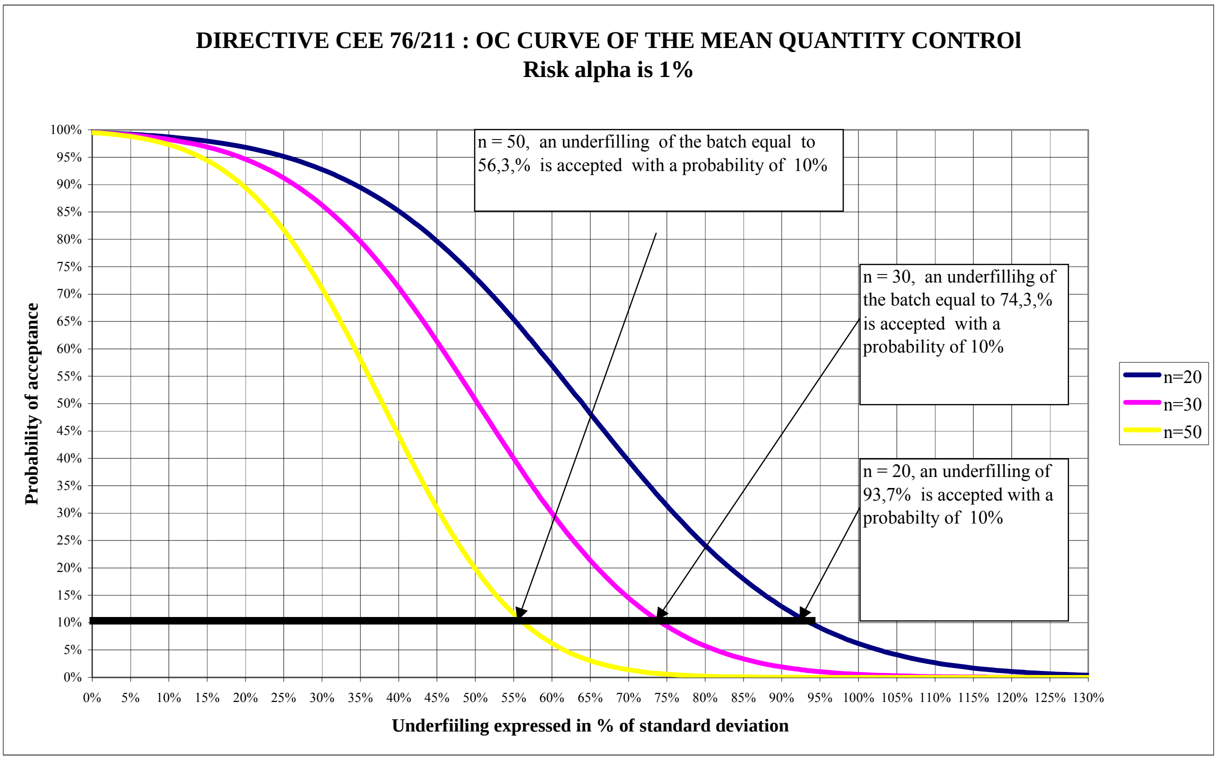
Since the confidence level of the test is (1-α) is 0,99, the **equation of the operating characteristic curve is**

$$\mathbf{P_A} = F\left[t_{0.995} - (\lambda.\sqrt{n})\right]$$

The following graph 4 shows the operating characteristic curves of the sampling tests laid down by the directive for checking the mean value of the contents.

Graph 4

EEC DIRECTIVE 76/211 :
OPERATING CHARACTERISTIC CURVES OF THE TESTS FOR CHECKING THE MEAN VALUE OF THE CONTENTS
n = size of the sample



Acceptance probability of the batches

Underfilling of the mean content of the batch (expressed as % of the estimated standard deviation)

n = 50, a mean underfilling of the batch of 56,3%
is accepted with a probability of 10%

n = 30, a mean underfilling of the batch of 74,3%
is accepted with a probability of 10%

n = 20, a mean underfilling of the batch of 93,7%
is accepted with a probability of 10%

Please note that the acceptance probability of a batch with zero underfilling is $1-\alpha$ at the risk α, i.e. 99,5%.

These curves show clearly that, if all other parameters remain unchanged, the test with the sample size n = 50 is more efficient than the test with n = 30, itself more efficient than the test with n = 20.

$$\mathbf{P_A} = F\left\lfloor t_{0.995} \quad -(\lambda.\sqrt{n})\right\rfloor$$

For an underfilling of one tenth of the standard deviation, the acceptance probability P_A for the mean value of the contents of the batch is 98,7 % for n = 20 and 97,3 % for n = 50 [5]

For a set-off equal to half a standard deviation, the acceptance probability for the mean value of the contents of the batch is 73 % for n = 20 and 50,7 % for n = 30 and 19,8% for n = 50

5.3.2 Comparable statistical tests to the reference statistical test for checking the mean value laid down in Annex II

In accordance with paragraph 5 of Annex I of the directive :

> *As regards the criterion for the mean calculated by the standard deviation method, a sampling plan used by a Member State shall be regarded as comparale with that recommended in Annex II if, taking into account the operating characteristic curves of the two plans having as the abscissa axis* $\frac{Qn-m}{s}$ *,(m=actual batch mean), the abscissa of the 0,10 ordinate point of the curve of the first plan (acceptance probability of the batch=0.10) deviates by less than 0.05 from the abscissa of the corresponding point of the curve of the sampling plan recommended in Annex II.*

It means that the difference between an underfilling λ_{10i} accepted by another testing plan with an acceptance probability of 10% and the underfilling λ_{10r} accepted by the reference testing plan with the same 10% acceptance probability may not exceed 5% of $\lambda_{10r.}$

$$|\lambda_{10i} - \lambda_{10r}| < 0.05\ \lambda_{10r}$$

λ_{10i} = mean content shortage expressed as a percentage of the standard deviation and accepted by the alternate test with a 10% probability

λ_{10r} = mean content shortage expressed as a percentage of the standard deviation and accepted by the reference test with a 10% probability

The λ_{10r} values calculated on the basis of the operating characteristic curve

$$\mathbf{P_{10}} = F\left\lfloor t_{0.995} - (\lambda_{\cdot 10r}\sqrt{n})\right\rfloor = \mathbf{10\%}$$

The λ_{10i} values calculated on the basis of the operating characteristic curve

$$\mathbf{P_{10}} = F\left\lfloor t_{1-\alpha/2} - (\lambda_{\cdot 10i}\sqrt{n})\right\rfloor = \mathbf{10\%}$$

α represents the risk of an erroneous decision by this other test.

[5] Cf Annex 1.

<u>Diagram 1</u>

n = sample size of the reference test	λ_{10r} = mean content shortage (expressed as a percentage of the estimated standard deviation) accepted with a 10% probability by the reference test of annex II
20	93,7%
30	74,3%
50	56.3%

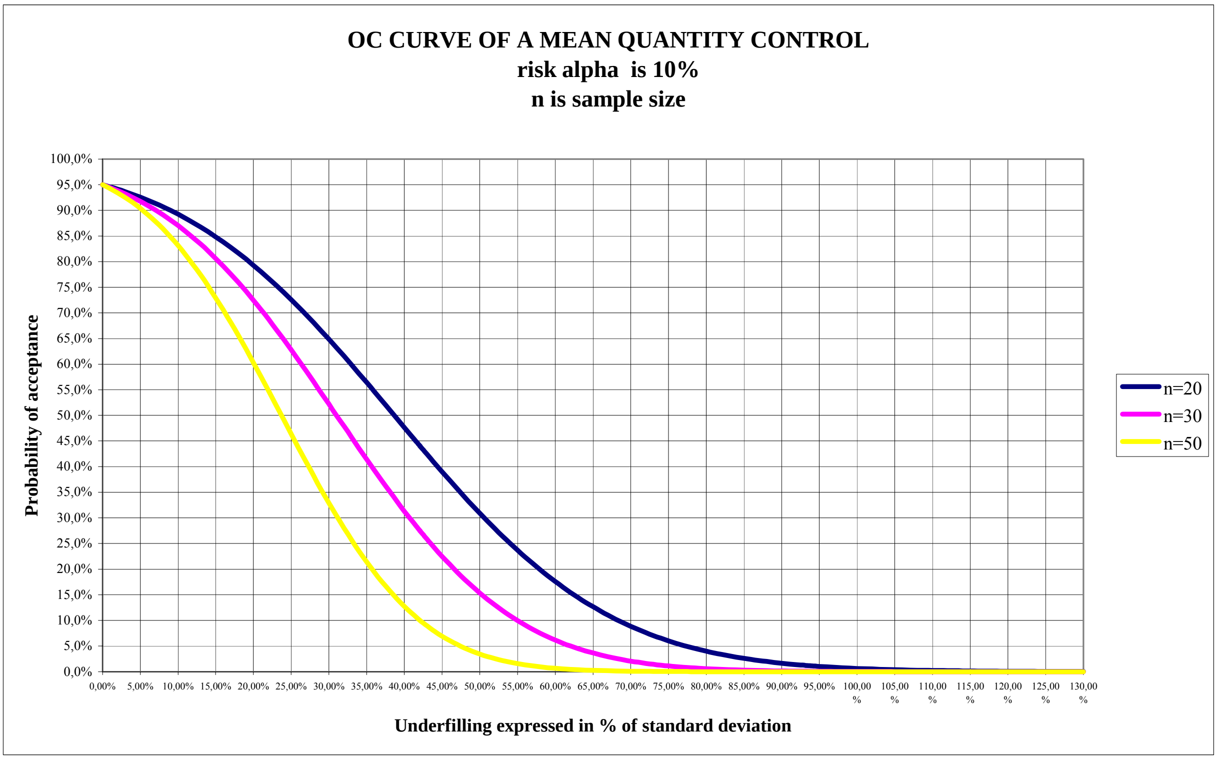
Graph 5 shows the operating characteristic curves of a mean value test with a risk of 10% to reach a wrong decision.

<u>Graph 5</u>

OPERATING CHARACTERISTIC CURVES OF A MEAN VALUE TEST

with a 10% risk to reach a wrong decision

n is the sample size taken from the batch



Test acceptance probability of the batch

Shortage of the mean content of the batch (expressed as a % of the estimated standard deviation)

Diagram 2 shows the mean content shortages (λ_{10i} expressed as % of the estimated standard deviation) accepted by the test with a 10% probability.

Diagram 2

n = sample size of a test with a 10% risk to reach a wrong decision	**λ_{10i} = shortage of the mean content (expressed as a % of the estimated standard deviation) accepted with a 10% probability by the test of annex II**
20	68,4%
30	55%
50	42,1%

5.3.3 Numerical examples

Example 1 Influence of the value of the standard deviation of a batch on the acceptance probability for checking the mean value of the content

The following numerical example shows that the better a manufacturer masters his conditioning processes the smaller the standard deviation will be and the lower the risk to reach a wrong decision will be.

A volumetric filling machine of a washing powder manufacturer is used to fill prepackages with a nominal quantity of 1000 g. For the batch under test, the filling machine was badly adjusted and the mean content m_0 was 998,8 g for a declared nominal quantity of 1000 g. The control was done at the end of the filling device and the production rate was 2000 packages per hour. The sample size n taken from this hourly production is 50 packages and the estimated standard deviation *s* calculated from the sample is 5,0 g.

Question 1 The batch is not conform since the mean production value is less than the nominal quantity of 1000 g. What is the risk that the official control will wrongly decide that the batch is conform by accepting it?

To determine this probability we use :

a) either graph 4 and the diagrams of annex I. These show for λ = (relative underfilling) = (1000g - 998,8 g)/5 g = 24%, an acceptance probability of the order of 83.5%

b) or the equation $P_A = F\left\lfloor t_{1-\alpha} - (\lambda.\sqrt{n})\right\rfloor$ coupled with statistical tables

- $t_{1-\alpha}$ is the confidence level at 0.995 of a student distribution with 49 degree of freedom $\approx 2{,}68$
- λ = (relative underfilling) = (1000g - 998,8 g)/5 g = 24 %;
- $t_{0.995} - \lambda\sqrt{n} = (2.68) - (0.24 * 7.07) = 0.9829$
- P_A = F[0,9829] = 83,48 %[6]

The non-conform batch is accepted with a high probability.

Question 2 The packer betters his conditioning process and the standard deviation is lowered; the new estimated standard deviation calculated from a sample of 50 units is now 2,4 g. What happens to the risk of the official control reaching a wrong decision by accepting the non-conform batch as conform?

The reasoning is the same as for question 1 with an estimated standard deviation of 2,4 g and a relative underfilling of 50%. λ = (relative underfilling) = (1000g - 998,8 g)/2.4 g = 50%;

a) Graph 4 and the tables of annex I give an acceptance probability of the order of 20%

b) The equation $P_A = F\left\lfloor t_{1-\alpha} - (\lambda.\sqrt{n})\right\rfloor$ and the statistical tables give :

- $t_{1-\alpha}$ is the confidence level at 0.995 of a student distribution with a 49 degree of freedom $\approx 2{,}68$
- λ = (relative underfilling) = (1000g - 998,8 g)/2.4 g = 50%;

[6] Value given by the Excel software.

- $t_{0.995} - \lambda\sqrt{n} = (2.68) - (0.5 * 7.07)$ = -0.8556
- P_A = F[-0.8556] = 19,82 %

The acceptance probability for this non-conform batch sinks from 85 % to 22%.

Question 3 What would become of the acceptance probability of batches for checking the mean content if the packer would aim his production on μ_s = QN – E (E is the maximum permissible error) with a standard deviation of 5 g?

The reasoning is the same as for question 1

$$P_A = F\left[t_{1-\alpha} - (\lambda.\sqrt{n})\right] = F\left[\frac{(\mu_s - \overline{x_c}) \cdot \sqrt{n}}{s}\right] = F\left[\frac{(QN - E_s - \overline{x_c}) \cdot \sqrt{n}}{s}\right]$$

E = maximum permissible error = 15 grams (paragraph 2.4 of annex I of the directive)
Estimated standard deviation s = 2,4 g,

μ_s = QN – E, = 1000 – 15 = 985

$\overline{x_c}$ = 997,3 = critical mean value = limit value under which the batch will be rejected when checking the mean content = : $QN - \frac{t_{0.995} * s}{\sqrt{50}}$

$$\overline{x_c} = QN - \frac{t_{0.995} * s}{\sqrt{50}} = 1000 - \frac{2.68 * 5}{7.07} = 1000 - 1.9 = 998{,}1 \text{ g}$$

$$P_A = F\left[t_{1-\alpha} - (\lambda.\sqrt{n})\right] = F\left[\frac{(\mu_s - \overline{x_c}) \cdot \sqrt{n}}{s}\right] = F\left[\frac{(QN - E_s - \overline{x_c}) \cdot \sqrt{n}}{s}\right] = F[-18.52]$$

P_A = F[-18.52] = $5*10^{-24}$= 0%

The acceptance probability of the batch is practically nul.

<u>Example 2 Is a sampling test comparable to the sampling test of annex I?</u>

A member state uses a sampling test for checking the mean content of a batch. This test has the following features :

- α of the test = 0,1

Is the efficiency of this test comparable to the reference test of the directive ($\alpha/2 = 0.005$, n = 50, $\lambda_{10r} = 56,3\%$[7]) ?

The equation of the operating characteristic curve of this test is

$$\mathbf{P_A} = F\left[t_{0.95} - (\lambda i \; .\sqrt{50})\right]$$

- P_A : acceptance probability of the batch
- F : cumulative distribution function of the Student distribution
- $t_{0..95}$ = is the confidence level at 0,95 of a student distribution with (n-1) degree of freedom
- $\lambda_i = -\left[\frac{\mu_s - Qn}{s}\right] = \frac{QN - \mu_s}{s}$

Graphic 5 and the above diagram 2 give the values λ_{10i}, of the mean underfilling accepted with a 10% probability in function of the sample size. The following diagram 3 shows the differences between λ_{10i} and λ_{10r} of the reference test. This diagram allows to conclude that the efficiencies of the two tests are not comparable.

THE EFFICIENCIES OF THE TWO TESTS FOR CHECKING THE MEAN CONTENT ARE NOT COMPARABLE

Diagram 3

n = sample size of both the reference test of directive 76/211 and the test of example 2	**Iλ_{10i} - λ_{10r}I**	**0.05% λ_{10r}**
20	I68,4% - 93,7%I = 25.3%	4,68% **The efficiencies of the two tests are not comparable**
30	I55% - 74,3%I = 19.3%	3,72% **The efficiencies of the two tests are not comparable**
50	I42.1%- 56.3%I = 14.2%	2,82% **The efficiencies of the two tests are not comparable**

[7] cf. Annex 1

ANNEX 1

EFFICIENCY OF A TEST OF THE MEAN VALUE, risk α= 1%

Calculated values[8] of P_A = $F\left[t_{0.995} \quad -(\lambda.\sqrt{n})\right]$

$\lambda = \left[\frac{\mu_s - Qn}{s}\right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ**		
	n=20	**n=30**	**n=50**
0,00%	99,5%	99,5%	99,5%
1,00%	99,4%	99,4%	99,4%
2,00%	99,4%	99,4%	99,3%
3,00%	99,3%	99,3%	99,1%
4,00%	99,3%	99,2%	99,0%
5,00%	99,2%	99,0%	98,8%
6,00%	99,1%	98,9%	98,6%
7,00%	99,0%	98,8%	98,3%
8,00%	98,9%	98,6%	98,0%
9,00%	98,8%	98,4%	97,7%
10,00%	98,7%	98,2%	97,3%
11,00%	98,6%	98,0%	96,8%
12,00%	98,4%	97,8%	96,3%
13,00%	98,3%	97,5%	95,8%
14,00%	98,1%	97,2%	95,1%
15,00%	97,9%	96,9%	94,4%
16,00%	97,7%	96,5%	93,6%
17,00%	97,5%	96,1%	92,7%
18,00%	97,3%	95,6%	91,7%
19,00%	97,1%	95,2%	90,6%
20,00%	96,8%	94,6%	89,4%
21,00%	96,5%	94,0%	88,1%
22,00%	96,2%	93,4%	86,7%
23,00%	95,9%	92,7%	85,1%
24,00%	95,5%	92,0%	83,5%
25,00%	95,1%	91,2%	81,7%
26,00%	94,7%	90,3%	79,8%
27,00%	94,3%	89,4%	77,8%
28,00%	93,8%	88,4%	75,6%

[8] With the Excel software

$\lambda = \left[\frac{\mu_s - Qn}{s}\right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ**		
29,00%	93,3%	87,4%	73,4%
30,00%	92,7%	86,3%	71,1%
31,00%	92,2%	85,1%	68,6%
32,00%	91,6%	83,8%	66,1%
33,00%	90,9%	82,5%	63,5%
34,00%	90,2%	81,1%	60,8%
35,00%	89,5%	79,6%	58,1%
36,00%	88,7%	78,0%	55,3%
37,00%	87,9%	76,4%	52,5%
38,00%	87,0%	74,8%	49,7%
39,00%	86,1%	73,0%	46,9%
40,00%	85,1%	71,2%	44,1%
41,00%	84,1%	69,3%	41,4%
42,00%	83,1%	67,4%	38,7%
43,00%	82,0%	65,4%	36,0%
44,00%	80,9%	63,4%	33,4%
45,00%	79,7%	61,4%	30,9%
46,00%	78,4%	59,3%	28,5%
47,00%	77,1%	57,2%	26,1%
48,00%	75,8%	55,0%	23,9%
49,00%	74,4%	52,9%	21,8%
50,00%	73,0%	50,7%	19,8%
51,00%	71,6%	48,5%	17,9%
52,00%	70,1%	46,4%	16,2%
53,00%	68,5%	44,2%	14,5%
54,00%	67,0%	42,1%	13,0%
55,00%	65,4%	40,0%	11,6%
56,00%	63,7%	37,9%	10,3%
56,30%	63,2%	37,3%	10,0%
57,00%	62,1%	35,9%	9,2%
57,30%	61,6%	35,3%	8,8%
58,00%	60,4%	33,9%	8,1%
59,00%	58,7%	31,9%	7,1%
60,00%	57,0%	30,0%	6,2%
61,00%	55,2%	28,2%	5,4%
62,00%	53,5%	26,4%	4,7%
63,00%	51,7%	24,7%	4,1%
64,00%	50,0%	23,0%	3,6%
65,00%	48,2%	21,4%	3,1%
66,00%	46,4%	19,9%	2,6%
67,00%	44,7%	18,4%	2,2%
68,00%	42,9%	17,0%	1,9%

$\lambda = \left[\frac{\mu_s - Qn}{s} \right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ**		
69,00%	41,2%	15,7%	1,6%
70,00%	39,5%	14,5%	1,4%
71,00%	37,8%	13,3%	1,2%
72,00%	36,2%	12,2%	1,0%
73,00%	34,5%	11,2%	0,8%
74,00%	32,9%	10,2%	0,69%
74,30%	32,5%	10,0%	0,66%
75,00%	31,4%	9,3%	0,6%
76,00%	29,8%	8,5%	0,5%
77,00%	28,4%	7,7%	0,4%
78,00%	26,9%	7,0%	0,3%
79,00%	25,5%	6,4%	0,3%
80,00%	24,1%	5,7%	0,2%
81,00%	22,8%	5,2%	0,2%
82,00%	21,5%	4,7%	0,2%
83,00%	20,3%	4,2%	0,1%
84,00%	19,1%	3,8%	0,1%
85,00%	17,9%	3,4%	0,1%
86,00%	16,8%	3,0%	0,1%
87,00%	15,8%	2,7%	0,1%
88,00%	14,8%	2,4%	0,0%
89,00%	13,8%	2,1%	0,0%
90,00%	12,9%	1,9%	0,0%
91,00%	12,1%	1,7%	0,0%
92,00%	11,3%	1,5%	0,0%
93,00%	10,5%	1,3%	0,0%
93,60%	10,0%	1,2%	0,0%
94,00%	9,8%	1,2%	0,0%
95,00%	9,1%	1,0%	0,0%
96,00%	8,4%	0,9%	0,0%
97,00%	7,8%	0,8%	0,0%
98,00%	7,2%	0,7%	0,0%
99,00%	6,7%	0,6%	0,0%
100,00%	6,2%	0,5%	0,0%
101,00%	5,7%	0,5%	0,0%
102,00%	5,3%	0,4%	0,0%
103,00%	4,9%	0,4%	0,0%
104,00%	4,5%	0,3%	0,0%
105,00%	4,1%	0,3%	0,0%
106,00%	3,8%	0,2%	0,0%
107,00%	3,5%	0,2%	0,0%
108,00%	3,2%	0,2%	0,0%

$\lambda = \left[\frac{\mu_s - Qn}{s} \right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ**		
109,00%	2,9%	0,2%	0,0%
110,00%	2,7%	0,1%	0,0%
111,00%	2,5%	0,1%	0,0%
112,00%	2,2%	0,1%	0,0%
113,00%	2,0%	0,1%	0,0%
114,00%	1,9%	0,1%	0,0%
115,00%	1,7%	0,1%	0,0%
116,00%	1,6%	0,1%	0,0%
117,00%	1,4%	0,1%	0,0%
118,00%	1,3%	0,0%	0,0%
119,00%	1,2%	0,0%	0,0%
120,00%	1,1%	0,0%	0,0%
121,00%	1,0%	0,0%	0,0%
122,00%	0,9%	0,0%	0,0%
123,00%	0,8%	0,0%	0,0%
124,00%	0,7%	0,0%	0,0%
125,00%	0,7%	0,0%	0,0%
126,00%	0,6%	0,0%	0,0%
127,00%	0,5%	0,0%	0,0%
128,00%	0,5%	0,0%	0,0%
129,00%	0,5%	0,0%	0,0%
130,00%	0,4%	0,0%	0,0%

ANNEX 2

EFFICIENCY OF A TEST OF THE MEAN VALUE risk α= 10%

Calculated values[9] of P_A = $F\left[t_{0.95} \quad -(\lambda.\sqrt{n})\right]$

$\lambda = \left[\frac{\mu_s - Qn}{s}\right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ,**		
	n=20	n=30	n=50
0,00%	95,0%	95,0%	95,0%
1,00%	94,6%	94,5%	94,3%
2,00%	94,1%	93,9%	93,4%
3,00%	93,6%	93,2%	92,5%
4,00%	93,1%	92,5%	91,5%
5,00%	92,6%	91,8%	90,4%
6,00%	92,0%	90,9%	89,2%
7,00%	91,4%	90,1%	87,8%
8,00%	90,7%	89,1%	86,4%
9,00%	90,0%	88,1%	84,8%
10,00%	89,2%	87,1%	83,1%
11,00%	88,4%	85,9%	81,3%
12,00%	87,6%	84,7%	79,4%
13,00%	86,7%	83,4%	77,4%
14,00%	85,8%	82,1%	75,2%
15,00%	84,8%	80,6%	73%
16,00%	83,8%	79,1%	70,6%
17,00%	82,8%	77,6%	68,1%
18,00%	81,7%	75,9%	65,6%
19,00%	80,5%	74,2%	63%
20,00%	79,3%	72,5%	60,3%
21,00%	78,0%	70,6%	57,6%
22,00%	76,7%	68,8%	54,8%
23,00%	75,4%	66,8%	52%
24,00%	74,0%	64,8%	49,2%
25,00%	72,6%	62,8%	46,4%
26,00%	71,1%	60,7%	43,6%
27,00%	69,6%	58,6%	40,9%
28,00%	68,1%	56,5%	38,1%

[9] With the Excel software

$\lambda = \left[\frac{\mu_s - Qn}{s} \right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ,**		
	n=20	n=30	n=50
29,00%	66,5%	54,4%	35,5%
30,00%	64,9%	52,2%	32,9%
31,00%	63,2%	50,0%	30,4%
32,00%	61,6%	47,9%	28%
33,00%	59,9%	45,7%	25,7%
34,00%	58,2%	43,6%	23,5%
35,00%	56,4%	41,5%	21,4%
36,00%	54,7%	39,4%	19,5%
37,00%	52,9%	37,3%	17,6%
38,00%	51,2%	35,3%	15,9%
39,00%	50,6%	33,3%	14,2%
40,00%	47,6%	31,3%	12,7%
41,00%	45,9%	29,4%	11,4%
42,00%	44,1%	27,6%	10,1%
42,10%	43,5%	26,9%	10,0%
43,00%	42,4%	25,8%	8,9%
44,00%	40,7%	24,1%	7,9%
45,00%	39,0%	22,5%	6,9%
46,00%	37,3%	20,9%	6,1%
47,00%	35,7%	19,4%	5,3%
48,00%	34,0%	18,0%	4,6%
49,00%	32,5%	16,6%	4%
50,00%	30,9%	15,4%	3,5%
51,00%	29,4%	14,1%	3%
52,00%	27,9%	13,0%	2,6%
53,00%	26,5%	11,9%	2,2%
54,00%	25,1%	10,9%	1,9%
55,00%	23,7%	10,0%	1,6%
56,00%	22,4%	9,1%	1,4%
57,00%	21,1%	8,3%	1,1%
58,00%	19,9%	7,5%	1,0%
59,00%	18,7%	6,8%	0,8%
60,00%	17,6%	6,2%	0,7%
61,00%	16,5%	5,6%	0,6%
62,00%	15,5%	5,0%	0,5%
63,00%	14,5%	4,5%	0,4%
64,00%	13,6%	4,1%	0,3%
65,00%	12,7%	3,6%	0,3%
66,00%	11,8%	3,3%	0,2%
67,00%	11,0%	2,9%	0,2%
68,00%	10,3%	2,6%	0,2%

$\lambda = \left[\frac{\mu_s - Qn}{s} \right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A** **probability to accept the underfilling λ,**		
	n=20	n=30	n=50
68,40%	10,0%	2,5%	0,1%
69,00%	9,5%	2,3%	0,1%
70,00%	8,9%	2,1%	0,1%
71,00%	8,2%	1,8%	0,1%
72,00%	7,6%	1,6%	0,1%
73,00%	7,1%	1,4%	0,1%
74,00%	6,5%	1,3%	0,0%
75,00%	6,0%	1,1%	0,0%
76,00%	5,6%	1,0%	0,0%
77,00%	5,1%	0,9%	0,0%
78,00%	4,7%	0,8%	0,0%
79,00%	4,4%	0,7%	0,0%
80,00%	4,0%	0,6%	0,0%
81,00%	3,7%	0,5%	0,0%
82,00%	3,4%	0,5%	0,0%
83,00%	3,1%	0,4%	0,0%
84,00%	2,8%	0,4%	0,0%
85,00%	2,6%	0,3%	0,0%
86,00%	2,4%	0,3%	0,0%
87,00%	2,2%	0,2%	0,0%
88,00%	2,0%	0,2%	0,0%
89,00%	1,8%	0,2%	0,0%
90,00%	1,7%	0,2%	0,0%
91,00%	1,5%	0,1%	0,0%
92,00%	1,4%	0,1%	0,0%
93,00%	1,3%	0,1%	0,0%
93,60%	1,2%	0,1%	0,0%
94,00%	1,1%	0,1%	0,0%
95,00%	1,0%	0,1%	0,0%
96,00%	0,9%	0,1%	0,0%
97,00%	0,9%	0,1%	0,0%
98,00%	0,8%	0,0%	0,0%
99,00%	0,7%	0,0%	0,0%
100,00%	0,6%	0,0%	0,0%
101,00%	0,6%	0,0%	0,0%
102,00%	0,5%	0,0%	0,0%
103,00%	0,5%	0,0%	0,0%
104,00%	0,4%	0,0%	0,0%
105,00%	0,4%	0,0%	0,0%
106,00%	0,4%	0,0%	0,0%
107,00%	0,3%	0,0%	0,0%

$\lambda = \left[\frac{\mu_s - Qn}{s} \right]$ (underfilling of the mean content expressed as a percentage of the estimated standard deviation)	**P_A probability to accept the underfilling λ,**		
	n=20	n=30	n=50
108,00%	0,3%	0,0%	0,0%
109,00%	0,3%	0,0%	0,0%
110,00%	0,2%	0,0%	0,0%
111,00%	0,2%	0,0%	0,0%
112,00%	0,2%	0,0%	0,0%
113,00%	0,2%	0,0%	0,0%
114,00%	0,2%	0,0%	0,0%
115,00%	0,1%	0,0%	0,0%
116,00%	0,1%	0,0%	0,0%
117,00%	0,1%	0,0%	0,0%
118,00%	0,1%	0,0%	0,0%
119,00%	0,1%	0,0%	0,0%
120,00%	0,1%	0,0%	0,0%
121,00%	0,1%	0,0%	0,0%
122,00%	0,1%	0,0%	0,0%
123,00%	0,1%	0,0%	0,0%
124,00%	0,1%	0,0%	0,0%
125,00%	0,1%	0,0%	0,0%
126,00%	0,0%	0,0%	0,0%
127,00%	0,0%	0,0%	0,0%
128,00%	0,0%	0,0%	0,0%
129,00%	0,0%	0,0%	0,0%
130,00%	0,0%	0,0%	0,0%