Project
funded by the EU

Development of Quality Infrastructure
and Metrology - Montenegro

adetef.
Assistance Technique France

A project implemented by ADETEF in
consortium with LNE and SMU

LEGISLATION CONCERNING PRE-PACKAGED PRODUCT (PPP) IN EU

Mojca Požar, Short Term Expert

Podgorica, 15.11. 2013

Project funded by the EU

A project implemented by ADETEF in consortium with LNE and SMU

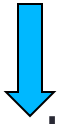
CONTENT

- PPP directives – reason, purpose, introducing
- Basic definitions
- Responsibility
- Metrological requirements for packers and importers: quantities, marking, measuring instruments, system of internal quantity control
- Metrological supervision over PPP
- Measuring container bottles
- Implementation of PPP directives in national legislation
- Metrological organisations concerning PPP

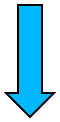
PPP DIRECTIVES - reason

Huge market with PPP

(annual turnover, variety of products)



Automatic packing process



Uniform criteria for difference of content between actual content and marking content on a package

PPP DIRECTIVES - porpuse

- **Consumer protection**

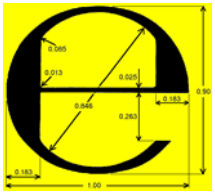
  (reliable measurement and quantity indications)
- **Fair trade and competition**

  (clear rules equally applied to all, efficient supervision)
- **Free movement of goods**

  (increased world trade, same products in all EU-harmonised legislation)

PPP DIRECTIVES (e-directives)

75/106/EEC (V, range) — repealing → **76/211/EEC** (m, V) ← amending — 80/232/EEC (range) ← repealing — + 8 amend.



2007/45/EEC (range) :
11 April 2009 – in use in member states

BASIC DEFINITIONS

Prepackage, pre-packed product, pre-packaged product (PPP)

is combination of a product and any individual package. The product is packed in consumer's absence and the containing quantity has some in advance defined value, which cannot be changed, unless the package is damage or open.

BASIC DEFINITIONS

- **Package** is container or wrapper in which the products was placed into market /everything, which is thrown away, when product is consumed, with the exception of ingredients, which are naturally present in the products.
- **Nominal quantity, Qn** is mass or volume indicated on the package, i.e. the quantity of product which the PPP is deemed to contain.
- **Actual quantity (contents)** is mass or volume of products, actually contained in the PPP.

BASIC DEFINITIONS

- **Batch** are PPPs of the same Q_n, the same type and the same production run, packed in the same place, which are checked.

- **Tolerable negative error, TNE** is fixed quantity by which the actual content of PPP are less than Q_n. Its value we calculate or read from the table.

RESPONSIBILITY

That PPPs fulfil requests of the directives is responsible:

- **Packer** – person in EU, responsible for the packing

- **Importer** – any person who place on the EEA market a PPPs from third country.

TARGET PPP

“e”- directives valid for PPI:

1. with **uniform** nominal quantities
2. marked with units for **mass** or **volume**
3. in the range of packing **from 5 grams / millilitres**
   up to 10 kilograms / litres.

BASIC METROLOGICAL REQUESTS (BMR)-QUANTITIES

1. **Average** of the actual of PPPs is not smaller than the nominal quantity

2. Only small proportion (2,5%) of batch of PPP can exceed the **tolerable negative error** (**TNE**) and limit T_1 for defective products.

3. **None PPP**, marked with "**e**" mark, is allowed to exceed the double tolerable error (2TNE) and limit T_2.

BMR-QUANTITIES

Nominal quantity, Q_n g / ml	Tolerable negative error, TNE	
	% Qn*	g / ml
5 - 50	9	/
50 - 100	/	4,5
100 - 200	4,5	/
200 - 300	/	9
300 - 500	3	/
500 - 1000	/	15
1000 - 10000	1,5	/

* Rounded up to the nearest tenth of g/ml

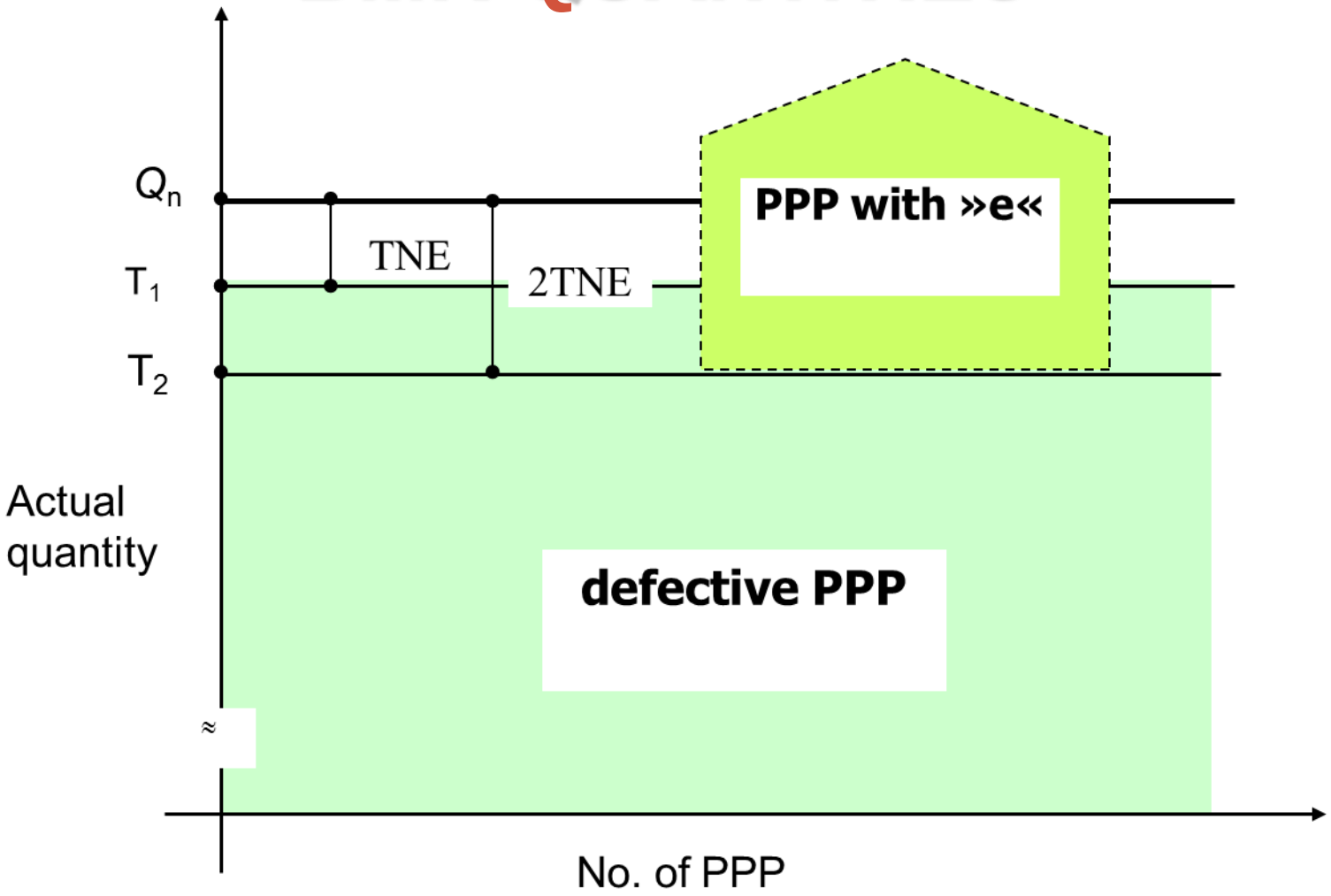
Example:

- Q_n = 150 ml ⟹ TNE = 4,5 % = 6,8 ml; T_1 = 143,2 ml; T_2 = 136,4 ml
- Q_n = 250 g ⟹ TNE = 9 g; T_1 = 241 g; T_2 = 232 g

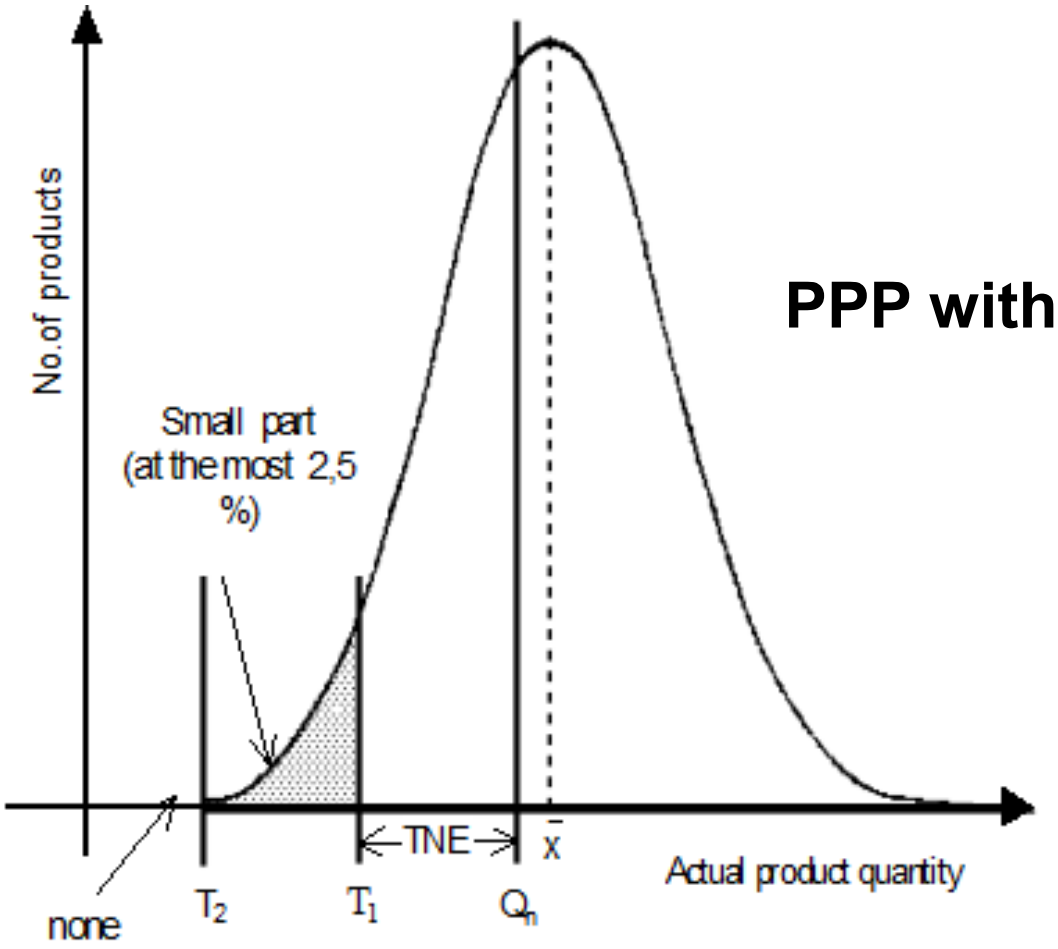
Project
funded by the EU

A project implemented by ADETEF in
consortium with LNE and SMU

BMR-QUANTITIES



BMR-QUANTITIES



PPP with „e“ mark

ACTUAL QUANTITIES DETERMINATION

Two different way:

- **Non-destructive testing**
  (it is no need to destroy a package)

- **Destructive testing**
  (we have to destroy a package)

ACTUAL QUANTITIES DETERMINATION

Methods:

- Determination of PPP and **average** package
- Determination of PPP and **individual** package
- Determination of content (filled direct into measure)

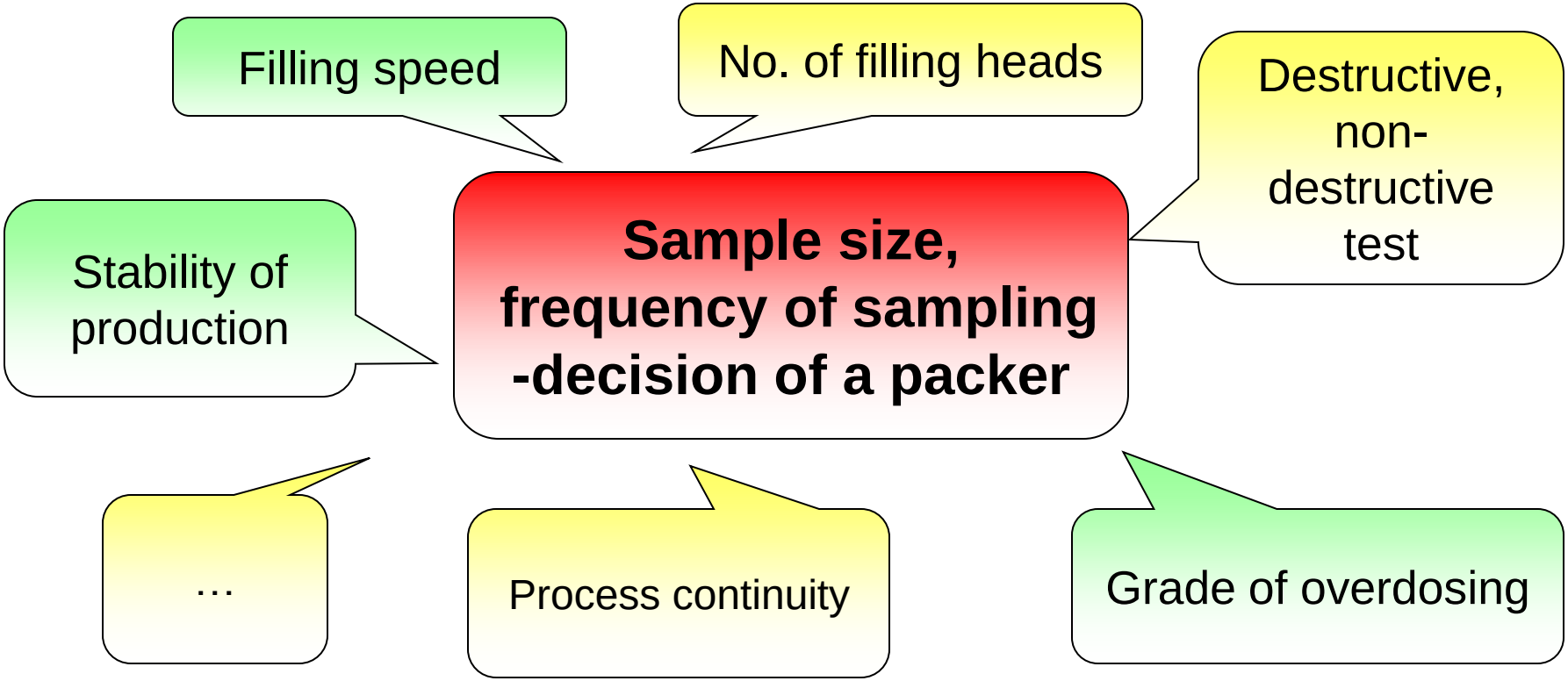
Packed in vacuum and protective atmosphere: non-real mass

ACTUAL QUANTITIES DETERMINATION

- **Measuring or 100 % control**
  (automatic balances with a records…)

- **Sampling**

ACTUAL QUANTITIES DETERMINATION



ACTUAL QUANTITIES DETERMINATION

Result procesing:

- manually
- **automatically**

Results:

- **average** (and standard deviations)
- **number (%) of defective PPP** (under T_1)
- (number of PPP under T_2)

MARKING ON PACKAGE

- Nominal quantity of content
- Name or recognisable marking of the packer / importer
- “e” mark

Have to be imprinted indelible, easily readable and at normal conditions visible

MARKING – NOMINAL QUANTITY

100 ml

Number:	**Units of measuring**:
100, 200, 250,	gram, kilogram
1, 2,…	mililitre, centilitre, litre

Imperial units of measuring (ounces, pounds, fluid ounces, pints, gallons) not dominate

MARKING – NOMINAL QUANTITY

Nominal quantity (g / ml)	Minimum number size (mm)
Up to 50	2
Over 50 to 200	3
Over 200 to 1000	4
Over 1000	6

MARKING – NOMINAL QUANTITY

Symbols of Units of measuring- correct writing:

- g, kg
- ml, mL, cl, cL, l, L

Not correct:
G, KG, Ml, ML, Cl, CL,
g, *kg*, g., L., k g, c l,...

MARKING – NOMINAL QUANTITY

Way of marking on a package:

500 ml

Also permitted:

Content: 500 ml

Net quantity/volume: 500 ml

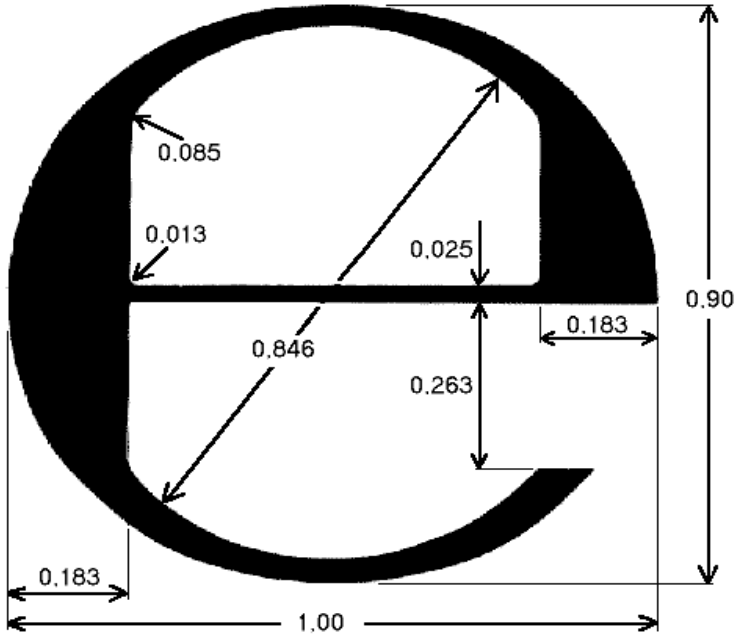
Net: 500 ml

etc.

~~Net weight~~

MARKING – „e“ mark

Shape:



Size: at least 3 mm

Location: in the same visual field as mark of Q_n

“e” mark **is not mandatory**

MARKING – RANGE OF NOMINAL QUANTITIES

Mandatory ranges for:

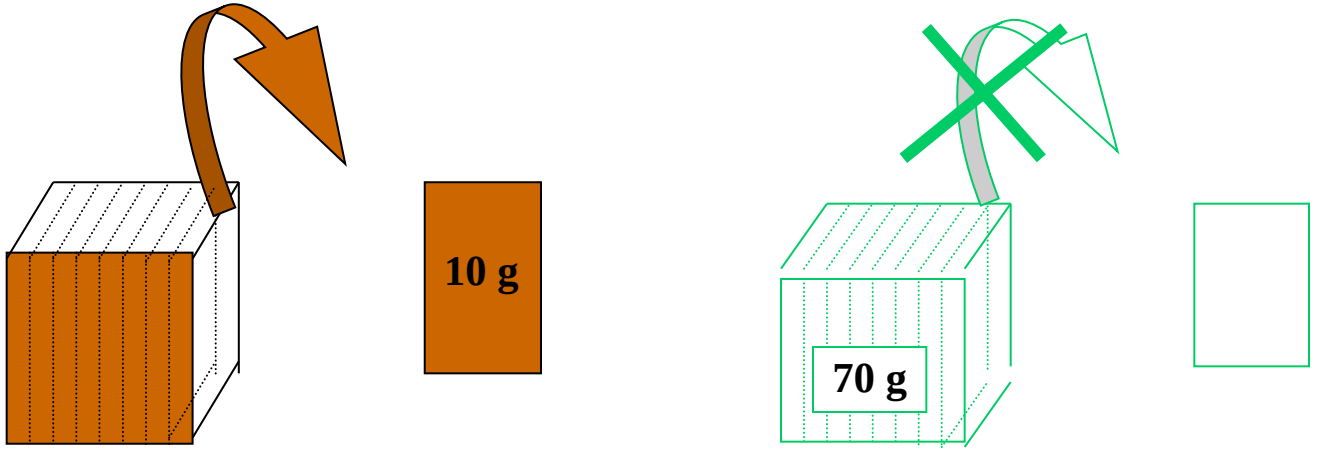
- Still wine (ml):100-187-250-375-500-750-1000-1500
- Yellow wine (ml): 620
- Sparking wine (ml): 125-200-375-750-1500
- Liqueur wine (ml): 100-200-375-500-750-1000-1500
- Aromatised wine (ml): 100-200-375-500-750-1000-1500
- Spirit drink (ml): 100-200-350-500-700-1000-1500-1750-2000

Directive (2007/45/EEC, annex)

MARKING – MULTI-PACKAGES

Valid for PPP with mandatory ranges –

directive (2007/45/EEC, annex)



MEASURING INSTRUMENTS

Must be:

- **Verified** (if measuring instruments is part of legal metrology – usually NAWI and AWI)
- **Calibrated** (in other cases – usually for density, volume and temperature determination)
- **Suitable** (scale division, type of products)

MEASURING INSTRUMENTS

Verification	Calibration
■Protection against non-authorised intervention ■To keep metrological characteristics until to next verification ■MPE ■Prescribed fixed term of re-verification ■Prescribed procedures	■Results valid in time of measuring ■Uncertainly of measuring ■Not prescribed period for re-calibration ■Procedures are depend of a performer

MEASURING INSTRUMENTS

Recommended scale division for weighing instruments and volumetric measures:

Error ≤ 1/5 TNE

(obligation for reference method)

M. uncertainty

Nominal quantity [g] or [ml]	**Scale division** [g] or [ml]
5 and more	0,1 or less
15 and more	0,2
35 and more	0,5
125 and more	1,0
350 and more	2,0
1750 and more	5,0
3500 and more	10,0
7000 - 10000	20,0

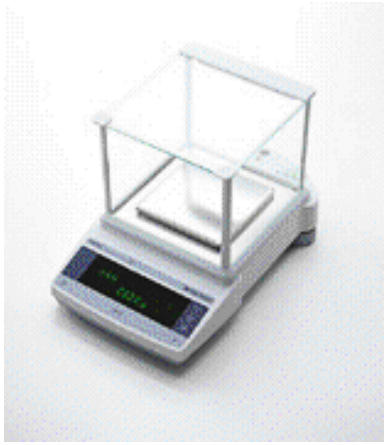
MEASURING INSTRUMENTS

Mass determination – NAWI

Use:

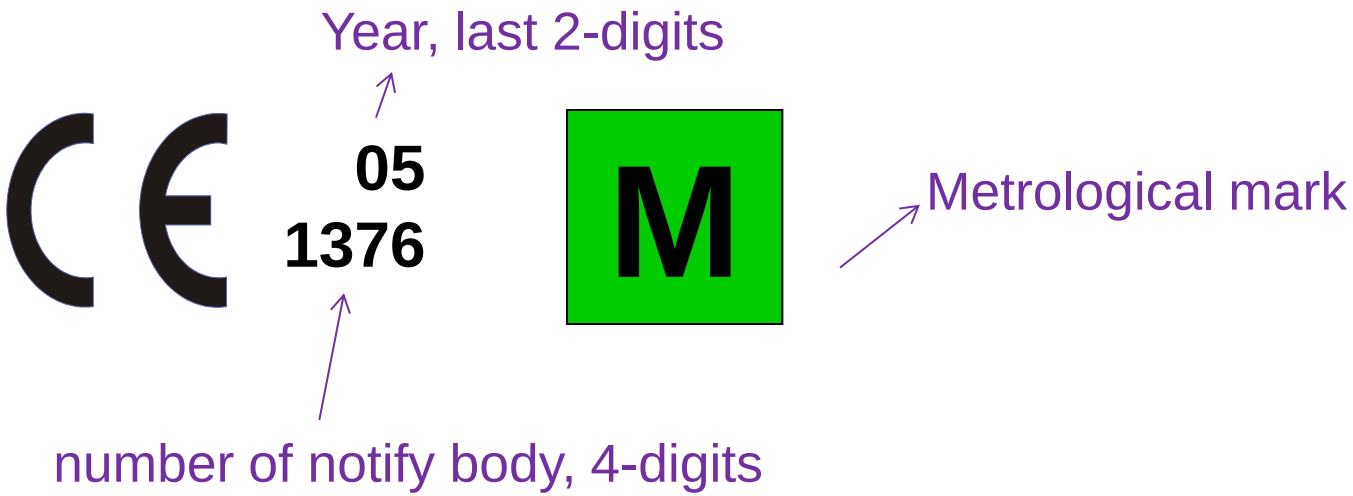
sampling: determination mass of PPP and packages

density determination



MEASURING INSTRUMENTS

NAWI – marking accordance to directive 90/384EEC:



MEASURING INSTRUMENTS

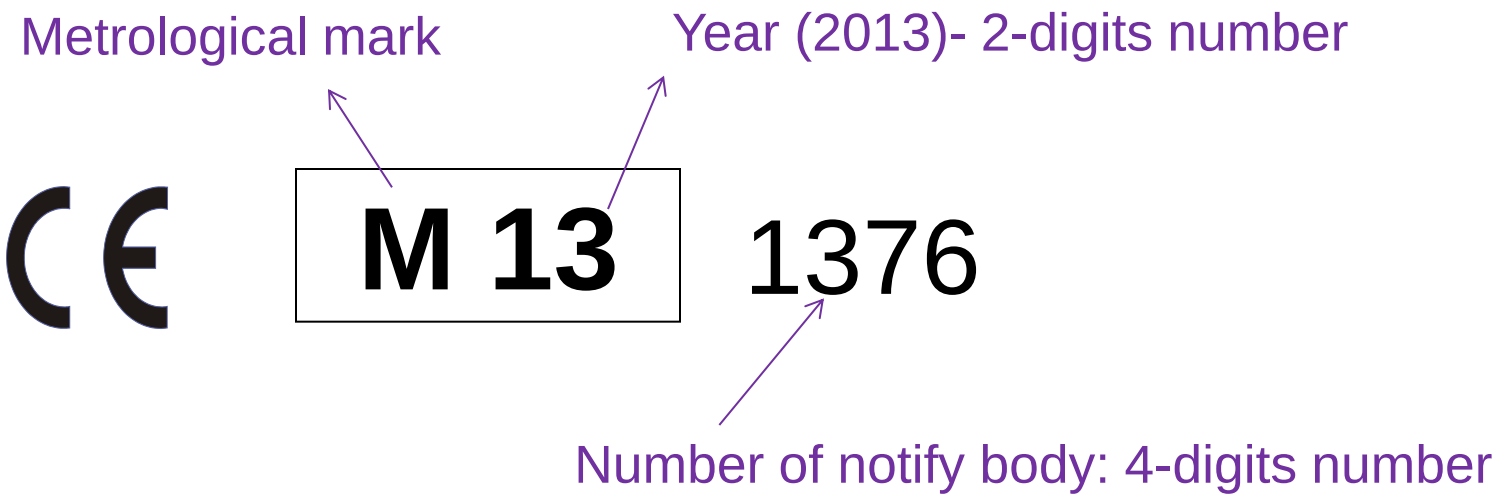
Mass determination – AWI

Checkweigher, (automatic gravimetric filling weigher)

Use: measuring of PPP – 100 % control (+ records)

MEASURING INSTRUMENTS

AWI – marking accordance to directive 2004/22/EEC:



MEASURING INSTRUMENTS

Volume determination (T = 20 oC for no-frozen products):

- **direct** by volume measures
- **indirect** by mass (m) and density (ρ) determination

and calculation:

$$V = \frac{m}{\rho}$$ g/ml or g/cm^3

MEASURING INSTRUMENTS

Volume determination

(T = 20^{o}C for no-frozen products):

cylinder, volumetric flask

<u>Advantage</u>: easy using

<u>Disadvantage</u>: big scale division, mistake at reading a meniscus

MEASURING INSTRUMENTS

Density determination (T = 20ºC ± 0,5 ºC):

- **digital eletronic densitometer**
- **picnometer** - metal or glass
- plunging body
- aerometer
- …
- specific measures (for ice-cream, soil for transplanting plants, with marking bottle level…)

Project
funded by the EU

Development of Quality Infrastructure
and Metrology - Montenegro

adetef.
Assistance Technique France
A project implemented by ADETEF in
consortium with LNE and SMU

MEASURING INSTRUMENTS

Digital electronic densitometer

Picnometer

(be careful: bubbles!)

SYSTEM OF INTERNAL QUANTITY CONTROL (SIQC)

specifies the system of packing and regular control

Set target and limit criteria

Performing corrective actions

Recognised

system of internal quantity control

Documentation

Working instructions, forms - records

DOCUMENTATION of SIQC

Records:

- Prove that procedures of quantity control are actually performed
- Have to be simple and clear

RECORDS - CONTENTS

a) Basic data:

- Date and time of measuring and sampling
- Product name, nominal quantity
- Batch (marking and size)
- Signature of measuring performer and / or responsible person

RECORDS - CONTENTS

b) Measuring results:

- samples of PPP (in case of sample system) or hour inspections (in case of 100% control), density (if necessary)
- samples of mass package (in case of individual masses) and/or average mass of package (and its variability)

RECORDS - CONTENTS

- Control of target and limit values of packing:

- target value or defined value of adequate weigher (checkweighers)
- limit of quantity control of average
- limit of process variation (standard deviations)
- average and deviations of actual contents of sample
- **average and deviations of actual contents of batch**

RECORDS - CONTENTS

- **number of products (%) under limit T_1**

- **number of products (%) under limit T_2 -»e«mark products**

c) Corrective action:

• reason, why batch is inadequate and stopped

• performed actions

RECORDS

Inadequate batch → eliminated from regular production = should not be placed on a market

(marked, waits)

Performed corrective actions

Adequate batch → placed on the market

RECORDS – CORRECTIVE ACTIONS

Possible further actions with inadequate batch of PPP:

- Destroying with repeated product packing
- Repeated weighing of all products and elimination of inadequate
- Products mixing with adequate batch, which has increased average or does not have defect products
- Change product marking

RECORDS SAVING

Type of media:

❖media, which enables their safety, accessibility and understanding

Time saving:

- at least one year and/or
- until next control of competent department
- expired term of products

IMPORTER‘s DOCUMENTATION

- Certificate on recognition of the quality control system
- Packer’s records on sampling
- Results of sampling, performed by competent department
- Assurance that packer pack accordance to “e” marking directive

METROLOGICAL SUPERVISIONS

COMPETENT DEPARTMENT performs metrological supervision over PPP

tasks:

- recognition of packer/importer SIQC
- (regular) control of PPP
- in case of infringements: precaution accordance to national legislation

METROLOGICAL SUPERVISIONS

Control over:

- quantity of batch(s) of PPP by reference test mentioned in the Directive
- marking
- measuring instruments
- documentation of SIQC

Location: premises of packer

or importer / its representative

METROLOGICAL SUPERVISIONS – REFERENCE TEST

Definition for batch size:

- on production line:1-hour output
- other cases (storehouse) : maximum 10 000 products

(Packer has his own definition for batch size,

for example:1-day production)

REFERENCE TEST

Sample size, batch size:

Way of testing	Number in batch	Sample size		
		Order	Number	∑
Non-destructive	100 to 500	1. 2.	30 30	30 60
	501 to 3200	1. 2.	50 50	50 100
	3201 and over	1. 2.	80 80	80 160
Destructive	≥ 100	1.	20	20

REFERENCE TEST

1. criteria: number of defective products (TNE, T_1)

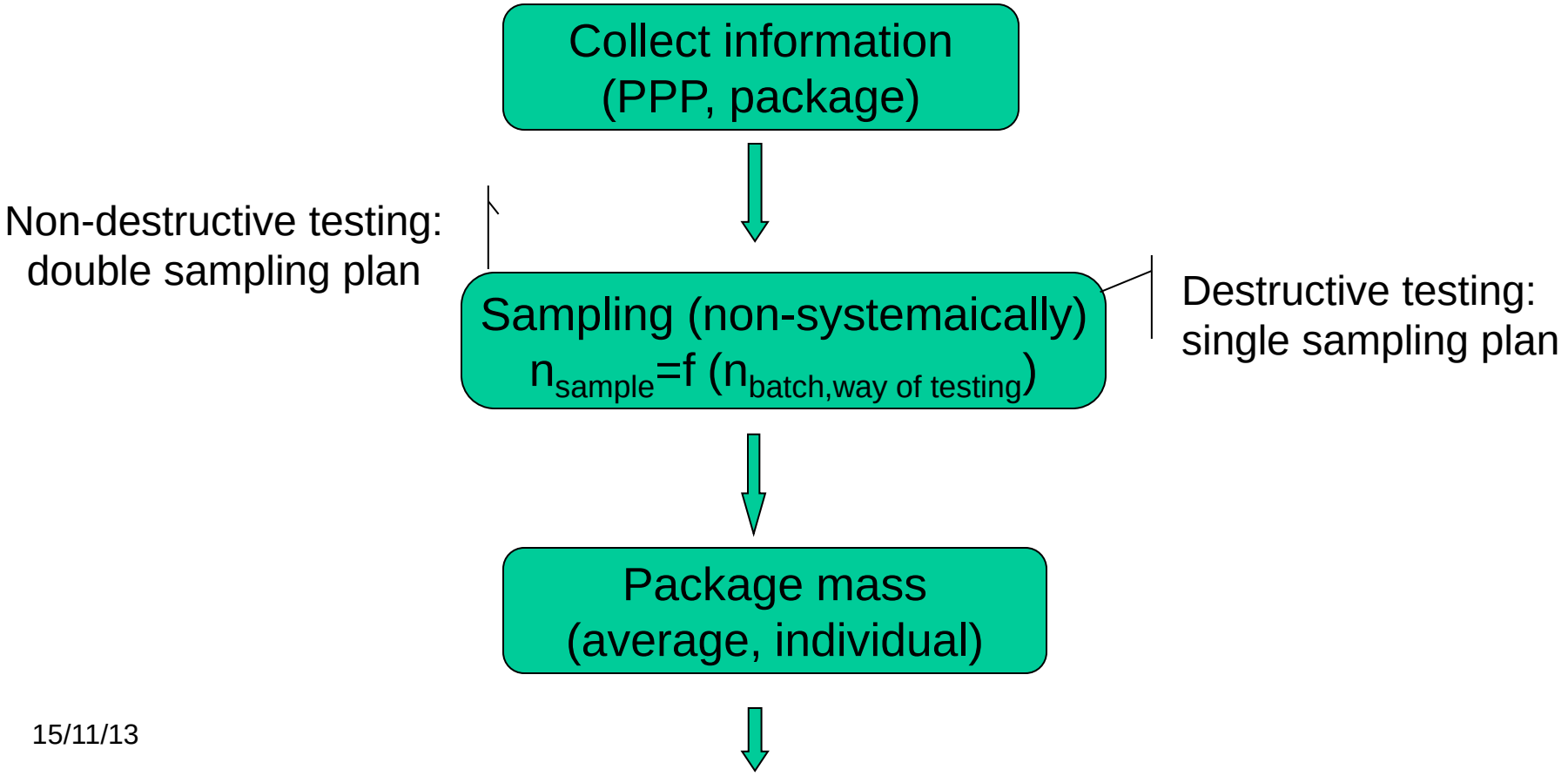
Way of testing	Sample size	Number of defective units	
		acception	rejection
Non-destructive Non-destructive	30 60	**1** **4**	3 5
	50 100	**2** **6**	5 7
	80 160	**3** **8**	7 9
Destructive	20	**1**	2

REFERENCE TEST

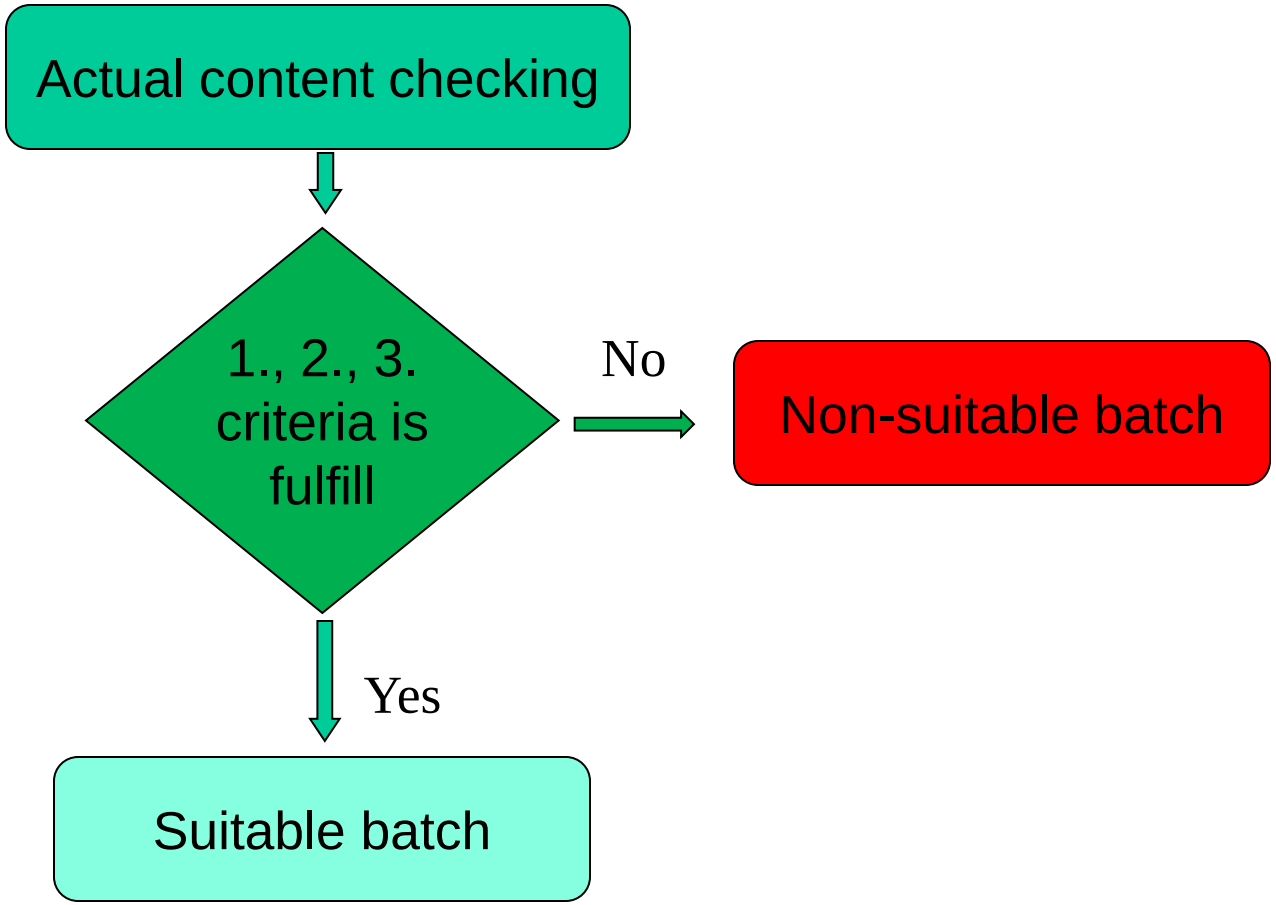
2. criteria: average

Way of testing	Number in batch	Number in sample	Acceptance
Non-destructive	< 100	all	$\bar{x} + t/\sqrt{n} \cdot s \geq Q_n$
	100 - 500	30	$\bar{x} + 0{,}503 \cdot s \geq Q_n$
	> 500	50	$\bar{x} + 0{,}379 \cdot s \geq Q_n$
Destructive	≥ 100	20	$\bar{x} + 0{,}640 \cdot s \geq Q_n$

REFERENCE TEST- step by step (1)



REFERENCE TEST- step by step (2)



Project
funded by the EU

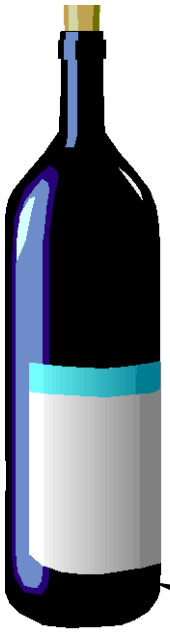
Development of Quality Infrastructure
and Metrology - Montenegro

adetef.
Assistance Technique France
A project implemented by ADETEF in
consortium with LNE and SMU

MEASURING CONTAINER BOTTLES (MCB)

Q_n: 0.05 l – 5 l

℮



Function: measure and package

Material: glass or other rigidity and stability material

Metrolical requirements: in the directive 75/107/EEC

Markings: 75 cl ♣ ℮ 80 and/or 5 mm

MEASURING CONTAINER BOTTLES (MCB)

Measuring instrument for PPP-control

MCB + **measuring template**

- division in ml or mm
- made for single type of MCB
- Verificaton / calibration

„E“-DIRECTIVES IN NATIONAL LEGISLATION

I. Requests valid for all PPPs:

- packer / importer normally has lower cost
- (lower confidence on the system?)
- non-regular control by c.d.
- competent department is state body and non-accredited for the supervising

❖**for all PPI is valid “average principle”**

„E“-DIRECTIVES IN NATIONAL LEGISLATION

I. Certificated system for recognition of the quality control system – just **for “e” mark PPP**:

- high cost for packer / importer
- (higher confidence on the system ?)
- regular control (~once/twice per year) by c.d.
- competent department is private person and usually accredited for the supervising

❖**for non-”e”mark PPI is valid “minimum principle”**

METROLOGICAL ORGANISATIONS CONCERNING PPP

- **WELMEC** (European organization for legal metrology)

  Working group, **WG 6** (Guides)

  www.welmec.org

- **OIML** (International Organization for Legal Metrology)

  Technical committee, **TC 6** (Recommendations)

  www.oiml.org

WELMEC WG 6

Guides:

6.0 Introduction

6.1 Definitions of terms

6.2 Translations of terms

6.3 Implementations

6.4 Packers and importers

6.5 Competent departments

6.6 Recognition of procedures

6.7 Market surveillance

6.8 Drained weight

6.9 Uncertainty of measurement

6.10 Control on PPP-implementation

6.11 Quantity changes after packing

6.12 Measuring container bottles

Project
funded by the EU

A project implemented by ADETEF in
consortium with LNE and SMU

Thank you very much for your attention

Contact:
Mojca Požar
Short term expert
E-mail: mojca.pozar@gov.si

Project
funded by the EU

A project implemented by ADETEF in
consortium with LNE and SMU

"This presentation has been produced with the assistance of the European Union. The contents of this presentation are the sole responsibility of ADETEF in consortium with LNE and SMU and can in no way be taken to reflect the views of the European Union."