Prepackages in the Internal Market

Seminar in Pre-packaging and use of e-Mark for weight and volume in Trade

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Organised in co-operation with
Neytendastofa (Customer Agency –
Iceland NMI)

Internal Market

Development

the Coal treaty, 1951

the Rome treaty, 1956, introduced EEC and 'common market'

Elimination of 'tariffs and quotas' in 1968 (exception – non tariff barriers)

The Single European Act, 1986 (Council of Ministers may adopt necessary decisions by majority vote)

The single market works from 1993.

Internal Market

Economic overview:

- 27 EU member states
- 9 candidate and pre-accession countries
- The EU's GDP (€12 279.033 trillion) is higher than that of the US (2010)
- 7% of the world's population
- Appr. 2/3 of trade among the EU Member states

Trade in prepackages

Several figures (estimate):

- turnover of retail trade of foodstuffs is around 1000 billion EUR (2010), 4.2% of GDP
- Turnover of retail trade of non food products in prepackages may amount to 4% of GDP
- Total value may be as high as 2000 billion EUR (EU27)
- Up to ½ of prepackages are sold e-marked.

Trends affecting trade

Demographical situation

- Reduction in household size (more and more are made of 1 or 2 persons)

Trends affecting prepackages

Food labelling

- Regarding nutrition (Guideline daily amounts).
- Reduction salt (sodium) in food.
- Adding vitamins, minerals and other substances to food.

Development in manufacturing technology

A single product production line is being replaced by flexible gravimetric filling machines (however, recalibration is needed)

Kinds of trade

There are three main kinds in trade

- Local/regional,

- National,

- International.

Each represents a different risk category

Value of products

Calculation of value of 1 g of a product

- At 5 EUR/kg

- A prepackage of nominal weight of 500 g

- At a packer's line – nominal production rate 10 000 prepackages per hour

- At an 8 hours' shift

- 5 days a week, 50 weeks a year.

Value of products

Calculation of a value of 1 g of a product:

- 20 000 000 g per year,
- Equals to 100 000 EUR per year,

A packer may achieve a competitive advantage based on higher flexibility, operation at the thresholds.

Risk assessment

Control frequency by authorities in the EU

Frequency depends on the risk the business poses and is related to:

- the area of distribution,

- the value of the product

- the difficulty of packing, and

- the result of previous checks, including quantity control systems audits.

Advantages of e-mark

Advantages:

Generally, they are as follows:

- Rely on the same requirements over the EU-27

- Historically better known or recognised by the EU-15 citizens

- Become more popular in the new Member States.

- Allows to save comparing to minimum system.

Disadvantages

Several can be identified

- Necessity of use of statistical procedures for checking pre-packages
- Frequently requires a recognition from public authorities
- Generally, not useful outside Europe.

Other relevant legislation

Other relevant EU legislation

- NAWI directive   2009/23/EC
- MID directive 2004/22/EC

System of prepackages control

- The Competent Department shall recognize the quantity control system in the way specified **in national legislation.**

- Where there have been changes in the quality (quantity control) system these changes need to be recognized by the Competent Department before they are brought into use. **Guidance on** recognition of the packer's procedure for carrying out production checks is given in WELMEC 6.6

System of prepackages control

Methodology of testing

- destructive testing or
- non destructive testing

Preferably non destructive tests are used.

System of prepackages control

Methodology of testing

Statistical method of the control generally means that:

- the number of samples taken from the batch to be controlled depends on the size of the batch which in practice determined from hourly production of a packing line.
- maximum size of a batch is limited to 10 000 pieces.
- the average value is then corrected by a coefficient depending on the method of statistic used

System of prepackages control

Measuring the actual content

The actual contents of prepackages may be measured directly by means of

weighing instruments or volumetric instruments or, in the case of liquids, indirectly, by weighing the prepacked product and measuring its density

System of prepackages control

Checking batches

Carried out by sampling in two parts:

- a check covering the actual contents of each prepackage in the sample,

- another check on the average of the actual contents of the prepackages in the sample.

System of prepackages control

Checking batches

A batch of prepackages shall be considered acceptable if the results of both these checks satisfy the acceptance criteria.

System of prepackages control

Checking of the actual content

- The minimum acceptable contents shall be calculated by subtracting the tolerable negative error for the contents concerned from the nominal quantity of the prepackage.

- Prepackages in the batch whose actual contents are less than the minimum acceptable contents shall be considered defective.

System of prepackages control

Non-destructive testing – sampling plan

Number in batch	Samples			Number of defective units	
	Order	Number	Aggregate number	Acceptance criterion	Rejection criterion
100 to 500	1st	30	30	1	3
	2nd	30	60	4	5
501 to 3 200	1st	50	50	2	5
	2nd	50	100	6	7
3 201 and over	1st	80	80	3	7
	2nd	80	160	8	9

Seminar on prepackaged products

System of prepackages control

Destructive testing – sampling plan

used only for batches of 100 or more

Number in batch	Number in sample	Number of defective units	
		Acceptance criterion	Rejection criterion
Whatever the number ($\geq$ 100)	20	1	2

System of prepackages control

Manufacturer's or the importer's responsibilities concerning the actual content of the prepackage

- The manufacturer or the importer is responsible for ensuring that the prepackages meet the requirements

System of prepackages control

Importer

- in case of import from countries outside the EEA

System of prepackages control

It means that checks are needed to confirm that the equipment used to make up the prepackages is legal and suitable and that records are available for competent departments to verify

Checks shall be so organized so as to effectively guarantee the quantity of product in a prepackage

System of prepackages control

Measuring

- During the filling the actual content of the prepackage is measured by means of a legal and suitable measurement instrument

System of prepackages control

recognizing procedures

- Methods of process control shall effectively ensure that the prepackages meet the requirements.

- The determination of whether this requirement is met is determined by the competent department based on an evaluation of the procedures.

System of prepackages control

Procedures suitability

The characteristics of filling and packing process are highly dependent upon
- the nature of the product which is packed
- the type of package and
- the way in which it is filled.

System of prepackages control

Procedures suitability

Characteristics such as the average quantity packed, and the variation of the individual packages round this average, give important indications for the quality of the process, and how it should be controlled.

System of prepackages control

Procedures suitability

The procedures have to ensure that, through control and correction of the packaging process, the e-marked prepackages that are put on the market satisfy the Directives' requirements

System of prepackages control

Procedures suitability

Measurement results must be representative

- At least once an hour the average content of the produced prepackages must be determined and evaluated.

- The same applies for the number or percentage of prepackages with a content below the TU1 and TU2 limits.

System of prepackages control

Procedures suitability

Identification of variations of the production process

- Variations in the filling process that cause repackages to fail to meet the requirements must be identified

- In general a deviation must be detected within an hour, since every hour's production must meet the requirements.

System of prepackages control

Procedures suitability

The measuring and sampling methods

- A packer must draw a sample of enough items of the running production on a regular basis. The content of each item in the sample is determined.

- Parts of this may be automated (for instance by using a checkweigher).

System of prepackages control

Procedures suitability

Sampling Frequency

The sampling frequency depends on the deviation of the filling process and the number of adjustments, but it should be at least once an hour and after adjustment.

In certain situations (for instance bottle filling carousels that can not be adjusted) a lower frequency might be possible.

Checks must be carried out before the prepackages are distributed.

System of prepackages control

Import (from third countries)

- The importer has the same responsibilities as a packer but they may not physically come into contact with the prepackages being imported.
- 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

System of prepackages control

Import (from third countries)

Acceptable guarantees:

a) evidence from a competent department in a Member State,

b) evidence from an EEA accepted competent department in the exporting country,

c) records of checks carried out by a competent sub-contractor at the place of first entry into the EEA,

d) to obtain records from the packer and to carry out checks to verify the data contained in them.

System of prepackages control

Import (from third countries)

Evidence shall state that the quantity control system had been assessed and that the controls and records guarantee compliance with the requirements.

Control on Market

- As the Directives on pre-packages are not New Approach Directives, **the concept of market surveillance is not explicitly mentioned as a requirement**. There are various checks in checking the conformity of pre-packages to the requirements specified in the Directives mentioned.

Control on Market

- 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.

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 later...

Equivalence of checks

- 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).

- 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

The checks that can be performed while carrying out market controls

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

2. screening test that is statistically equivalent to the standard screening test,

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

4. check on labeling 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.

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	

Types of checks

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 IN THE MEMBER STATE
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	

Types of checks

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)	

Use of MCB in packing process

RESPONSIBILITY OF THE PACKER OR IMPORTER

- The packer or importer shall be responsible for ensuring that prepackages meet the requirements
- 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

Use of MCB in packing process

RESPONSIBILITY OF THE PACKER OR IMPORTER

- Where the actual contents are not measured, the check carried out by the packer shall be so organized that the quantity of the contents is effectively ensured

Use of MCB in packing process

RESPONSIBILITY OF THE PACKER OR IMPORTER

- 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

MCB – 75/107/EEC

Directive on prepackages and MCB

Directive 76/211/EEC on prepackages permits using of MCB when making up prepackages, where the quantity is expressed in units of volume, when filled to the appropriate fill level.

Use of weighing instruments

NAWI

- When the quantity of product in prepackages is determined by sampling, often a NAWI is used for the control and it performs a static weighing. NAWI's may also be used to test automatic weighing instruments and also for density measurements.

Use of weighing instruments – volume determination

Volume determination

- The volume can be directly determined by emptying the product into a liquid measure,

- Indirectly determined based on measurements of density and weight.

- Measures of capacity must be verified.

Development in Lithuania

Lithuania

- Until 1990 there were no obligatory requirements on packed products.
- Self-standardisation (manufacturer's technical specifications registered at the standardisation body).
- Market control institution established in 1996.
- First training in Germany (2 persons) – 1999.
- Legislation based on the EU directives – 2003.
- Review to cover non e-marked part – 2007-2008.

Success stories

Lithuania

- JSC Norvelita (joint Lithuanian and Norwegian company) established in 1995.

- Products – fish (smoked, salted), crab sticks

- Area of sales – local and international (2 trademarks)

- Originally started with 17 persons and packing of up to 10 tons per month.

- Next stage in development in 2003 – exports to the EU member states

- Presently employs 350 persons and treats up to 1000 tons of fish products a month

System of prepackages control

Thank you for your attention

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