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Guidance for Market Control on Prepackages For Competent Departments

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WELMEC

European cooperation in legal metrology

WELMEC is a co-operation between the legal metrology services of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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1 FOREWORD

1.1. As agreed by the WELMEC Committee, in Resolution number 8 of 8-9 June 2000, the Terms of Reference of WELMEC Working Group 6 were amended to include market controls of pre-packaged products. Working Group 6 has produced this specific guide on market control to share best practice and to promote uniformity of approach in this activity.

1.2. This guidance covers checks that may be carried out by the competent departments of the Member States at any stage in the marketing process, in particular for the purpose of verifying that pre-packages meet the requirements of the Directive.

1.3. As the Directives[1] on pre-packages are not New Approach Directives, the concept of market surveillance is not explicitly mentioned as a requirement. This guide looks at the various checks and the use that can be made of them in checking the conformity of pre-packages to the requirements specified in the Directives. Where these checks are applied after the pre-packages have been placed on the market they may be referred to as 'market control' in order to avoid confusion with the term 'market surveillance'. The term "reference test" in annex 2 paragraph 1.5 of the Directives is used both to recognize procedures and to carry out market control. In this document only those 'other checks' in annex 2 paragraph 1.6 of the Directives are considered.

1.4. This guide aims to draw on the general good practice mentioned in the Guide on the implementation of New Approach Directives[2] and the Global Approach (Blue Guide) and the specific metrological guidance in the OIML[3] document on the principles of metrology supervision[4] (OIML D9).

1.5. Market control implies all the situations specified in table 1.

- When for the purposes of market control a reference test or statistical equivalent check is not practicable, a screening check can be performed. However it should be recognised that the result of a screening check cannot generally provide a basis for enforcement/legal action in the case of the average or the number of defective packages (packages having a deficiency

[1] Directives 75/106/EEC and 76/211/EEC
[2] The Commission's "*Guide to the implementation of directives based on the New Approach and the Global Approach"*
[3] International Organisation for Legal Metrology
[4] OIML Document 9 Principles of Metrology Supervision.

greater than the tolerable negative error[5] specified in the Directives, referred to as TU1).

- Two indicators (P_1 and P_2 in annex C below) are fixed to enable market control to identify the pre-packages that may be defective.

Table 1 - Different stages of Process of Market Control

Preparation, organisation of market control	**Checks**	**Follow up actions**
❖ Who carries out the checks? ❖ What kind of pre-packages to check? ❖ Where to do the checks take place (see table 2) ❖ Specific problems (products, methods, packer or importer, country of origin)	**Quantity of product** : Screening (or equivalent checks)[6] in appropriate places **Labelling** **Identify:** unknown packers, persons arranging for the packing to be done and/or importers	❖ Ensure compliance with legal requirements ❖ Inform the competent department that is 'responsible' for the packer or the importer ❖ Information to trade organisations, consumer organisation ❖ Preventive and corrective actions done by the competent authority or the responsible person (packers, importers, retailers) ❖ Administration notices or fines (penalty) arrangements ❖ Court action

According to this model, the assessment and recognition of procedures is not considered to be market control. However, in some member states assessment and recognition of procedures takes place when market control activities take place and/or the reference test is performed.

[5] Annex I, 2.4 of the Directives
[6] See statistic annex make better referral

2 OBJECTIVES OF THE GUIDE

This guide is intended to cover market control of e-marked products. The guide may also be used for non-e-marked products that (based on national legislation) should comply with the same requirements.

This guide has been produced with a view to achieving a consistent level of market control in respect of e-marked pre-packages throughout the EU/EEA. Directives 76/211/EEC and 75/106/EEC, together with 80/232/EEC, constitute the legal basis for pre-packages sold by weight or volume in the EEA and Switzerland.

The guide is intended for those who prepare, organise and carry out market control functions, which is a type of metrological supervision that is directed to pre-packages, which are placed on the market, or are intended to be placed on the market, in order to ensure conformity of the products with the requirements.

National differences in the organisation of the supervision in the Member States are permitted in relation to the "e marking directives". In some Member States, the competent department and the market control authority come under the same authority[7] but for other Member States they are different.

3 SCOPE

The application of this document is limited (as stated in annex I paragraph 6 of the directives) to the other checks carried out on pre-packages covered by the Directives.

This documents looks at:

- the location of the checks
- the various checks that may be used by the competent authorities inside a Member State**,** and the nature of the checks done
- the circumstances in which the check results may be used,
- suggested methods of using the results, and
- further actions to be taken as a result of the checks.

[7] The Commission's "*Guide to the implementation of directives based on the New Approach and the Global Approach"* recommends the exclusion of notified bodies from the responsibility of market surveillance activities, "National authorities". However this is not a New Approach Directive and so this is permitted. http://www.eotc.be/newapproach/cdrom/cap8/ms4.htm.

4 COMPETENT AUTHORITIES

National authorities responsible for market control for e-marked products are listed in WELMEC 6.0.

5.CHECKS

5.1 Definitions:

- 'reference test' is a test as specified in annex I paragraph 5 to the Directive
- 'standard screening test' is the test that is defined in appendix B of this document
- 'other checks' are checks as specified in annex I paragraph 6 of the Directive, including but not limited to checks statistically equivalent to the reference test and the standard screening test
- scope of this document is confined to those 'other checks'

5.2 Location of checks

As every Member State has its own national legislation implementing the directives. The location where checks, including the reference test, may take place may vary between the Member States. However, the reference test can only be carried out in one of the places specified in table 2 in part 1 and 2.

The basic principle of the directive is that the reference test should be performed at the premises of the packer or importer (or the importer's agent). The description of the 'reference test' is taken from annex I, 5. It is clear that the directive does not envisage that the reference test could be performed in places other than those listed in annex 1.5, but checks that are statistically equivalent to the reference test, are also envisaged, If checks are carried out in places other than at the premises of the packer or importer, they must fall under the heading 'other checks' in annex 1.6 and should be regarded as checks that may not be statistically equivalent to the reference test. However, when the check is not statistically equivalent to the reference test the result of the check is not suitable for legal enforcement in respect of the average of the batch or the number of defective packages in the batch.

The following are the checks that can be performed while carrying out market controls:

1. a test that is statistically equivalent to the reference test,

2. a screening test that is statistically equivalent to the standard screening test defined in appendix B of this guide,

3. a screening test that is not statistically equivalent to the reference test nor the standard screening test,

4. a check on labelling requirements relating to
   - *a.* legibility and visibility under normal conditions of presentation,
   - *b.* height of the figure and the abbreviation of the unit of measurement used for the quantity marking,
   - *c.* liquids to have a nominal quantity in volume, all other in weight, unless there is contrary requirements throughout the EU,
   - *d.* the mark or inscription enabling the Competent Department to identify the packer or importer in the Community.

TABLE 2 – Types of checks

1. ORIGINATING in EEA and Switzerland	
PLACES AT WHICH CHECKS SHOULD BE MADE	**NATURE OF CHECKS DONE BY THE COMPETENT AUTHORITIES IN THE MEMBER STATE**
PREPACKER'S FILLING LINES	Tests required by annex I, §5, of directive 76/211, which have effectiveness comparable to the reference method specified in Annex II.(see appendix C)
PREPACKER'S WARE HOUSES	
2. PACKAGING CONTROLS pre-packages originating from a third country	
PLACES AT WHICH CHECKS SHOULD BE MADE	**NATURE OF CHECKS DONE BY THE COMPETENT AUTHORITIES**
PREMISES OF IMPORTER OR AGENT	Tests required by annex I, §5, of directive 76/211, which have effectiveness comparable to the reference method specified in Annex II.(see appendix C)
PREMISES OF IMPORTER OR AGENT'S WARE HOUSES	
3. MARKET CONTROLS	
PLACES AT WHICH CHECKS SHOULD BE MADE	**NATURE OF CHECKS DONE BY THE COMPETENT AUTHORITIES**
PACKER'S WAREHOUSE	Checks mentioned in appendix B (standard screening check specified in B1 or other checks with effectiveness comparable as specified in appendix B2)
DISTRIBUTION TO THE RETAILER	
RETAILER PREMISES PRIOR TO PURCHASE BY THE CONSUMER (including SUPERMARKETS)	

For *imports* from third countries, the competent departments will have to verify the evidence, (or other means available to ensure that the pre-packages meet the requirements) which the importers are obliged to provide. The evidence should demonstrate the conformity of the pre-packages to the metrological requirements applicable within the **EEA and Switzerland.**

For products that are desiccating[8] or hygroscopic[9], the 'other checks' may be completed based on information about the quantity at the time when the product left the production site or at the time of import, provided the national legislation permits such actions.

5.3 Nature of checks

5.3.1 STANDARDISED PACKING SIZES

In addition to the metrological requirements applicable to the pre-packages, there are, for certain products, mandatory ranges governing the nominal quantity in which those products may be pre-packaged. These mandatory ranges have been reviewed and Directive 2007/45/EC specifies what is permitted from 11 April 2009. On that date all prescribed ranges will be revoked except the ranges will be retained for wines and spirits; with the use of existing prescribed ranges in Member States for milk, butter, dried pasta, coffee and sugar for a further 4 or 5 year.

5.3.2 REQUIREMENTS FOR MARKING AND INSCRIPTIONS

The labelling of pre-packages should also be checked. The labelling requirements are as follows:

- The height of the figures of nominal quantity,

[8] Such as some delicatessen products or soap.
[9] Such as cat litter.

Table 3 - Minimum height of the nominal quantity figures

NOMINAL QUANTITY VALUE	Minimum height of the nominal quantity figures
If it is not more than 50 g or 5 cl	2 mm
Above 50 g or 5 cl and less then or equal to 200 g or 20 cl	3 mm
Above 200 g or 20 cl and less than or equal to 1000 g or 100 cl	4 mm
Above 1000 g or 100 cl	6 mm

- A mark or inscription enabling the competent department to identify the packer or the person arranging for the packing to be done or the importer established in the Community. These marks or inscription have to be in conformity with the legislation applied in the member state where the prepackage is sold,

- Use of the correct unit of measurement and symbol. The nominal quantity for liquids must be in volume and everything else in weight, unless there is EU-wide contrary requirements,

- A small “e” at least 3 mm high, shall be placed in the same field of vision as the indication of the nominal weight or nominal volume; this letter should have the form shown in the drawing contained in section 3 of annex II to Directive 71/316/EEC.

All of the above-mentioned markings shall be affixed in such a manner as to be “ … indelible, easily legible and visible on the pre-package in normal conditions of presentation.”

‘Easily legible’ covers subjects like contrast, colouring, font types

UK guidance states that legibility requires use of an appropriate font, and that the colour of print of the marking is in good contrast to the background. Where the container is transparent the marking must be in good contrast to the colour of the product forming the visible background. The UK Royal National Institute for the Blind has produced helpful ‘clear print guidelines’, which recommend fonts such as Arial, Univers and New Century Schoolbook, the use of a minimum point size of 12 or 14, and selective use only of block capitals and italics. Use of these guidelines will be helpful in ensuring legibility of the text. As regards the marking of the nominal quantity, however, note the minimum height of figures specified below.

‘Visible in normal conditions of presentation’ can be complied with by marking on the front or possibly the top of the package.

5.3.3 TESTS FOR CHECKING THE QUANTITY OF PRODUCT

The metrological control of the quantity of product contained in pre-packages, specified in the directives, is intended to check that the average of the actual quantity of product of the batch is at least equal to the nominal quantity and, at the same time, that the number of pre-packages with a quantity of product less than TU1 and TU2 is acceptable.

'Other checks', in accordance with annex 1.6 are intended to assess whether the average quantity of product and the number of pre-packages with a quantity less than TU1 and TU2 are acceptable. Also labelling checks can be carried out. Formal action based on the average quantity found could only be taken if the 'other check' is statistically as efficient as the reference test; see the OIML expert report[10].

A. For inspection lots of 100 pre-packages or more, two types of statistical checks are used. They are based on the evaluation of samples taken at random from the batch to be controlled and using a method that is statistically equivalent to the methods mentioned below. The **average quantity** of product is checked by measuring the quantity of product in pre-packages in a sample taken from the batch to be inspected; the statistical principle of this check is described in the ISO standards 2854-1976 and 3494-1976

The control of the **actual quantity** of product of individual pre-packages (to determine whether the number of packages with a quantity below T1 is acceptable) is determined using a statistical check by attributes, the principles of which are described in the ISO 2859 standard.

B. For inspection lots of under 100 pre-packages, a standard screening test is defined in appendix B. The results of this screening test are the only way to get data on the metrological quality quickly.
As these screening tests are attribute sampling plans intended to check the percentage of non-conforming pre-packages in the batch, formal legal action may

[10] *Dr Alain Duran,* The Statistical Principles of the Metrological Surveillance of the Net Content of Pre-packages as laid down by the CEE 76/211 Directive, *OIML Bulletin 2004-4*.

normally only be taken in respect of any pre-packages with an actual quantity less than TU2.[11]

If the test is passed, by reason of the limited efficiencies of such tests, it does not mean that the inspection lots are in conformity with metrological requirements of directive 76/211; it is not an indication of acceptable metrological quality.

For inspection lots of less than 25 pre-packages, the standard screening test is not appropriate.
The only option left is to use a screening test that is not statistically equivalent to the standard screening test**.** The results of these tests can only give an indication on the metrological quality and may indicate the need to carry out further tests that are statistically valid in order to take formal action.

Table 4 and Table 5 summarise the scenarios applicable to inspection lots under 100 pre-packages when screening checks are used.

Table 4 - 'other checks' for market control

Batch size, N	'other checks'
N $\geq$ 100 pre-packages	Checks equivalent to those mentioned in annex II directive 76/211
25 pre-packages $\leq$ N < 100 pre-packages	Checks mentioned in appendix B
N< 25 pre-packages	In general, statistical tests are not appropriate. If the quantity of product in one or more pre-packages is less than the nominal, further recommended actions could be considered (see 6).

TABLE 5 – Outcomes of checks

Success screening tests	It is not a indication of metrological quality
Failure screening tests	One or more pre-packages has a content between QN and TU2 recommended actions could be considered (see 6)
	One or more pre-packages has a content below TU 2, formal actions are mandatory

[11] The existence of the standard screening test does not preclude the use of any other screening test that is not statistically equivalent to the standard screening test. However, whenever possible, the standard screening test is recommended.

6. RECOMMENDED ACTIONS

When a screening test is failed, or the labelling does not meet the requirements, the authorities should follow the protocol in WELMEC 6.0, section 2 which includes:

- conduct further investigation and/or inform the competent department from which member state the pre-packages originate
- determine whether the procedures at the packer or importer are still effective

Consideration should be given to removing defective product from the marketplace and carrying out further checks to gauge the extent of the problem.

APPENDIX A: DEFINITIONS

A1 Inspection lot

Inspection lot is the lot defined by domestic legislation

A2 Operating Characteristic Curve

For a given sampling plan, an **Operating Characteristic (OC) curve** describes the probability of acceptance of a lot as a function of its actual quality. It relates the rate of defective items in lots (x-axis) with the probability of accepting these lots at control (y-axis).

A3 The Acceptable Quality Level (AQL) and Limiting Quality (LQL) Level

The **Acceptable Quality Level** (AQL) for a given sampling plan is the rate of non-conforming items at which a lot will be rejected with a low probability[12], usually 5 %. This does not mean that all lots having a rate of defective items greater than the AQL will be rejected at the control, but it does mean that the greater the extent by which the rate of defective items exceeds the AQL the greater is the probability of rejection of a lot. For any given sample size, the lower the AQL the greater the protection for the consumer will be against the acceptance of lots with high defective rates, and the greater the likelihood of compliance by the producer.

The **Limiting Quality Level** (LQL) for a given sampling plan is the rate of non-conforming items at which a lot will be accepted with a low probability[13], usually 10 %. This does not mean that all the lots having a rate of defective items greater than LQL will be rejected at the control, but it does mean that the higher the rate by which

[12] 2.5% in reference actual content check (§2.2 annex II, directive 76/211)

defective items exceed the LQL, the greater is the probability that the lot will be rejected. For any given sample size, the lower the LQL, the greater the protection for the consumer against accepting lots with high defective rates, and the greater the likelihood of compliance by the producer.

A4 Producers' risk (PR), P_{95}

On the OC curve of a sampling plan, the producers' risk corresponds to the probability of rejecting a lot having a proportion P_1 of defective items (generally low) fixed by the sampling plan. According to the producer such a lot should not be rejected. In other words, the PR is the probability that a lot will be rejected in error. Generally, the PR is expressed by a proportion noted P_{95} corresponding to the proportion of defective items in the lot accepted in 95 % of the cases (i.e. rejected in 5 % of the cases).

A5 Consumers' risk (CR), P_{10}

On the OC curve of a sampling plan, the consumers' risk corresponds to the probability of accepting a lot having a proportion P_2 of defective items (generally low), fixed by the sampling plan. According to the consumer, such a lot should be rejected. In other words, it is the probability of wrongly accepting a lot. Generally, the CR is expressed by a proportion noted as $P_{10,}$ which corresponds to the proportion of defective items in the lot accepted in 10 % of the cases (i.e. rejected in 90 % of the cases).

A6 Comparing efficiency of sampling plans

A6a Attribute test to check the quantity

To check the quantity of product in a pre-package, a sampling plan used by a member state shall be regarded as a comparable with that defined in this guide (appendix B) or with reference test defined in 2.2 annex II of directive 76/211 (see values in table in paragraph C.3), if the absolute value of difference between P_{10r} (P_{10} or LQL of these reference sampling plans) and P10i (P_{10} or LQL of the sampling plans used by the member state is under the value of 0.15 P_{10r}

$$|P_{10i} - P_{10r}| < 0.15\ P_{10r}$$

A6b Average test

To check the average of quantity of product in a pre-package, a sampling plan used by a member state shall be regarded as a comparable for the purposes of section 2.2 annex II of directive 76/211, if the absolute value of difference between λ_{10r} (λ_{10} this

[13] 2.5% in reference actual content check (§2.2 annex II, directive 76/211)

reference sampling plans, see values in table in paragraph C.1) and λ_{10i} (λ_{10} of the sampling plans used by the member state is under the value of 0.05 P_{10r}

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

λ expressed an underfilling as a percentage of the estimated standard deviation conventionally called.

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

- μ_s *:* mean of the underfilled batch,
- *QN* : nominal quantity and
- s : the standard deviation of the quantities within the sample.

APPENDIX B: SPECIAL SCREENING CHECKS AND EQUIVALENT SCREEENING CHECKS, RISKING SCHEME

B1 Standard Screening Test

These checks are only recommended when the batch size is under 100 pre-packages. In such cases t**he defective item is defined as a pre-package with an actual quantity less than the <u>nominal quantity</u> (x_i < QN).**

If the prepackages fail the screening test the results cannot be basis for legal action, except for prepackages with a deficiency of greater than 2 tolerable negative errors (TNE).

SAMPLING PLANS FOR SCREENING CHECKS				
N (batch size)	**n** (sample size)	**Ac** (acceptance criteria maximum of defective items permitted in sample)	**P_{95}**[14] (Rate of defective items accepted by the sampling plans with a probability of 95%)	**P_{10}** (Rate of defective items accepted by the sampling plans with a probability of 10%)
N<25	In general, statistical tests are not appropriate. The quantity in one or more pre-packages has to be measured; if one or more pre-packages has an actual content less than the nominal quantity further actions could be developed.			
25 ≤ N<40	5	0	1,02%	36.9%
40 ≤ N<65	8	0	0,64%	25.0%
66 ≤ N<100	13	0	0,4%	16.1%

[14] Values calculated on equation given on § C.2.1 or given by tables of ISO 2859-1

B2 Equivalence Screening check

Every check that complies with the following principle extracted from § 5 of Annex I of directive 76/211 is considered to be equivalent to the screening check

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 check and the percentage of defective units P_{10r} accepted by the reference check may not exceed 15% of $P_{10r.}$

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

B3 Risk assessment scheme

Depending on domestic legislation where it exists, equivalence could be improved by using risk analysis. An example is:

Risk	**Distribution**	**Frequency of inspection**
High	National and international	Once a year
Medium	Regional in one Member State	Once every two years
Low	Local in one Member State	Once every five years

APPENDIX C: EQUIVALENCE OF CHECKS ACCORDING DIRECTIVE 76/211

Directive of 76/211 annex 1 § 5 fixes the rules to demonstrate the statistical equivalent efficiency to reference checks of annexe 2[15].

C 1 Characteristics of sampling plans for average check (§ 2.3 annex II)

Operating characteristic curve of average check

The operating characteristic curve of the check for checking the average 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 *:* average of the underfilled batch,
- *QN* : nominal quantity and
- $\bar{x}$ is the arithmetical average of the actual quantity x_i of each of n pre-packages making up the sample; it is also an estimator of the unknown average quantity of product in the pre-packages making up the batch

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

- *s* : estimated standard deviation of the batch based on the measurements made on the pre-packages 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

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

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

[15] The explanation of these rules, with numerical examples are presented in OIML Bulletin (n° 4-2004).

Comparable statistical checks to the reference test for checking the average quantity laid down in Annex II

In accordance with paragraph 5 of Annex I of the directive, regarding the criterion for the average check calculated by the standard deviation method, a sampling plan used by a Member State shall be regarded as comparable 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 = average actual quantity of product in pre-packages in the batch), 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 checking plan with an acceptance probability of 10% and the underfilling λ_{10r} accepted by the reference checking plan with the same 10% acceptance probability may not exceed 5% of λ_{10r}.

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

- λ_{10i} = values of abscissa axis accepted by the alternate check with a 10% probability
- λ_{10r} = values of abscissa axis accepted by the reference check with a 10% probability

The λ_{10r} and λ_{10i} values are calculated or determined on the basis of the following operating characteristic curve

$$P_{10} = F\left[t_{0.99} - (\lambda_{10r}\sqrt{n})\right] = 10\%$$

$$P_{10} = F\left[t_{1-\alpha} - (\lambda_{10i}\sqrt{n})\right] = 10\%$$

α represents the risk of an erroneous decision by this alternative check.

n = sample size of reference test	**λ_{10r}**
20	93,7%
30	74,3%
50	56.3%

C 2 Characteristics of sampling plans for actual contents check (§ 2.2 annex II)

C. 2.1 Efficiency of single sampling plan by attribute

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

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

- 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

C.2.2 Efficiency of double single sampling plan by attribute

The equation of the operating characteristic curve of the sampling check 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 $c1 \leq r1 \leq c2$
- P_{10r} is the percentage of defective items accepted with a probability of 10%; it is calculated from the equation of the OC Curve or determined by the value on the graphic below.
- It means that the difference between the percentage of defective units P_{10i} accepted by another control check and the percentage of defective units P_{10r} accepted by the reference check may not exceed 15% of $P_{10r.}$
- $|P_{10i} - P_{10r}| < 15\% P_{10r}$

C.3 Comparable sampling checks to the reference test for checking the actual quantity of product laid down in Annex II

According to paragraph 5 of annex I of the directive, a sampling check for checking the actual quantity of product 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 check and the percentage of defective units P_{10r} accepted by the reference test may not exceed 15% of P_{10r}.

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

N (batch size)	**P_{10r}** (Rate of defective items accepted by the sampling plans with a probability of 10%)
$100 \leq N < 500$	13.0 %
$501 \leq N \leq 3200$	10.9 %
N>3200	8.63 %

C.4 Numeric examples

C.4.1 Average check

This section gives an example of how to compare the efficiency of a check with unknown standard deviation for the average quantity requirement with that of the reference test. This check has the following features: sample size is n = 50, risk of the check is α = 0,1

It answers the question: is this check equivalent to the reference test of the directive (α= 0.01, n = 50, λ_{10r} = 56,3%) ?

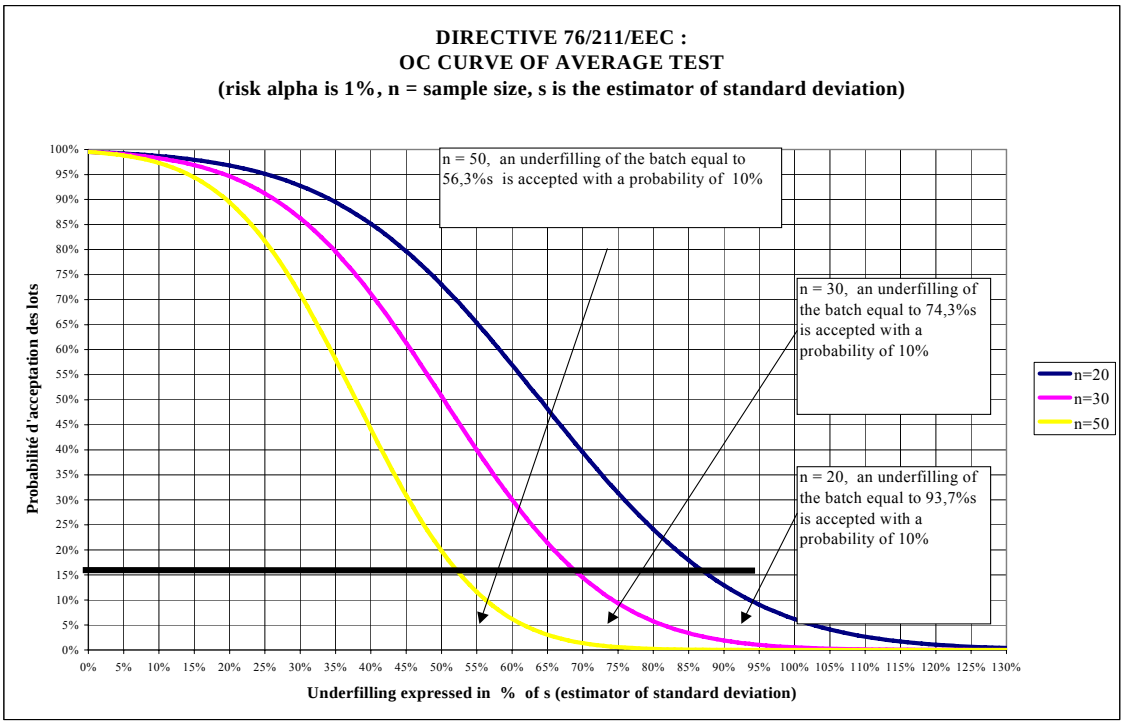
The equation of the operating characteristic curve of this check is

$$P_A = F\left[t_{0.95} - (\lambda_i . \sqrt{50})\right]$$

- 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
- $\lambda_i = -\left[\frac{\mu_s - QN}{s}\right] = \frac{QN - \mu_s}{s}$

λ_i values determined on the OC CURVE or calculated according the OC CURVE equation are:

n = sample size of a check with a 10% risk to reach a wrong decision	**λ_{10i} = (Qn – average actual quantity of product) / standard deviation** (expressed as a % of the estimated standard deviation) accepted with a 10% probability by the reference test of annex II
20	68,4 %
30	55,0 %
50	42,1 %



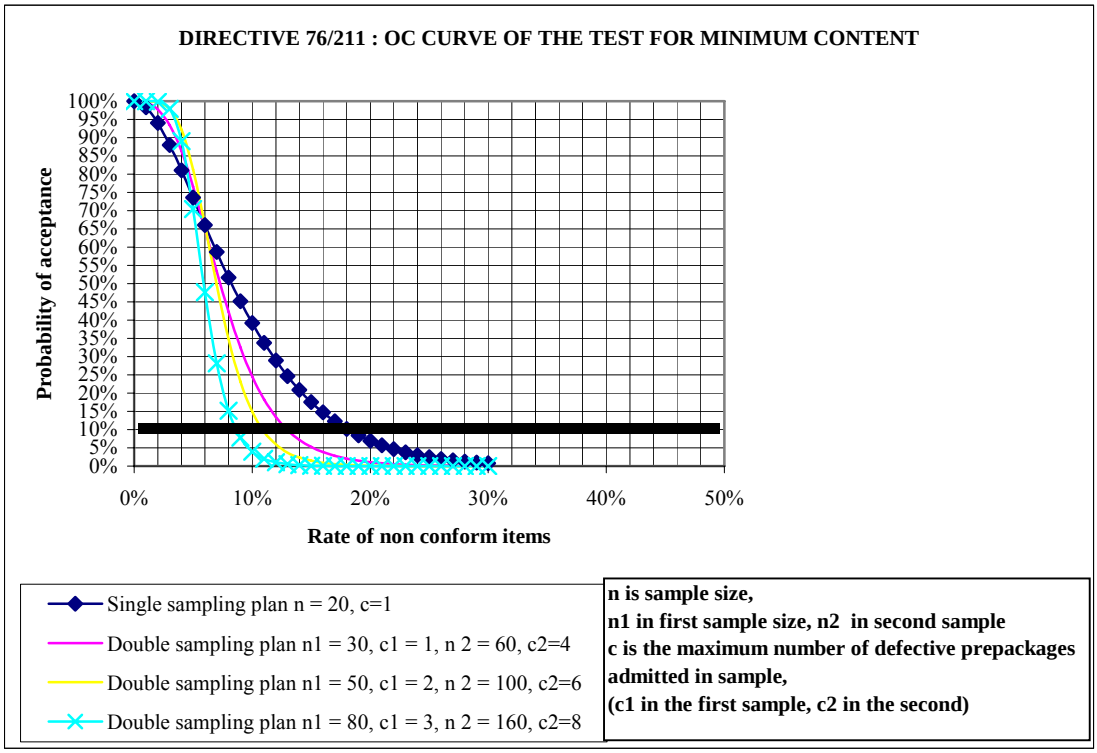
The following table shows the differences between λ_{10i} and λ_{10r}[16] of the reference test. This diagram allows concluding that the efficiencies of the reference test and the check of example 2 are not comparable.

n = sample size of both the reference test of directive 76/211 and the check of example 2	$\lvert\lambda_{10i} - \lambda_{10r}\rvert$	**0.05** λ_{10r}
20	|68.4% - 93.7%| = 25.3%	4.68 % The efficiencies of the two checks are not comparable because 25,3% is greater than 4,68%
30	|55.0% - 74.3%| = 19.3%	3.72 % The efficiencies of the two checks are not comparable because 19,3% is greater than 3,72%
50	|42.1%- 56.3%| = 14.2%	2.82 % The efficiencies of the two checks are not comparable because 14.2% is greater than 2.82%

[16] λ_{10r} Values of are given in annex B.1.

C.4.2 check of actual quantity of individual pre-packages

This section gives an example of how to compare the efficiency of a check of actual quantity of individual pre- packages with that of the reference test. A member state uses the following single sampling plans for minimum content check with AQL = 2.5% (plans extracted from ISO 2859-1).



Numeric example

A member state uses the following single sampling plans for checking minimum content test with AQL = 1.5% (plans extracted from table 7A of ISO 2859-1: 1999).

N (batch size)	**n** (sample size)	**P_{10i}** (Rate of defective items accepted by the sampling plans with a probability of 10%, values given by ISO 2859-1)
$100 \leq N < 500$	32	12,2 %
$501 \leq N \leq 3200$	50	10,6 %
N>3200	125	7,42 %

The question is: Are these tests equivalent to those of the directive 76/211?

In all the cases the difference between the percentage of defective units P_{10i} accepted by the alternative test and the percentage of defective units P_{10r} accepted by the reference test does not exceed 15% of P_{10r}.

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

N (batch size) Of both the reference test of directive 76/211 and the test for this example	**$|P_{10i} - P_{10r}|$** The values of P10i are given on the table above. The values of P10r are given on the table page 17.	**15% P_{10r}** The values of P10r are given on the table page 18
$100 \leq N < 500$	13.0 % -12,2 % = 0,8 %	1,95 % The efficiencies of the two tests are comparable because 0.8% is lower than 1.95% 1
$501 \leq N \leq 3200$	10.9 %- 10,6 % = 0,3 %	1,64 % The efficiencies of the two tests are comparable because 0.3% is lower than 1.65%
N>3200	8.63 % - 7,42 % = 1.21 %	1.29 % The efficiencies of the two tests are comparable because 1.21 % is lower than 1.29%

The test by the member state is accepted since, in accordance with definition A 6a, its efficiency is comparable to that of the reference test of Annex II of this directive.

C.4.3 Screening check in appendix B

This section gives an example of how to compare the efficiency of a check of actual quantity of individual pre-packages with that of the reference test.

For a batch size 47 pre-packages a member state uses the following single sampling plans for the check of the actual quantity of individual pre-packages:

N (batch size)	**n** (sample size)	**Ac** (acceptance criteria maximum of defective items permitted in sample)	**P_{10i}** (Rate of defective items accepted by the sampling plans with a probability of 10%, values given by ISO 2859-1)
47	3	0	53,6 %

Is this check equivalent to the one mentioned in appendix B?

According the principle of equivalence developed in appendix A

P_{10r} for a batch size 47 is 25.0%

$$|P_{10i} - P_{10r}| = 53,6\% - 25.0\% = 28,6\%$$

$$15\%P_{10r} = 8.34\%$$

$$28,6\% > 8,34\%$$

$$|P_{10i} - P_{10r}| > 15\%P_{10r}$$

The sampling plan is **not** equivalent to the one mentioned in annex I of the Directive

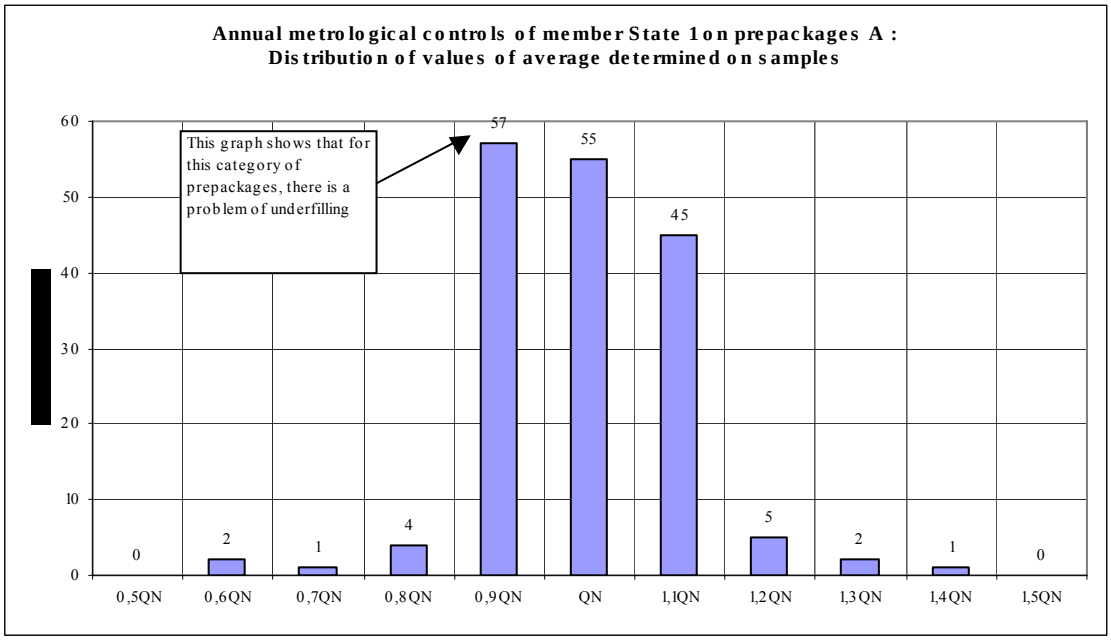
When one of the checks mentioned above fails, it is recommended that investigations be made at the premises of the packer or importer, or the matter be referred to the Competent Department following the protocol in WELMEC 6.0 section 2.

APPENDIX D: ADDITIONAL INFORMATIONS

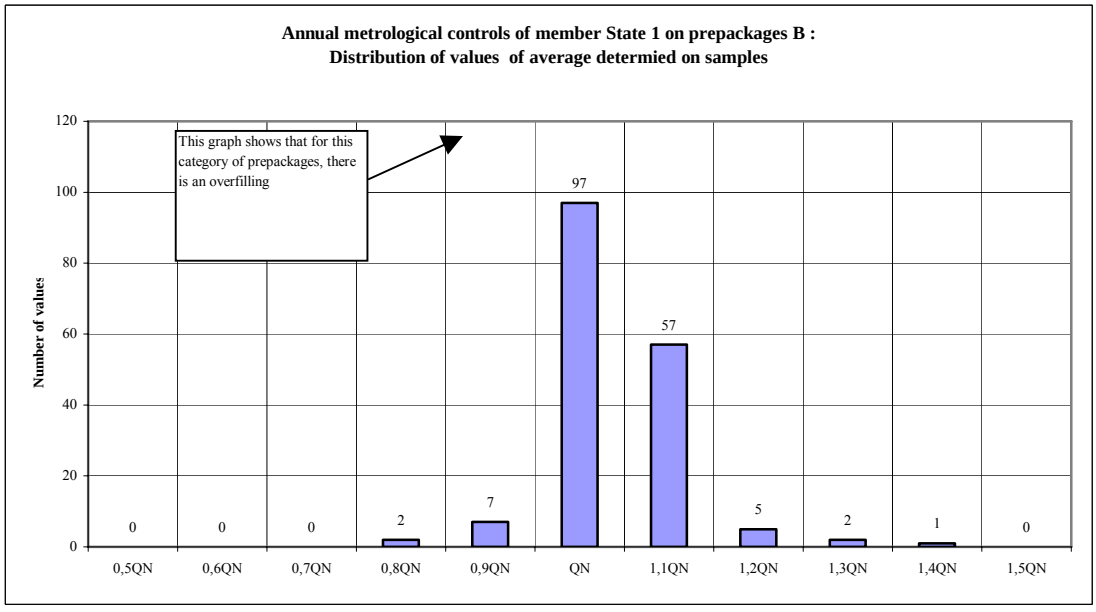
The two diagrams below, present an overview of similar types of products in pre-packages from different packers and in different nominal quantities.

Graphs 1 and 2 give examples of the level of fill from the annual results of the average screening check done each year, on a category of pre-packages inside a member state.

1. Graph identifying pre-packages with underfilling problem



2. Graph identifying good filling process



APPENDIX E: MEASURING INSTRUMENTS

Measuring instruments used for market control by competent departments, and by professionals mentioned in table 2 have to be in compliance with domestic legislation.

For packers packing pre-packages, 'suitable' is defined in WELMEC 6.4

For inspectors, the permitted measurement error is a maximum of 1/5 of TNE of the prepackage

For retail sales, Directive 90/384/EEC may give guidance on the use of non automatic weighing instruments (NAWI) and for other measuring instruments Directive 2004/22/EC (MID) may be relevant dependent on domestic legislative requirements.

APPENDIX F BIBLIOGRAPHY

- *ISO 2854: 1976(E): Statistical interpretation of data – Techniques of estimation and checks relating to means and variances*
- *ISO 2859-0:1995(E): Sampling procedures for inspection by attributes - Part 0: Introduction to the ISO 2859 attribute sampling system*
- *ISO 2859-1:1999(E): Sampling procedures for inspection by attributes - Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*
- *ISO 2859-2-1985(E): Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*
- *ISO 3494:1976: Statistical interpretation of data – Power of checks relating to means and variances*
- *ISO 3951:1989(E): Sampling procedures and charts for inspection by variables for percent nonconforming*
- *ISO/CDTR 8550-1: Guide to the selection of acceptance sampling systems for inspection of discrete items in lot – Part 1: General guide to acceptance sampling*
- Dr Alain Duran, *The Statistical Principles of the Metrological Surveillance of the Net Content of Pre-packages as laid down by the CEE 76/211 Directive,* OIML Bulletin 2004-4.