WELMEC 6.3
Issue 1

# WELMEC

**European cooperation in legal metrology**

# Guidance for the Harmonised Implementation of Council Directive 76/211/EEC

June 2000

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**European cooperation in legal metrology**

WELMEC is a cooperation 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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## Introduction to the document

General
Member states of the European Economic Area have implemented the Council Directives 75/106/EEC of 19 December 1974 and 76/211/EEC of 20 January 1976 in their national legislation. The directives deal with marking and quantity control of e-marked prepackages.

This document is part of a series of documents (to be) published by WELMEC:



This series of documents intends to provide guidance to all those concerned with the application of directives 75/106 and 76/211/EEC on e-marked prepackages.

They will lead to a uniform interpretation and enforcement of these directives and assist in the removal of barriers to trade.

## Disclaimer

Please note that this series of documents does not deal with matters not covered by the above directives, such as requirements for certain products to be made up in prescribed quantities, and controls on non e-marked packages.

**Format of Document**

This document is divided into four parts:

Part 0 : Introduction, methodology, and definitions
Part 1 : Annex I to Council Directive 76/211/EEC
Part 2 : Annex II to Council Directive 76/211/EEC
Part 3 : Issues not specifically covered by the Directive.

## PART 0 : Introduction, methodology and definitions

**0.1** At the meeting of the Working Group held on 22 May 1997 Resolution 44 required that a document be produced specifying how signatories to the WELMEC Memorandum of Understanding would like to implement Directive 76/211/EEC, (the Directive). It was appreciated that Directive 75/106/EEC was phrased in a similar manner.

**0.2** The document produced as a result of pexc-04 version 9, dated 19 November 1997, was to be used as a basis for this document. Members were asked to consider each part of the Directive and agree acceptable ways of implementing the requirements in a practical manner, but which would also give confidence to them that 'e' marked products, in quantities of 5 g to 10 kg or 5 ml to 10 l, would comply with the Directive.

**0.3** The Working Group recognised the importance of international trade and at their meeting of 15 May 1998, agreed that the World Trade Organisation acceptance of OIML Recommendations be reflected in its work. Consequently OIML Recommendations[1] have been noted in this document for guidance, it being recognised that domestic legislation may differ from these recommendations. It is also recognised that only the Courts can definitively interpret the legislation, and this document does not affect domestic legislation. It is a recommendation based on the opinions of the experts in the Working Group.

**0.4** To assist in cross-referencing, the wording from the Directive is in italics and the paragraph numbers in Parts 1 and 2 relate to the paragraph reference in the appropriate Annex of the Directive. It will be evident that not all of the Directive's Annexes have been quoted, these parts contain non-contentious requirements or definitions accepted as written.

**0.5** The aims of this document are:

a) to clarify the Directive where it is vague, to lay down guidelines for the EU when the Directive is reviewed, and to assist in removing any problem areas.

b) In due course to assist WELMEC countries in aligning their legislation to remove any barriers to trade,

c) to assist other Countries wishing to implement quantity controls that will enable packages to comply with the Directive.

[1] OIML R 79, Labelling requirements for prepackaged products, and
OIML R 87, Net content in packages

## 0.6 Definitions - see WELMEC document 6.1 and the International Vocabulary of Basic and General Terms in Metrology (VIM)

***Actual contents of the prepackage are the quantity of product which it in fact contains[2].*** **This should be taken as the actual net content of the prepackage. Procedures for verifying the actual contents are set down in the Annex II to the Directive.**

**Identified product**
**the product that is specified on the package as being contained within the package, exclusive of wrappers and any other material contained within the package.**

**Importer**
any person who places on the EEA market a product from a third country, which is covered by a relevant Directive.

***MCB***
***measuring container bottle, a bottle whose volume and labelling comply with the Council Directive 75/107/EEC.***

**Net content**
the net quantity of the commodity in the package exclusive of wrappers and any other material packed with such commodity[3].
Where food has been glazed, the declaration of net contents of the food shall be exclusive of the glaze. Similarly the net content shall be exclusive of any wax put on cheese after its manufacture.

The Working Group resolved that the Directive should be amended to read that 'individual package'[4] is everything that is meant to be left after use, except for items naturally present in the product. Furthermore that for products marked with the net drained weight required by Directive 79/112, this quantity should be regarded as the nominal quantity and should be 'e' marked as such.

***Nominal quantity of the content of a prepackage is the weight or volume indicated on the packaging, i.e. the quantity of product which the prepackage is deemed to contain[5]***.
This should be taken as the identified net quantity of the identified product in the package exclusive of wrappers and any other material packed with such product. Nominal quantity relates to marking on packages and does not account for the actual contents in individual packages.

**Packer**
the term packer is applied in the directives with a broad definition, as the person responsible for the packing.

***Prepackage***
*a package containing product which is placed in a package of whatever nature without the purchaser being present and the quantity of product contained in the package has a*

[2] 76/211/EEC Annex I para 2.2
[3] OIML R79 para 1.2
[4] 76/211/EEC article 2
[5] 76/211/EEC Annex I para 2.1

*predetermined value and cannot be altered without the package being opened or undergoing a perceptible modification.*[6]

[7] Prepackaged product is any commodity that is enclosed in a container or wrapped in any manner, and for which its quantity has been determined and indicated on its label prior to being offered for sale.

**Principal display panel**
the part of the package that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display.[8]

**Product**
is that which is described on the packaging as to what the package contains.

**Verified**
means verified to comply with the requirements of an appropriate Directive. For equipment for which there is no relevant Directive it means testing and approval by a competent organisation.

**Wrappers and any other material**
is anything, which is not part of the identified product and is contained within the package, it may be present for the purpose of protecting, preserving or consuming the identified product.

**Wrapping**
a package of whatever nature which encloses the product. With regard to food, if the wrapping is intended to be eaten it is treated as part of the net contents.

[6] 76/211/EEC art. 2.2

[7] OIML R79 para 2.1

[8] OIML R79 paragraph 2.4

**PART 1 : Annex I to Council Directive 76/211/EEC**

**1.** ***OBJECTIVES***
***Prepackages covered by the Directive shall be made up in such a way that the completed packages satisfy the following requirements.***

**1.1** ***"the actual contents shall not be less, on average, than the nominal quantity"***

The nominal quantity refers to the net nominal quantity.

The packers/importers can decide for themselves what quantity control system they use as long as the competent department is satisfied with it.

The prepackages shall be capable of passing a reference test whose effectiveness is comparable to the reference method. The reference test shall be carried out by the competent department and shall be performed on a sample drawn from:

a) when sampled after the packing line, consist of 1 hour's production, or a lesser time if the whole batch is packed in this period, or
b) when sampled once the packages have left the packing line, consist of up to 10,000 packages from the same batch.

**1.2** ***"the proportion of prepackages having a negative error greater than the tolerable negative error laid down in 2.4 shall be sufficiently small for batches of prepackages to satisfy the requirements of the tests specified in Annex II."***

The 'tolerable negative error' for each nominal quantity is specified in paragraph 2.4 of Annex 1 of the Directive. The quantity which is one tolerable negative error below the nominal quantity is sometimes referred to as 'TU1'.

A 'defective prepackage' is one whose contents is below TU1.
For these purposes 'sufficiently small' should be taken to mean that not more than 2.5% of the prepackages in the batch may be defective and the reference test in 2.3 of annex II is also satisfied.

NOTE: Reference tests are only for the Competent Department to use, they may not be used by Packers or Importers to show compliance with the Directive.

**1.3** ***"no package having a negative error greater than twice the tolerable negative error given in the table in 2.4 may bear the EEC sign provided for in 3.3"***

The quantity which is two tolerable negative errors below the nominal quantity is sometimes referred to as 'TU2'.

Solely for the purposes of setting up a quantity control system, it will be considered acceptable if the probability of producing one prepackage below TU2 is not more than 1 in 10,000.
NOTE : There is no equivalent minimum quantity requirement in OIML R87.

## 3. *INSCRIPTIONS AND MARKINGS*

***All prepackages made up in accordance with this Directive shall bear on the package the following markings affixed in such a manner as to be indelible, easily legible and visible on the prepackage in normal conditions of presentation:***

OIML[9] recommends that the statement of the net quantity shall appear on the principal display panel in easily legible boldface type or print that contrasts conspicuously with the background and with other information on a package; however, when the value of the net quantity is blown, embossed or moulded on the surface of the package, then all other required label information shall be provided conspicuously elsewhere on the surface or on a label.

### 3.1 "*The nominal quantity (weight or volume)..*"

[10] The quantity should be in terms of volume for liquid, or viscous products and mass for solid, sem-solid or viscous product. For aerosols the OIML recommends that the quantity stated should be the net quantity in mass that will be expelled when instructions for use are followed. The propellant is included in the net quantity statement. For current legislative requirements see Part 3 paragraph 0.4.

### 3.2 *"a mark or inscription enabling the competent departments to identify the packer or the person arranging for the packing to be done or the importer established in the Community."*

The minimum requirement is for the name or mark, together with the post code or a geographical code. This marking must be 'easily legible and visible on the prepackage in normal conditions of presentation'.
Other vertical Directives may require extra information such as the full address, or address of the Registered Office to be supplied. The OIML recommends that when the name is not that of the packer or importer the name may be qualified by a phrase that reveals the connection such person has with the product, for example "manufactured for...". [11]

Other legislation may require the Country of Origin to be stated on the label when the product is manufactured outside the EEA.

### 3.3 *"a small 'e', at least 3 mm high, placed in the same field of vision as the indication of the nominal quantity...."*

Only one of the quantity declarations is considered to be the 'nominal quantity' and the 'e' mark should be in the same field of vision. This combination must be 'easily legible and visible on the prepackage in normal conditions of presentation'.

In addition to the metric quantity other quantity markings, not in the metric system, are permitted on the label as long as they are not misleading.

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[9] OIML R 79 para 5.5.2

[10] OIML R79 para 5.3

[11] OIML R79 para 4

## 4. *RESPONSIBILITY OF THE PACKER AND IMPORTER.*

**4.1** ***"The packer or importer shall be responsible for ensuring that the prepackages meet the requirements of this Directive.***"

For packages produced in the EEA, the packer is responsible for meeting this requirement.

For packages produced outside the EEA, the first importer based in the EEA is responsible for meeting this requirement.

Domestic legislation may specify whether the company or individual employee is held responsible.

**4.2** ***"The quantity of product contained in a prepackage (or packing quantity), known as the 'actual contents', shall be measured or checked by weight or volume on the responsibility of the packer and/ or importer."***

The 'actual contents' shall be taken to be the net contents.

An importer may contract with another person to carry out the necessary checks on his behalf. The checks must be carried out before the packages leave his possession. The importer remains responsible for meeting this requirement and needs to ensure that the checks and records made are adequate.

**4.3** ***"The measurement or check shall be carried out by means of a legal measuring instrument suitable for effecting the necessary operation."***

Where the type of equipment used is controlled by legislation, then it must be verified and checked thereafter to ensure that it continues to comply with those legislative requirements.

Other equipment shall only be used if permitted by the competent department and shall be:
a) calibrated by an agreed method, or
b) certificated by an approved body
in both cases demonstrating traceability and uncertainty of measurement.

The value and uncertainty obtained shall be taken into account. The total uncertainty of measurement ( at the 95% confidence level ) for the measurement being made shall not exceed one-fifth of the tolerable negative error of the prepackage. The requirements on measurement uncertainty can be reduced if the packer compensates by overfilling.

The measurement equipment must be selected in a way that takes into consideration the **total** measuring uncertainty. When considering the measurement uncertainty all components and circumstances that can influence the measurement result, such as equipment, environment and tare, should be included.

It is recognised that the errors on mcb exceed one-fifth of the tolerable negative error.

Tolerances shall not be exploited.

**4.4** ***Where the actual contents are not measured, the checks carried out by the packer shall be so organised that the quantity of goods is effectively ensured.***
***This condition is fulfilled if the packer carries out production checks in accordance with procedures recognised by the competent departments in the Member State...”***
This paragraph does **not** apply to prepackages where each one is made up using legal and suitable equipment where the packer ensures that the actual contents of each prepackage is greater than the nominal quantity (minimum system). In this instance no records are required to be made.

There must be a documented adequate quantity control system, which domestic legislation may require to be recognised by a competent department.

For the system to be adequate it must:

a) specify the system from setting up, to monitoring and regular reviewing,
b) justify the targets and limits,
c) contain a procedure to be followed when limits are breached
d) require records to show that it is being followed

Suitable measuring equipment is listed in appendix 1.

**4.5** ***"...he holds at the disposal of those departments the documents containing the results of such checks, in order to certify that these checks, together with any corrections and adjustments which they have shown as necessary, have been properly and accurately carried out."***

The records must be made available on demand from an Inspector. They may be held on any type of media as long as their security is guaranteed and they are accessible in a readable and easy to understand state.

The records must contain process capability data, the monitoring data and any corrective actions taken for each batch of product. The records required to be kept are listed in appendix 2.

The records must be kept for at least 1 year, but it may be in the interest of the packer or importer to keep records longer to answer queries relating to older stock.

**4.6** ***"In the case of imports from non-EEC countries, the importer may instead of measuring and checking provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility***

The importer must provide a certificate stating the compliance of the packer’s quantity control system to the Directive for each type of product.

In the case of checking prepackages (and not measuring the quantity going into each package) the importer, when requested by the competent body, shall present the same kind of records from the production line that are required for products packed within the EEA.

The certificate can be issued by either:
a) the competent department in a Member State, or
b) an EU accepted competent department in the exporting country.

NOTE: Regardless of which alternative is used, this does not prevent the competent department in the importing country from performing tests in accordance with Annex 1 point 5 of the Directive.

***4.7 "In the case of products in quantities expressed in units of volume, one of several methods of meeting the measuring and checking requirements is to use, when making up the prepackage, a measuring container of the type defined in the Directive relating thereto, filled under the conditions prescribed in that Directive and herein"***

The verification, or certification, of the templets must include the indications of nominal volume, the tolerance marks TU1 and TU2, the unit of measurement, the identification of the bottle type, the type of enclosure to be used and, if it is not at used at 20 $^{o}$C, the reference temperature and co-efficient of cubical expansion of the liquid. The templet should be used only for the bottle for which it was designed.

For the templets to be suitable they should be graduated in millilitres or if in millimetres there must be a calibration curve to give the corresponding volume.

For the MCB to be suitable for testing with templets the dimensions of the neck between TU2 and the nominal quantity should be such as to move the meniscus at least 1 mm when a volume of liquid equal to one fifth TNE is added. There should be no distortion of the meniscus in this range so that the meniscus is visible and can be measured to $\pm$ 1 mm.

There will be a fuller consideration of the use of mcb in WELMEC document 6.6.

## 5 *CHECKS TO BE CARRIED OUT BY THE COMPETENT DEPARTMENT ON THE PREMISES OF THE PACKER OR IMPORTER*

***Checks to ensure that prepackages comply with the requirements of this Directive shall be carried out by the competent departments of the Member States by sampling on the packers' premises, or if this is not practicable, on the premises of the importer or his agent established in the Community.***

The checks should cover the adequacy of the quantity control system, confirm that it was being followed, and that its appropriateness had been regularly reviewed. This will include:

a) the accuracy and suitability of the equipment and whether it was adequately maintained,
b) the adequacy of the records, and their accuracy by checking packages from that batch,
c) the labelling of the product,
d) the quantity in packages.

Generally checks on 'e' marked products should be carried out at packers' and importers' premises at least once a year

***This statistical sampling checks shall be carried out in accordance with accepted methods of quality acceptance inspection. Its effectiveness shall be comparable to that of the reference method specified in Annex II.***

Other sampling plans are in use, see appendix 3.

## 6 *OTHER CHECKS CARRIED OUT BY THE COMPETENT DEPARTMENTS*

***This Directive shall not preclude any checks which 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 prepackages meet the requirements of the Directive.***

Checks on the net quantity in prepackages need to bear in mind the statistical significance of the results.

Checks may also be made on the compliance with other requirements such as labelling.

Concerning 'desiccating' products, refer to Part 3 of this document.

**PART 2 : Annex II of Council Directive 76/211/EEC**

***This Annex lays down the procedures of the reference method for statistical checking of batches of prepackages in order to meet the requirements of Article 3 of the Directive and of section 5, Annex I thereto***

**1. *REQUIREMENTS FOR MEASURING THE ACTUAL CONTENTS OF PREPACKAGES***

Error refers to the uncertainty of measurement. The expanded combined standard uncertainties ( k=2) for the measurement should not exceed one-fifth of the TNE.

**2. *REQUIREMENTS FOR CHECKING BATCHES OF PREPACKAGES***

***2.1 Prepackage batches***

***2.1.2 When prepackages are checked at the end of the packing line, the number in each batch shall be equal to the maximum hourly output of the packing line, without any restriction as to the batch size.***
***In other cases the batch size shall be limited to 10,000.***

This definition is only for inspectors carrying out reference tests. Tests can be applied as soon as prepackages are available.

## PART 3 : Issues not specifically covered by the Directive

### Introduction

The delegates of the Working Group have experienced various problems when enforcing the provisions of the Directive and other issues not addressed by the Directive. This Part of the document gives guidance on those issues and is mutually accepted by the delegates. It is envisaged that these issues could be resolved when the Directive is next updated, and that the terminology should be in line with VIM, the international vocabulary of metrology.

### .1 Quantities to be controlled

It is accepted that most countries have extended the 'average system' to cover packages over 10 kg or 10 l using the following TNE which are found in OIML R87:

| Nominal quantity range | Tolerable negative error |
|---|---|
| 10 kg to 15 kg | 150 g |
| 10 l to 15 l | 150 ml |
| 15 kg to 25 kg | 1 % |
| 15 l to 25 l | 1 % |

Until these products are controlled by the Directive they should not be 'e' marked.

Under 5 g or 5 ml the minimum system should be applied as the tolerable negative errors become too significant.

There may be a need for some products, such as coal, to be given limits up to 100 kg or 100 l.

### .2 Desiccating Products

Product which, even though in packages, can diminish in quantity by evaporation ,whether of the product or of an ingredient, are referred to as desiccating products. Examples are soap, cheese, sausages, bread and white spirit.

At the time such product is put on the EEA market, whether by the packer or importer, the product shall comply with the requirements of the Directive.

Thereafter the quantity in the package shall not reduce below TU2 at any time while being offered for sale.

The packer should be able to substantiate that the product, as packaged, is a desiccating product.

Ideally the labelling should make it clear to the consumer that the product desiccates

When the Directive is updated the time at which the 'packer's rules' apply need to be clarified.

OIML[12] recommendations implies the goods only have to be correct when leaving the packers / importers possession.

[12] OIML R 87 paragraph 2

**.3 Product contained in a liquid medium**

The drained weight of the product must comply with Directive 79/211 (amended by Directive 89/895) once an accepted test method and tolerances have been agreed.

**.4 Product in aerosols**

The original Directive on aerosol dispensers required both weight and volume to be declared. The weight of the product (including propellant) can easily be determined. Directive 80/232/EEC gave a derogation to aerosols made up in prescribed quantities and in prescribed capacity dispensers to display only the volume. This may be justified on the grounds of safety and obviating deceptive packaging but makes quantity checking very difficult and expensive. OIML[13] recommended that a weight declaration is made, that being the quantity expelled.

**.5 Misleading Practices**

If the quantity in a package (the nominal quantity) is reduced by packers it is important that consumers are not mislead in any way. Recent research has shown that consumers pay more heed to the size of the packaging than the declared nominal quantity. Section 6 of OIML R79 endeavours to ensure consumers are not misled and that packers have fair competition by setting out the following recommendations:

*6.1 Fill level*
Packages should be filled in such a manner that a purchaser may not reasonably be misled with respect to the quantity or identity of the product it contains, taking into consideration any recognised and accepted production practices that may be necessary for the manufacturer or packer.

*6.2 Package design and display*
Packages shall be manufactured, constructed or displayed in such a manner that a purchaser may not reasonably be misled with respect to quantity or identity of product contained therein.

*6.3 Labelling*
If the prepackaged product is labelled on more than one location of its package, the information on all labels shall be equivalent and in accordance with the requirements of the Directive.'

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[13] OIML R 79 paragraph 5.3.2

## Appendix 1 Equipment permitted to be used by packers and importers

**For all equipment**
All calibrations shall be traceable to national or international standards, and certificates shall specify the measurements and the uncertainty of measurement.

The equipment shall be deemed suitable if the **total** expanded uncertainty of measurement (k=2) in the system does not exceed one-fifth TNE, unless the quantity control system targets guarantee an overfill.

All equipment shall be maintained to ensure accuracy, and be periodically calibrated, or re-verified if required by domestic legislation. The calibration period should not exceed the period over which the user can prove ( from previous records ) that the equipment will not exceed any permitted error range or agreed tolerance.

**Equipment used for making up packages** (that is where each pack's contents is measured) must be verified as complying with the legislation or, where not under legislative control, it must be approved or certificated by the competent department for that purpose.

**Equipment used for checking packages** (where only a sample of packages is tested) shall be:
a) non-automatic weighing instruments must comply with Directive 90/384, or previously applicable legislation, and be verified.
b) automatic weighing instruments must comply with domestic legislation which may require conformity to type and verification.
b) volume measures shall be verified or calibrated in accordance with domestic legislation.
c) templets for use with MCB, verified or calibrated in accordance with domestic legislation.
d) thermometers and density meters shall be verified or calibrated in accordance with domestic legislation.

## Appendix 2 Records required to be made and kept by the packer.

### 1 Identification and specification of product

1.1 product identity

Batch data

1.2 batch identity
1.3 batch size
1.4 density, if applicable
1.5 nominal quantity

and where checks are carried out on finished product:-

1.6 target value, or set points for checkweighers
1.7 average quantity control limits
1.8 process variation limits
1.9 tare variability and other allowances
1.10 for checkweighers- the zone of indecision, checks on data collection and calculations

### 2 In production checks

2.1 identification of checkpoint / packing line
2.2 reference to product identity
2.3 batch identity
2.4 time of sampling
2.5 number of packages in a sample
2.6 tare if applicable
2.7 average and variance of actual net contents (sample data)
2.8 average and variance of actual net contents (batch data)
2.9 number (%) of packages below TU1, and corrective action taken when >2.5%
2.10 number (%) of packages below TU2, and corrective action taken.
2.11 for checkweighers - checks on set points, to ensure no drift.

### 3 Batch tests (small production)

3.1 As in 2 above except 2.7 and 2.8 will be the same.

### 4 Corrective action & review

4.1 Records showing isolation of suspect packages; rectification or disposal
4.2 Review of the quantity control system at least annually, or when ever the production line or product changes.

### 5 Storage

Sample data shall be stored for at least one year, cumulated and general data shall be kept for one year after the expiration of the lifetime of the product (unless otherwise specified by legislation or certification of the system).

**Appendix 3**

**.1 Tests comparable to the reference tests.**

Other sampling plans are acceptable if they meet the requirements of equivalence stated in annex 1 point 5 of the Directive. Countries introducing such plans should be able to provide documentary evidence that the requirements are met.

Acceptable sampling plans are:

A single sampling plan for defective units (non-standards packages) introduced by UK and Germany.

A single sampling plan for defective units (non-standard packages) is specified, the criteria being:

| Number in group | Number in sample | Acceptance criteria | Rejection criteria |
|---|---|---|---|
| 100 to 500 | 50 | 3 | 4 |
| 501 to 3200 | 80 | 5 | 6 |
| over 3200 | 125 | 7 | 8 |

The German sampling plan also has different acceptance criteria for the average quantity based on the weights of all the items in the sample ( using the appropriate k value), and not just a sub-sample of 50.

A destructive double sampling plan is used by Belgium and the Netherlands. The test for the mean is carried out on the total number of packages weighed (which could be 60,100 or 160) with the appropriate t-factor. This is different from the criteria stated in the Directive at Annex II paragraph 2.3.3.

| No in batch | Sample order | Sample size | Total number | Acceptance criteria. Mean $\geq Q_n$ - ..... |
|---|---|---|---|---|
| 100-500 | 1 st | 30 | 30 | 0.503 s |
| | 2 nd | 30 | 60 | 0.334 s |
| 501-3200 | 1 st | 50 | 50 | 0.379 s |
| | 2 nd | 50 | 100 | 0.263 s |
| 3201- | 1 st | 80 | 80 | 0.296 s |
| | 2 nd | 80 | 160 | 0.204 s |

### .2 Tests on groups less than 100 packages

The Directive applies to batches of 100 or more and does not specify a sampling plan, nor criteria, for batches less than 100 packages.

A non-destructive test for batches containing less than 100 prepackages was provided by Sweden.

For defective prepackages:

| Number in batch | Sample size | Acceptance criteria | Rejection criteria |
|---|---|---|---|
| <40 | whole batch | 0 | 1 |
| 40-79 | whole batch | 1 | 2 |
| 80-99 | whole batch | 2 | 3 |

For the mean:

| Number in batch | Sample size | Acceptance criteria | Rejection criteria |
|---|---|---|---|
| Regardless of number | whole batch | mean $\geq Q_n$ | mean $< Q_n$ |