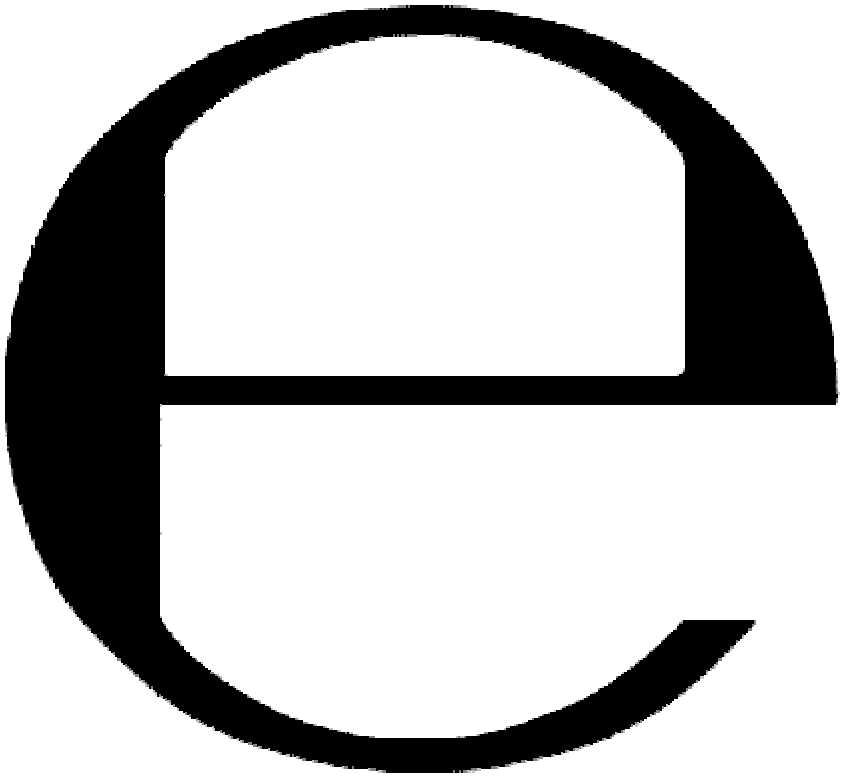
Business Impact Analysis on conformity assessment in prepackages



24 october 2003

0 Executive Summary

The SLIM-IV exercise (Simpler Legislation for the Internal Market) reviewed the rules applying to products (liquid/non liquid, food/non food) that are prepacked in given quantities without the purchaser.

These rules are mainly stipulated in two Directives which have not been substantially amended since their adoption in the mid and late nineteen seventies.

The two Directives (75/106/EEC and 76/211/EEC) fix the so-called average quantity method for the volumes and quantities in which products are pre-packaged. Application is voluntary and to indicate its use the e-mark may be affixed. These e-marking Directives were initially adopted because the divergence of existing national laws was creating an obstacle to trade and to the provision of correct information for consumers.

As result of this exercise, the SLIM team, comprising of members designated by the Council and independent experts, issued a report containing a number of remarks and recommendations aimed to review the legislation. Its main suggestions were to retain the average method as in total harmonization, to clarify EC definitions and include drained net weight and to extend the checks to prepackages of 25 kg.

The cost benefit exercise is to ensure that full account is taken of the costs and benefits to packers, as requested by the Commission. **retailer**s and consumers are also identified as stakeholders and included in the exercise.

The objective of this project is therefore to perform a cost benefit analysis of regulation of the metrological requirements of pre-packed sizes and possible alternatives.

0.1 Definitions and drained weight

Relevant pieces of EU legislation and the latest draft of OIML Recommendation 87 (quantity of product in prepackages) have been examined and differences identified. In order to arrive at a coherent set of definitions, a distinction has been made between product and packing material.

For products that are sold in a liquid, it is suggested to mention the content of the drained weight instead of on the drained weight + liquid.

0.1.1 definitions

The two existing e-marking Directives are consistent in the use of their definitions.

There are 14 other pieces of EU legislation that refer to or cover prepackages (see annex D). Most are found to be consistent with the e-marking Directives. Because the Foodstuff Directive[1] also applies to prepackaged foodstuffs without nominal quantity, its definitions are different from the e-marking Directives. In the future this Directive can refer the e-marking Directive, and make an exception for prepackaged foodstuffs with no nominal quantity.

The latest draft of OIML Recommendation 87 will be adopted in November 2003. It contains a set of definitions that is coherent with the recommendations in this report.

It is recommended to adopt this definition to distinguish between product and packing material[2]: packing material is everything of the prepackage that is meant to be left over after use of the product, except for items naturally in the product. Use includes consumption or subjecting to a treatment.

0.1.2 drained weight

The Foodstuff Directive requires two indications of quantity of product: with and without the fluid. The e-marking Directives are not clear on the subject.

Currently, some countries apply the e-mark to the drained weight, some to the drained weight + fluids and some allow the packer to choose.

The drained weight problem also exists with ice-glazed foodstuffs, where ice glazing instead of fluids covers the foodstuff.

The application of the definition of packing material (0.1.1) forces the drained weight to be e-marked. The Foodstuff Directive needs to be updated.

[1] *Foodstuff Directive: Council Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs*

[2] *consistent with latest draft of OIML Recommendation 87*

0.2 Differences in implementation, market surveillance[3]

Differences exist between Member States with regards to the implementation of legislation and with regards to measuring methods used by packers and competent departments[4].

Major differences exist with drained weight products as mentioned under 0.1.2 and desiccating and hygroscopic products.

0.2.1 Differences in implementation

- Procedures (Directive 76/211/EEC, Annex 1, article 4) are recognized differently resulting in different burden for packers: explicit recognition by competent departments, recognition through codes of practice, implicit recognition by inspectors (risk of conflict of interest!) and no recognition at all.
- Some countries do and some do not require packers/importers to get permission or have their procedures recognized before applying the e-mark.
- The term 'sufficiently small' (Directive 76/211/EEC, Annex 1, article 1.2) is interpreted in some countries as 2,5% and in others as 2%.
- Density measurement of carbonated drinks (Directive 76/211/EEC, Annex II, article 1) is performed in some countries including carbon dioxide and in some countries without.
- Density measurement of ice-cream (Directive 76/211/EEC, Annex II, article 1) is performed differently in different countries resulting in different measured volumes.
- The unit of measurement (g or ml) of the nominal weight or nominal volume (Directive 76/211/EEC, article 4.2) is interpreted differently according to national regulations or trade practice leading to different units for the same product.
- Batches smaller than 100 prepackages (Directive 76/211/EC, Annex II, article 2.1) cannot be tested destructively. Some countries still perform tests.
- Declaration of free product (Directive 76/211/EC, Annex I, article 3.1) is interpreted in some countries as part of the nominal quantity and in others not.
- Different interpretation of 'measuring while filling using a legal measuring instrument' (Directive 76/211/EC, Annex I, article 4): some countries exclude gravimetric filling instruments and automatic weighing instruments.
- Batch size for packers differs per country as some countries want packers to use the hours production, and others not (Directive 76/211/EC does not define the batch size for packers).
- Identification of packer or the person arranging for the packing to be done (Directive 76/211/EC, Annex I, article 3.2) is interpreted in some countries as a special code, some countries require name and address and others allow for only a brand name.
- What evidence may an importer provide that enables him to assume responsibility (Directive 76/211/EC, Annex I, article 4) is interpreted in some countries as 'records from the third countries packer', while other countries require validation of those records.

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[3] *Market surveillance as meant in new approach legislation does not exist in current legislation. However, checks other than the reference test that is defined in legislation, are allowed and used as market surveillance*

[4] *Competent department: under current legislation an organization recognizing procedures, performing pre-market control through reference tests and performing market surveillance activities.*

0.2.2 desiccating[5] and hygroscopic[6] products

The e-marking Directives give no guidance about the moment of compliance of prepackages, whilst the Foodstuff Directive requires foodstuffs to meet requirements at the moment of packing.

This has lead to different views in various Member States, namely in some countries prepackages have to meet the requirements at the moment of packing and in others until the moment of sale.

0.2.3 market surveillance

The e-marking Directives allow for checking at other locations than at the packer, for instance at the retailer (market surveillance).

Competent departments cannot really perform quantity checks at retailers, because of the use of the average quantity principle[7]. These checks require a large number of prepackages. This number is usually are not available in shops. However, for non-domestic packers and importers market surveillance does rely on activities at the point of sale.

Market surveillance could be more effective if:

- the minimum quantity principle[8] would be applied, i.e. quantity should always meet or exceed the indicated nominal quantity
- cooperation on market surveillance between national authorities is improved

In the USA the average quantity principle is also used. Enforcement primarily takes place at the point of sale through market surveillance after which further batch testing can be done on the packers' premises. This system works well because of the different juridical system. In the USA the retailer is held responsible for the quantity of product in prepackages and he will normally contractually bind the packer.

In Europe packers and importers are responsible for the quantity of product in prepackages. While retailers often require packers to apply the e-mark, they are nonetheless not held responsible for the quantity of the packs they sell.

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[5] *desiccating products: products that loose moisture during time*

[6] *hygroscopic products: products that attract moisture during time*

[7] *average quantity principle: the average quantity of product in prepackages must equal or exceed the nominal quantity. The actual quantity of product of prepackages may not be less than certain limit(s) under the nominal quantity.*

[8] *minimum quantity principle: the quantity of product in all prepackages must meet or exceed the nominal quantity (applied in national legislation in some Member States)*

0.3 The future in prepackaging

To provide the Commission input for her development of new legislation, three sub-studies took place.

1. Comparisons have been made with legislation in Japan, USA and South Africa.
2. Four possible future scenarios and their effect on packers, retailers and consumers in Europe have been developed.
3. The four scenarios have been 'tested' on stakeholders in the cost-benefit analyses.

0.3.1 Main trading partners

- The **Japanese** system is in essence the minimum quantity principle with a lower limit for the prepackages that lies below the nominal quantity. The limit is lower (i.e. wider) for 'difficult' products.

  European prepackages meet the requirements of the Japanese legislation. Japanese prepackages might not meet EU requirements.

- The **South African** legislative system for prepackages is almost[9] harmonized with the European. This means that European prepackages always meet the requirements of the South African legislation. South African prepackages below 10 kg or l meet requirements of EU legislation.

- **The USA system** also recognizes the average principle. The Handbook 133 of NIST recommends procedures to be followed when checking the quantity of product of prepackaged products. USA follows the current (but outdated) OIML R87 for 99%.

  The legal system stimulates retailers to force packers to meet requirements: retailers are legally kept responsible.

  USA has more requirements with regards to labeling than EU has. Reference temperatures for some liquid products differ from EU. The scope covers weight, volume, measure, and count. Tolerable negative errors are different from EU. Sometime EU goods will therefore not be accepted in the US, even though the quantity is correct.

[9] *South Africa allows for e-marked prepackages with a nominal quantity above 10 kg or l*

0.3.2 Four possible scenarios

For the purpose of the study four scenarios were developed each representing one type of conformity assessment procedure.

The average quantity principle is used. Market surveillance is the responsibility of the national authorities. For domestic packers, market surveillance will in all scenarios take place at the premises of the packers with whom the responsibility lies. For non-domestic packers and importers, market surveillance will take place at the retailer.

Scenario 1: Self declaration

This scenario relies on packers who are filling and checking without supervision of a notified body[10] and market surveillance.

Expectation of impact:

Many packers favour this solution, because it allows them to fill and check without notified body interference.

Retailers fear that they might be visited more often by market inspection and would rather have all activity centered on packers.

According to competent departments, the number of prepackages that not meet the specifications will increase when no notified body is involved.

Scenario 2: Product validation

This scenario involves a notified body that judges how a packer meets the requirements. Within this scenario there are two options:

1. The packer checks the quantity of product of every prepackage. The notified body judges the (in this case very simple) procedures and issues a certificate stating that (batches of) prepackages meet the requirements.
2. The packer checks the quantity of product according to procedures. The notified body samples batches at the packer (two times per year), assumes that the procedures of the packer are correct and issues a certificate stating that all other batches of prepackages probably meet the requirements.

When market surveillance determines that prepackages do not meet requirements, the notified body must stop issuing certificates.

expectation of impact

According to competent departments the number of prepackages that not meet the specifications will increase because the notified body control is not strict enough and market surveillance is inefficient.

packers are not in favour because this requires more red tape than scenario 1 and there is a risk that the market surveillance authorities will start to recognize procedures 'implicitly'.

Retailers fear that they might be visited more often by market inspection and would rather have all activity centered on packers.

[10] *notified body: in future scenarios an organization judging metrological aspects of prepackaging*

Scenario 3: Validated filling process

This scenario relies on judgment of the procedures of the packer. These are divided into two and can be treated separately:

1. *Validation* of the settings of the filling process and the checks performed by the packer to maintain these settings by the notified body.
2. *Certification* of the quality assurance system of the packer or random checks at the packer by the notified body.

When market surveillance determines that prepackages no longer meet the requirements, the procedures of the packer need to be re-judged by the notified body to prevent future problems. The notified body can withdraw her validation and/or certification.

Expectation of impact:

According to competent departments compliance will be better ensured because the notified bodies focus on the metrological aspects of the filling process (*validation)*.

Some packers fear more red tape although in combination with the (existing) quality system impact for the packer is reduced.

Retailers appreciate that most of the market surveillance only requires labeling inspections.

Scenario 4: Total packing quality

This scenario looks a lot like scenario 3, but assumes that the packer has enough knowledge to validate the settings of the filling process and his checks to maintain these settings.

The notified body certifies the quality system, including this validation.

When market surveillance suspects that prepackages no longer meet the requirements, the procedures of the packer need to be re-judged by the notified body. The notified body can withdraw her validation and/or certification.

Expectation of impact:

According to competent departments, quality assurance reduces judgment errors. There is a risk that general certification bodies do not have the specific metrological knowledge to judge the settings of the filling process and the packer's checks.

Retailers appreciate that market surveillance only requires labeling inspections.

Small packers cannot easily use costly quality assurance systems. Other packers will incorporate quality assurance systems regardless the scenario.

0.3.3 Cost-benefit analysis

The above findings were obtained by the following means:

- questionnaires were developed for packers, retailers and consumer organizations, distribution took place through a dedicated website
- competent department were asked to provide input
- interviews with organizations representing packers took place

Information gathering - results

Except from The Netherlands and Slovenia a very limited number of questionnaires were filled out. The competent departments in these countries helped by mailing packers directly in Dutch and Slovenian.

Hardly any European consumer organizations reacted. Moreover, the reactions of the ones who did had very limited value and did not contribute to a better understanding of the issues at stake.

In general packers wanted to cooperate through their European trade organizations, who did not possess the specific knowledge required to fill out the questionnaires. The answers given in the various questionnaires were of very limited value. Built in checks on the answers, showed that about half of the questionnaires needed to be discarded.

Because of the above, the following crucial information to perform the cost-benefit analyses was missing:

- time to perform checks by packers
- the number of prepackages, packers and retailers in Europe
- insight in internal costs of packers and retailers
- the cost decisions per packer and retailer
- stakeholder comparisons of the scenarios compared to their current system (because they could not identify their current system).

The difference between large and small stakeholders could not be made. However a study made by WELMEC Working group 6 revealed that there is no difference between large and small packers in their ability to meet the requirements.

Effects of scenarios on stakeholders: packers

The conclusions that could be drawn from the information obtained were the following.

The effort of a packer to meet requirements depends on perceived pressure. The pressure depends on:

- price per unit : it is easier to overfill a cheap product
- the profit margin : products with much added value have a higher profit margin that allows for a better control of the quantity of product
- batch sizes : prepackages in larger batches can meet requirements more easily, because while filling, there is more time to check and adjust
- fine height : when governmental 'punishment' is high, packers will be more willing to meet requirements (relates to chance of getting caught)
- packers status : brand names are afraid to smudge their name
- retailers power : retailers can demand packers to meet requirements
- company size : larger packers are better able to withstand demands from retailers

For a packer this pressure is a constant. He will always choose the most cost efficient option. The most cost efficient option depends on:

- product : some products are easier to fill
- filling process : filling process can vary from manual labor to completely automated
- product price : quantity control systems can be simpler for cheap products ('overfill' against 'no overfill through a lot of checking')

The above asks for a legal system with custom made solutions that allow packers to comply with the requirements.

The most efficient (read: cheap) system is self-declaration:

- it is cheaper than quality assurance
- big 'quality minded' and 'consumer sensitive' will increase pressure on packers to decrease the market surveillance

The most effective system is quality assurance (validated filling procedures and total packing quality). This is to the benefit of large packers as they usually already have better developed quality systems.

There is a trade off between both systems.

Effects of scenarios on stakeholders: retailers

The effort of a packer to meet requirements depends on perceived pressure. The pressure depends on:

- retailer status : brand A retailers will make sure that the quantity of product meets requirements
- consumer : when consumers would be able to check the quantity of product, they would increase pressure
- surveillance : when the retailer undergoes a lot of market surveillance, his costs will rise

For an importer this pressure is a constant. He will always choose the most cost efficient option. The most cost efficient option depends on:

- firm size : large retailers have more power to transfer consumer pressure to packers
- profit margin : high margin retailers re able to give part of this margin to packers, allowing for prepackages to meet requirements
- other supplier : retailers make packers dependent by threatening to change supplier

The most efficient system for retailers (read: cheap) system is to make use of enforcement at the packer, because that ensures prepackages that meet the requirements and leads to less (costly) market surveillance. The costs of the system are transferred to the packers.

Effects of scenarios on stakeholders: consumers

Consumers do not consider the quantity of product as their responsibility. Consumer protection implicates the introduction of the minimum quantity principle combined with market surveillance. That would increase costs. Consumers are not willing to pay for this.

Overview

	Self declaration	Product validation	Validated filling process	Total packaging quality
packer	Chooses his own cost-effective control system: overfilling for small packers and low cost product or quality assurance. Incentives needed from consumer (e.g. A-mark) or retailer or market surveillance	Cost of control by notified body. Carries cost of transferred risk of retailers.	Cost of control by notified body. Possible SME-burden. Firms with low cost product and small firms prefer overfilling.	Cost of control by notified body. Possible SME-burden. Firms with low cost product and small firms prefer overfilling
retailer	Carries the cost of market surveillance.	Carries the cost of market surveillance.	Low costs on average. Especially reduced costs for retailers competing on quality	Low costs on average. Especially reduced costs for retailers competing on quality.
notified body	No role in this system	Not very effective role in this system: witnessing packers' checks or sampling.	Has a great deal of work to do: validating filling procedures + judgment limited QA system	Has a great deal of work to do: judgment complete QA system
Market surveillance organization	Has a lot of work. Effective of overfilling packers, Difficulties to retrieve responsible packer, especially outside the EU	Has a lot of work. Effective of overfilling packers, Difficulties to retrieve responsible packer, especially outside the EU	Limited work to do. The control at the packer by is effective.	Limited work to do. The control at the packer by is effective.

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1 Introduction

1.1 Reasoning

The SLIM-IV [11] exercise (Simpler Legislation for the Internal Market) reviewed the rules applying to products (liquid/non liquid, food/non food), which are packed in given quantities not in the presence of the purchaser.

These rules are mainly stipulated in two *Directive*s which have not been substantially amended since their adoption in the mid and late nineteen seventies.

The two Directives (75/106/EEC and 76/211/EEC) fix the so-called average method for the volumes and quantities in which products are prepackaged. Application is voluntary and to indicate its use the e-mark may be affixed. These Directives were initially adopted because the divergence of existing national laws was creating an obstacle to trade and to the provision of correct information for consumers.

WELMEC document 6.3 (previously numbered 8.3) reflects the 'ideal' interpretation of the Directives. However the national implementation is completely different as the document in Annex F (National implementation of the Council Directive 76/211/EEC) demonstrates. In comparison to the situation before the introduction of the above mentioned Directives there are less obstacles to trade. Technical barriers to trade are still not removed by the country wise organized legal solutions.

The SLIM team, comprising of members designated by the Council and independent experts, issued a report containing a number of remarks and recommendations aimed to review the legislation. Its main suggestions were to retain the average method as in 'total harmonization', to clarify EC definitions and include drained net weight and to extend the checks to packages of 25 kg.

The Cost Benefit Analysis finds its ground in the Council Resolution of 3 December 1992 on administrative simplification for enterprises, especially small and medium-sized enterprises [12]. This resolution invites the Commission to ensure that full account is taken of the costs and benefits to enterprises by preparing an assessment on all Commission proposals, which may give rise to a substantial burden for enterprises.

The objective of this call for tender is therefore to perform a Cost Benefit analysis of regulation of the metrological requirements of prepacked sizes and possible scenarios.

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[11] *Report from the Commission. Results of the fourth phase of SLIM. COM(2000) 56 final(04.02.2000)*

[12] *Résolution du Conseil, du 3 décembre 1992, sur la simplification administrative en faveur des entreprises et notamment des petites et moyennes entreprises (Journal Officiel n° C 331 du 16/12/1992 p. 3-4).C:\temp\IECache\OLK9\Call for Tenders Metrological Requirements.doc 5*

2 Present and discuss all relevant definitions and methods of metrological control with a view to clarifying them on consistency and introducing drained net weight;

2.1 Problems

The Directives 75/106/EEC and 76/211/EEC[13] are not consistent on definitions of prepackage and prepacked product and do not define packing materials. There is no relation with 94/62/EEC (on packaging and packaging waste). A prepacked foodstuff (in Council Directive 2000/13/EC on labeling, presentation and advertising of foodstuffs) is defined differently from a prepacked product in the e-marking Directives, although both Directives may apply.

In various Directives the terms 'quantity' and 'content' are used to quantify product, packing material and prepackages, sometimes particularized with terms like 'net', 'gross', 'actual', 'average' and 'nominal'. Also 'weight' or 'volume' is used instead of 'quantity' and 'content'.

2.2 Work program

All definitions in Directives related to prepackaging have been examined on the use of the various definitions, interrelated and rebuild to a new set.

The new set of definitions have been tested on usability with examples of prepacked products currently causing problems[14]

The work that has been done by WELMEC Working Group 6[15] and by OIML Technical Committee TC6 (on the revision of OIML Recommendation 87) has been taken into account.

The problem of drained net weight with regard to definitions is reduced to a metrological problem when definitions of product and packing material are applicable on (respectively) the 'solid foodstuff' and 'liquid medium' used in the Council Directive 2000/13/EC (labeling, presentation and advertising of foodstuffs).

2.3 Deliverables

The purpose of the work was to interrelate the various definitions and to come up with a set of definitions that is consistent with as many definitions as possible.

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[13] *called hereafter: 'e-marking Directives'*

[14] *products currently causing problems: solid product in liquid, product with an added item to promote or use the product, liquid product with a solid ingredient added that contributes to taste or for promotional reasons, liquid with added residue, liquid with natural residue, parts of natural products not meant to be used, liquids with carbon dioxide dissolved, product under vacuum, product in pressurized gas, eatable package, hygroscopic and desiccating products*

[15] *Walter Frankvoort is chairman and Jeroen Rommerts is secretary of the WELMEC Working Group 6. Walter Frankvoort is member of OIML Technical Committee 6. Jeroen Rommerts has provided for the Dutch and WELMEC Working Group 6 point of view on the definitions used in draft 2 and 3 of OIML Recommendation 87.*

2.4 Discussion and results

2.4.1 Definitions in the field of prepackaging

Hints while reading this chapter:

Definitions that derive from legislation are placed in a box.

Definitions that will be used throughout the document are placed in a yellow box and marked with this symbol: 

References to legislation or interpretation to legislation are in the footer of a page and are marked in the text with a figure (for instance: [1]). This chapter gives the definitions of prepackage, packing material and prepacked product that are consistent and leave no room for misunderstanding. Several Council Directives provide definitions that sometimes are conflicting and sometimes might be usable for prepackaging purposes.

The content of this chapter has been published in the OIML Bulletin, Volume XLIII, number 3, July 2002, Definitions in Prepackaging. See Annex A. This publication has 3 annexes: Annex I gives an overview of the related terms. Annex II lists the various definitions in the major legal documents and Annex III gives examples of the application of the definition of packaging.

Annex B gives a list of definitions in EU legislation and official guides to legislation (OIML).

Annex C gives a cross reference of terms between various EU Directives.

WELMEC Working Group 6 has published WELMEC document 6.1 (previously numbered 8.1) containing definitions and terms of more or less all wording used in prepackaging. Document 6.2 (previously numbered 8.2) gives translations of these terms and definition in the major European languages. The document is currently being revised.

2.4.1.1 Prepackage

Council Directives 75/106/EEC (article 2.1) and 76/211/EEC (article 2.1) give this definition for prepackage:

> A prepackage within the meaning of this Directive is the combination of a product and the individual package in which it is prepacked.

As the words 'individual package' are used less often in legislation and in common language, we suggest replacement with the word 'packing material'[16]. Also the word 'package' is sometimes confused with 'prepackage'[17].

> A prepackage is defined as the combination of a product and the packing material in which it is prepacked.

[16] *Packaging is used in Directive 94/62/EC (packaging and packaging waste) and Directive 2000/13/EC (labeling, presentation and advertising of foodstuffs)*

[17] *In the USA prepackage is referred to as 'package'.*

2.4.1.2 Packing material

To distinguish between the product and the packing material, either one of them needs to be defined. No legislation or international recommendations provide for definitions of 'product'. It proves easier to define packing material instead of the product.

Article 3 of Council Directive 94/62/EC, on packaging and packaging waste, gives this definition for packing material ('packaging'):

> 'packaging' shall mean all products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. 'Non-returnable' items used for the same purposes shall also be considered to constitute packaging.
>
> packaging consists only of:
>
> a) sales packaging or primary packaging, i. e. packaging conceived so as to constitute a sales unit to the final user or consumer at the Point of Purchase;
>
> b) grouped packaging or secondary packaging, i. e. packaging conceived so as to constitute at the Point of Purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics;
>
> c) transport packaging or tertiary packaging, i. e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers;

For the majority of prepackages, the definitions of sales packaging or primary packaging and the grouped packaging provide enough clues to differ between the product and the packing material.

However for a number of prepackages (see Annex II in Annex A and Annex B) the definition is not sufficient, as it does not differentiate between product and packing material within the sales packaging or primary packaging.

Resolutions of WELMEC Working Group 6 suggest this definition:

> Packing material is everything that is intended to be left over after use, except for items naturally in the product. Use includes consumption or subjecting to a treatment[18].

The 251102 draft of OIML R87 (Quantity of product in prepackages) suggest this definition:

> Packing material (also called individual package, tare, packaging or packaging material): Everything of the prepackage that is meant to be left over after use of the product, except for items naturally in the product. Use includes consumption or subjecting to a treatment.

[18] *WELMEC Working Group 6, resolution 81, where 'individual package' is replaced with 'packing material'*

Based on the above this is the definition of packing material:

Packing material is everything of the prepackage that is meant to be left over after use of the product, except for items naturally in the product. Use includes consumption or subjecting to a treatment.

Packaging is also referred to as 'individual package[19]', 'package', 'packing material(s)' and 'packaging material(s)'.

Packing material is generally used to contain, protect, handle, deliver, preserve, transport, inform about and as an aid while using the product it contains.

Instead of leaving it up to the packer to identify the product on the label on which the indication of quantity applies, this definition does it for him, leaving no room for misunderstanding, thus facilitating fair competition.

The definition distinguishes between product and packing material with the phrase 'intended to be left over after use'. The US Weights and Measures Law differentiates with the phrase 'items not considered to be part of the commodity'[20] which should give the same result.

The words 'intended to be left over after use' also include recycling, reusable (refillable) packing material or using the packing material by an end-user.

2.4.1.3 Drained weight

The term 'drained weight' usually applies to foodstuffs. The term might also be applicable to all products in a liquid medium. For instance: 50 nails in oil (prevent from rusting). It might even be possible that a solid product (by trade practice or national regulations is) is declared in units of volume and still is put into another liquid medium. The term 'drained weight' then should be read as 'drained quantity of product in a liquid medium'.

When a prepackage contains solid goods in a liquid medium the definition of 'packing material' helps to differentiate between 'product' and 'packaging'. There are tree types of solid goods in a liquid medium.

By applying the definition of 'packing material' the problem of drained weight is reduced to a measurement problem. Several international standards and recommendations deal with that. More information on drained weight is to be found in chapter 3.

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[19] *European Council Directives 75/106/EEC and 76/211/EEC, article 2, clause 1*

[20] *USA Weights and Measures Law, section 1 Definitions, 1.10: The term "net mass" or "net weight" means the weight of a commodity excluding any materials, substances, or items not considered to be part of the commodity. Materials, substances, or items not considered to be part of the commodity include, but are not limited to, containers, conveyances, bags, wrappers, packaging materials, labels, individual piece coverings, decorative accompaniments, and coupons, …*

2.4.1.3.1 The liquid medium is intended to be left over after use

This applies to the liquid mediums meant in Directive 2000/13/EC, 8.4[21] (for instance to pears in water).

The indication of the content of the prepackage and quantity of the product in the prepackage apply to the solid goods.

In this case the solid goods are the product in the prepackage excluding the packing material and the liquid medium.

The definition of packing material differs between product (solid goods) and packing material (= liquid medium and packing material). This is in accordance with the definition of 'net weight' of the Unites States Weights and Measures Law[22].

2.4.1.3.2 The liquid medium is not intended to be left over after use

This applies for instance to liquor with raisins, but also to fruit juice with pulp.

The indication of the content of the prepackage and quantity of the product applies to the solid goods and the liquid medium.

The definition of packing material differs between product (solid goods and liquid medium) and packing material (packaging).

2.4.1.3.3 The liquid medium might or might not intended be left over after use

This applies to for instance sweetened juice with fruits and fish in oil.

The definition of package does not distinguish between the liquid medium and the goods.

For instance a recipe on the label could clarify if the liquid medium 'is intended to be left over after use' or not. Also an official list or a list published and maintained by for instance OIML could give clarification.

In this case one prepackage contains two different products: the solid items and the liquid medium. Both the nominal quantity of solid goods and the nominal quantity of the liquid medium should be on the label of the prepackage.

2.4.1.4 Product

By defining the terms 'prepackage' and 'packing material', there is no need to define the term 'product' as it is everything apart from the packing material in a prepackage.

Product is also referred to as 'commodity', 'Consumer commodity', 'goods' and 'contents'.

Usually the product is the reason the prepackage is purchased for.

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[21] *Directive 2000/13/EC, 8.4: Where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff shall also be indicated on the labeling. For the purposes of this paragraph, 'liquid medium' shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine, aqueous solutions of food acids, vinegar, aqueous solutions of sugars, aqueous solutions of other sweetening substances, fruit or vegetable juices in the case of fruit or vegetables.*

2.4.1.5 Prepacked product

Council Directives 75/106/EEC (article 2.2) and 76/211/EEC (article 2.2) give this definition for prepacked product:

> A product is pre-packed when it is placed in a package of whatever nature without the purchaser being present and the quantity of product contained in the package has a predetermined value and cannot be altered without the package either being opened or undergoing a perceptible modification.

Council Directive 2000/13/EC (article 1, 3b) gives this definition for pre-packaged foodstuff:

> 'pre-packaged foodstuff' shall mean any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging *(packing material)* into which it was put before being offered for sale, whether such packaging (packing material) encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging *(packing material)*.

Differences between the two definitions:

e-marking Directives	foodstuff Directive
quantity of product has predetermined value	no predetermined quantity of product
purchaser	ultimate consumer and mass caterers
product	single item for presentation
no statement about enclosure of packaging (packing material)	Packaging (packing material) can enclose completely or partially

Similarities between the two definitions:

e-marking Directives	foodstuff Directive
purchaser not present when product is placed in the package	foodstuff is put into packaging (packing material) before offered for sale
quantity of product cannot be altered without the package being opened or modified perceptible	quantity of product cannot be altered without opening or changing the packaging (packing material)

The e-marking Directives apply only to products in a predetermined value, where the definition in the Foodstuff Directive also applies to not predetermined products. The word 'product' must be made equal to 'foodstuff' in the Foodstuff Directive.

[22] *USA Weights and Measures Law, section 1 Definitions, 1.2: The term "weight" as used in connection with any commodity or service means net weight. When a commodity is sold by drained weight, the term means net drained weight.*

Both Directives demand that the quantity of product cannot be altered without opening or 'damaging' the packing material. Usually the quantity of product of hygroscopic and desiccating products gains or looses weight during normal conditions of storage. In the e-marking Directives they are not dealt with. In the foodstuff Directive they are. In the section on 'metrological control' suggestions are given.

The 251102 draft of OIML R87 provides for this definition:

> Prepackaged product - A single item for presentation as such to a consumer, consisting of a product and the packing material into which it was put before being offered for sale and the quantity of product has a predetermined value, whether the packing material encloses the product completely or only partially, but in any case in such a way that the actual quantity of product cannot be altered without the packing material either being opened or undergoing a perceptible modification.

We suggest the following definition:

> A product is prepacked when it is combined with packing material of whatever nature, whether such packing material encloses the product completely or only partially, without the ultimate consumer being present, the quantity of product contained in the package has a predetermined value and cannot be altered without the packing material either being opened or undergoing a perceptible modification.

This definition does not apply to packed products of which the quantity of product is determined (measured) after closing of the packing material. However, this definition can be made applicable for the Foodstuff Directive, with a remark that foodstuff also can be prepacked when the quantity of product is not predetermined before the prepacked foodstuff was offered for sale.

According to this definition, product cannot be prepacked when there is no packing material. A sticker with the necessary markings on fruit 'encloses the product only partially'. This is only possible when the quantity of product cannot be altered.

By this definition desiccating (losing weight or volume solely through evaporation) and hygroscopic (increasing weight or volume by adsorbing water(vapor)) products can only be prepacked in packing material preventing the effects (otherwise the quantity of product alters without opening…). The quality of the protective material is essential and not very easy to realize.

Knitting yarn is an example of a product that is enclosed only partially by the packing material.

2.4.1.6 Linguistic problems

The word 'content' has two meanings, illustrated by the following two phrases:

1. 'the content of this glass jar is marmalade' , where it is used with the meaning of 'product'
2. 'the content of this glass jar is 200 ml', where it is used with the meaning of 'amount'

An example of the first meaning can be found in Directive 75/106/EEC (Annex I, 1.1):

> the actual volume of the contents shall not be less, on average, than the nominal volume of the contents;

An example of the second meaning of the word 'contents' us used in the Directive 76/211/EEC (Annex I, 1.1):

> the actual quantity of product s shall not be less, on average, than the nominal quantity

This chapter sets the relationship between content and quantity, explains why the term 'net' may be abolished and explains about different types of content and quantity.

2.4.1.7 Content and quantity

In this sentence (from Directive 76/211/EEC, Annex I, 4) the relationship between content and quantity is set:

> The quantity of product contained in a prepackage …, known as the 'actual quantity of product', shall be measured...

For consistency reasons this relationship is modified to:

> The content of a prepackage is the quantity of product in a prepackage.

This is also the definition from the 251102 draft of OIML R87.

'Contents' is also referred to as 'content'.

The term 'contents' usually relates to the 'product' as that is what a prepackage contains. Contents of a product relates to ingredients.

The term 'quantity' can be replaced with:

- the 'weight' of product in a prepackage is the quantity of product in a prepackage expressed in a unit of mass
- the 'volume' of product in a prepackage is the quantity or product in a prepackage expressed in a unit of volume

To avoid confusion, we recommend not to use the word 'contents' in the meaning of 'product' in which case the above definition would be: 'the contents of a prepackage is the quantity of contents in a prepackage'.

The term 'quantity' can apply to the product and the packing material of a prepackage. Usually the quantity of product is meant. When the quantity of packing material of a prepackage is meant, this should be formulated explicitly to prevent misunderstanding.

2.4.1.8 Different kinds of quantity

The terms 'actual', 'nominal', and 'average' specify both the terms 'contents' and 'quantity'.

Annex I in Annex A gives an overview of the related terms.

2.4.1.9 Nominal quantity

Directive 75/106/EEC, article 4.1:

> …an indication of the volume of liquid, called the 'nominal volume of the contents', which they are required to contain.

Directive 75/106/EEC, Annex I, 2.1:

> The nominal volume of the contents of a prepackage is the volume indicated on the prepackage, i.e., the volume of liquid which the prepackage is deemed to contain.

Directive 76/211/EEC, article 4.1:

> …an indication of the weight or volume of the product, known as 'nominal weight' or 'nominal volume', which they are required to contain.

Directive 76/211/EEC, Annex I, 2.1:

> The nominal quantity (nominal weight or nominal volume) of the contents of a prepackage is the weight or volume indicated on the prepackage, i.e. the quantity of product which the prepackage is deemed to contain.

Regulation 1538/91 (marketing standards for poultry meat), article 8.4:

> …an indication of the weight of the product known as 'nominal weight', which they are required to contain.

The 251102 draft of OIML R87:

> Nominal Quantity - The quantity of product in a prepackage declared on the label by the packager.

All the above definitions state that it is the quantity that is indicated on the prepackage.

They also require that there is a relationship between the quantity of product in the prepackage and the nominal quantity. In all relevant Directives this is further specified with requirements for:

- the average quantity of product in batches of prepackages and
- the actual quantity of product in individual prepackages

For that reason there is no need for specifications relating to requirements within the definition of nominal quantity.

Therefore we suggest the following definition for nominal quantity:

The nominal quantity of product in the prepackage is the quantity indicated on the prepackage.

The symbol 'Q_n' is used to designate 'nominal quantity of product'.

The nominal quantity is also referred to as 'labeled' and 'declared'[23] quantity'.

The term 'nominal quantity of product in the prepackage' has the same meaning as 'nominal content of the prepackage'.

The nominal quantity of product is not a characteristic of prepackages. It gives a packer a target to aim at. There is a resemblance with the nominal quantity of a weight. In that sense the nominal quantity only differentiates between different 'sizes' of prepackages.

2.4.1.10 Actual quantity

The words 'actual quantity' (of product in a prepackage) are seldom used. Instead the words 'actual quantity of product s' are defined, which means the same[24].

Directive 76/211/EEC, Annex I, 2.2[25]:

The actual quantity of product s of the prepackage are the quantity (weight or volume) of product which it in fact contains.

Directive 76/211/EEC, Annex I, 4:

The quantity of product contained in a prepackage (or packing quantity), known as the 'actual quantity of product s',…

The actual quantity of product s is also used here: Directive 75/106/EEC, Annex I, 2.2:

The actual volume of the contents of a prepackage is the volume of liquid it in fact contains.

This can also be read as: the actual quantity of the product in a prepackage is the quantity of product it in fact contains.

[23] *Directive 75/106/EEC (article 1), 79/373/EEC (Annex, part A1)*

[24] *'Actual quantity of product s' (of a prepackage) means the same as 'actual quantity of product' (in a prepackage).*

[25] *commission regulation (EEC) No 1538/91 refers to Directive 76/211/EEC (article 8.4)*

Directive 75/106/EEC, Annex I, 4:

> The quantity of liquid contained in a prepackage, known as the actual volume of the contents,

This can also be read as: the actual quantity of product in a prepackage, known as the actual quantity of the product…

The 251102 draft of OIML R87:

> Actual quantity – The actual quantity of product that a prepackage in fact contains as determined by measurements made by legal metrology officials.

The scope of the OIML recommendation specifies (amongst other things): ...procedures for use by legal metrology officers.... That is where the phrase 'as determined by measurements made by legal metrology officials' comes from.

Of course not only legal metrology officials can determine the actual quantity. packers do so all the time.

When the definition also applies on packer it is better to remove the term 'as determined by measurements made by legal metrology officials.'

Based on the above definitions we suggest this one:

The actual quantity of the product in the prepackage is the quantity of product, which the prepackage in fact contains.

The term 'actual quantity of product in the prepackage' has the same meaning as 'actual quantity of product of the prepackage'.

The actual quantity is a characteristic of an individual prepackage.

2.4.1.11 Average quantity

Average quantity is not defined.

The average quantity of product in prepackages is the arithmetic average actual quantity of product in prepackages.

The term 'average quantity of product in the prepackage' has the same meaning as 'average content of the prepackage'.

The average quantity is a characteristic of any collection of prepackages, in spite of such collection is named population, batch, lot or sample.

2.4.1.12 Predetermined or not-predetermined quantity

The nominal, actual and average quantity relate differently to one other when used in a system of predetermined nominal quantity (the nominal quantity is set before dosing, like the e-marking system) and in a system of individual measured quantity (the nominal quantity is set after dosing, for instance sometimes used by foodstuff).

2.4.1.13 Net

Net contents and net quantity are frequently used terms in prepackaging and in legislation. The use of the word 'net' is superfluous: the quantity of product in a prepackage (or contents of a prepackage) is by definition net of packing material.

This has been recognized in the European Council Directive 2000/13/EC relating to the labeling, presentation and advertising of foodstuffs, where 'quantity' is regarded to be 'net quantity'[26] and in the USA.[27].

As the terms 'net quantity' and 'net content' appear in legislation, these are the definitions:

The net content of a prepackage is the quantity of product in a prepackage.

and

The net quantity of product in a prepackage is the quantity of product in a prepackage.

By these definitions, the term 'net content of a prepackage' is equal to 'content of a prepackage' and the term 'net quantity of product in a prepackage' is equal to 'quantity of product in a prepackage'.

In future, the term 'net' may be abolished as content and quantity of product are by definition 'net' of packing material. This has been recognized in the 251102 draft of OIML R87, where the term 'net' is not used anymore.

[26] *European Council Directive 2000/13/EC, article 8.2(a): Where the indication of a certain type of quantity (e.g. nominal quantity, minimum quantity, average quantity) is required by Community provisions or, where there are none, by national provisions, this quantity shall be regarded as the net quantity for the purposes of this Directive.*

[27] *USA Weights and Measures Law, section 1 Definitions, 1.2: The term "weight" as used in connection with any commodity or service means net weight. When a commodity is sold by drained weight, the term means net drained weight.*

2.4.2 Recommendations on definitions

This document can be used as a 'translator' between different legislation. The definitions below set the standard for future legislation. They leave no room for misunderstanding and facilitate fair competition.

- A **prepackage** is defined as the combination of a product and the packing material in which it is prepacked.
- **Packing material** is everything that is intended to be left over after use, except for items naturally in the product. Use includes consumption or subjecting to a treatment.
- For solid goods in a liquid medium (drained weight products) this definition differentiates between product (the solid goods) and packing material (the liquid medium and the packing material).
- **Prepacked product:** a product is prepacked when it is combined with packing material of whatever nature, whether such packing material encloses the product completely or only partially, without the ultimate consumer being present, the quantity of product contained in the package has a predetermined value and cannot be altered without the packing material either being opened or undergoing a perceptible modification.
- The **content of a prepackage** is the quantity of product in a prepackage.
  - The **nominal quantity** of product in the prepackage is the quantity indicated on the prepackage.

    The symbol 'Qn' is used to designate 'nominal quantity of product'.
  - The **actual quantity** of the product in the prepackage is the quantity of product, which the prepackage in fact contains.
  - The **average quantity** of product in prepackages is the arithmetic average actual quantity of product in prepackages.
- In future, the term '**net**' in relation to content and quantity should be abolished as content of a prepackage and quantity of product in a prepackage are by definition 'net' of packing material.

2.4.3 Definitions in EU Directives

Annex D gives an overview of the legal document checked on any statement in relation to conformity assessment. Two documents regulate the application of the metrological requirements for conformity assessment.

Directive 75/106/EEC (Council Directive of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids) relates to prepackages containing the liquid products (wines, beer, waters, oils, fruit juice, etc) measured by volume for the purpose of sale in individual quantities of between 5 ml and 10 liters inclusive. The Directive determines the nominal quantity, the maximum deviation in minus the labeling and the sample size for enforcing the requirements.

Directive 76/211/EEC (Council Directive of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products) relates to prepackages containing other products then referenced in 75/106/EEC (liquid products as wines, beer, waters, oils, fruit juice, etc) measured by weight and volume for the purpose of sale in individual quantities of between 5 ml and 10 liters inclusive. The Directive determines the nominal quantity, the maximum deviation in minus the labeling and the sample size for enforcing the requirements

These two Directives are the basic regulating documents for prepackages. Other Directives and regulations reference the word prepackages, prepackaging and the like.

From the documents referenced in Annex D only Regulation 1538/91 (poultry meat) reference 76/211/EEC.

Directive 76/768/EEC (cosmetic products) states that the nominal content shall be declared.

Directive 89/107/EEC and 89/108/EEC state that the net quantity shall be declared

Regulation 2200/96 (fruits and vegetables) states that the net weight shall be declared.

2.4.3.1 The 251102 draft of OIML R87

OIML is producing a new draft of their recommendation 87, now named 'quantity of product in prepackages'. Together with OIML R79 (*Labeling Requirements for Prepackaged Products, 1997)* prepackages are covered. At the moment the final draft (in this document named the 251102 draft) is voted about. It is expected that the document will be accepted after minor typographical changes.

The recommendation is founded on the average quantity principle (like the European e-marking system), which means that the average quantity of product in prepackages must equal or exceed the nominal quantity. The actual quantity of product of prepackages may not be less than certain limit(s) under the nominal quantity.

The paragraph on terminology is almost identical with those in chapter 2 of this report.

The document provides for these nominal quantities and tolerable errors (tolerable deficiency):

Nominal Quantity of Product (*Q*n) in g or ml	**Tolerable Deficiency *(T)*[a]**	
	Percent of *Q*n	**g or ml**
0 to 50	9	-
50 to 100	-	4.5
100 to 200	4.5	-
200 to 300	-	9
300 to 500	3	-
500 to 1 000	-	15
1 000 to 10 000	1.5	-
10 000 to 15 000	-	150
15 000 to 50 000	1	-
[a] *T* values are to be rounded up to the next tenth of a g or ml for *Q*n less than or equal to 1 000 g or ml and to the next whole g or ml for *Q*n higher than 1 000 g or ml.		

Nominal Quantity of Product (*Q*n) in length	**Percent of *Q*n**
*Q*n of 5 m or less	No tolerable deficiency allowed
*Q*n greater than 5 m	2

Nominal Quantity of Product (*Q*n) in area	**Percent of *Q*n**
All *Q*n	3

Nominal Quantity of Product (*Q*n) in count	**Percent of *Q*n**
*Q*n of 50 items or less	No tolerable deficiency allowed
*Q*n greater than 50 items	1[b]
[b]Compute the *T* value by multiplying the nominal quantity by 1 percent and rounding the result up to next whole number. The value may be larger than 1 percent due to the rounding but this is accepted because the products are whole items and cannot be divided.	

Figure 2-1: nominal quantities and tolerable negative error in the 251102 draft of OIML R87

Note that the nominal quantity may be as high as 50 l or kg. Heavy prepackages might require 'workers and/or their representatives receive general indications and, where possible, precise information on: the weight of a load, …'[28]. If the packing material is heavy, the weight of the prepackage (nominal quantity + weight of the packing material) should be indicated on the packing material. This might lead to confusion to the consumer.

The document has also solved the drained weight problem and the ice-glazed food problems through defining the fluid and the ice as packing material.

There is no guidance on dealing with desiccating and hygroscopic products, although in the previous draft this subject was covered.

For reasons of consumer protection the 251102 draft of OIML R87 contains an annex on misleading packaging. The subject is not covered in the e-marking legislation.

[28] Council Directive 90/269/EEC of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers, article 6

3 Present and discuss all relevant methods of metrological control with a view to clarifying them on consistency and introducing drained net weight

3.1 Problems

In various Directives different methods of metrological control metrological are used. Sometimes metrological control is not consistent with the e-marking Directives, sometimes the e-marking Directives are referred to. In various Member States the Competent Departments carry out 'other checks'[29], in particular for the purpose of verifying that prepackages meet the requirements of the e-marking Directives, sometimes applying them on prepackages of nominal quantities greater than 10 kg or l and performed at the moment prepackages are offered for sale.

The current Directives are not clear what the moment in time the quantity of product in prepackages must meet the requirements. Currently in various Member States the moment of compliance with the requirements is interpreted differently (sometimes at the moment of packing, sometimes at the moment of sale), which leads to unfair competition with regard to desiccating and hygroscopic products.

3.2 Work program

The Member States have no harmonized methods of determining the drained weight. This leads to unfair competition and diffused information to the consumer. The various methods have been investigated and summed up.

The work also includes:

1. imported prepackages
2. checks performed by the packer (might be taken into account when executing metrological control)
3. different batch sizes (the control might be more efficient when batches are defined differently)

3.3 Deliverables

The purpose of the work was to interrelate the various methods of metrological control metrological and other checks and to come up with an overview of set of metrological controls and other checks performed:

- at the end of the packing line
- in the warehouse at the packers premises
- at other moments in the distribution chain
- at the point of sale

[29] *article 6 of annex I of Council Directive 76/211/EEC*

Requirement: all methods of metrological control and checks should lead to the same decisions about rejection of acceptance of prepackages.

3.4 Discussion and Results

3.4.1 Existing situation

The existing interpretation of 75/106 and 76/211 are due to the voluntary nature not harmonized and equally well implemented in the various European Member States. Document PEXEC-04 generated by the members of WELMEC WG6 shows the differences in Implementation (see Annex E).

Amongst other things the purpose of the Directives was to open markets of EU Member States. The e-mark functions as a EU wide quantity control mark, often demanded by retailers and voluntary used even for non-Consumer goods. According to packers, the e-mark still opens doors in other Member States and outside the EU, because of their procedures being recognized.

3.4.1.1 three ways of bringing prepackages on the market

The Directives recognize three ways of bringing e-marked prepackages on the market:

1. by measuring while filling

   Common interpretation: manual filling while using a legal measuring instrument, in UK also through gravimetric filling machines are allowed. This option is hardly used, for large nominal quantities and very small batch sizes.

2. import

   The Directives allow an importer to provide for guarantees enabling him to assume his responsibility. No uniform interpretation is implemented. WELMEC Working Group 6 suggests this one:

   Acceptable guarantees would include:

   a. a certificate from a Competent Department in a Member State
   b. a certificate from an EU 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

   Certificates referred to in a. and b. above shall state that the quantity control system had been assessed and that the controls and records guarantee compliance with the requirements of the Directive. The certificate needs to specify the type of goods, the nominal quantity and packaging that has been assessed.

3. by having the procedures of importers or packers recognized

   The third (and most used) option of bringing e-marked prepackages on the market is by having procedures recognized by Competent Departments. This has been implemented differently:

   a. explicit recognition by an independent organization

b. recognition through codes of practice: packers producing the same product, work according to standardized procedures (codes of practice)
c. implicit recognition by inspectors of the Competent Department: this means that inspectors who perform reference tests, advice or require certain procedures
d. some countries do not recognize procedures

Regardless which type of recognition is implemented (a, b or c), more or less the same subjects make up the procedures. These 'requirements' are also applicable to small packers. In Annex F the common view of WELMEC Working Group 6 is provided.

In some Member States permission is required prior to applying the e-mark, in some Member States notification by the packer/importer is necessary and in some countries the e-mark may be applied without permission or notification.

This table shows the relation between the way procedures are recognized and the way permission is obtained:

		is permission needed?		
		no permission needed	**permission after notification**	**judgment before permission**
how are procedures recognized?	**explicit** (with certificates, stamped procedures etc)		SI	NL, DK, SWE, CZ, NORW, FI
	implicit (by inspector)	*UK, DE, AT*	SI BE	
	codes of practice	*UK, DE, AT CH*		
	none	BG, HU	F	

Figure 3-1: relation between the way of recognizing procedures and the way permission is obtained

Except for France, Greece and Island the Competent Department performs reference tests at the premises of the packer or importer.

A combination of the possibilities of import, measuring while filling and having procedures recognized is visualized below:

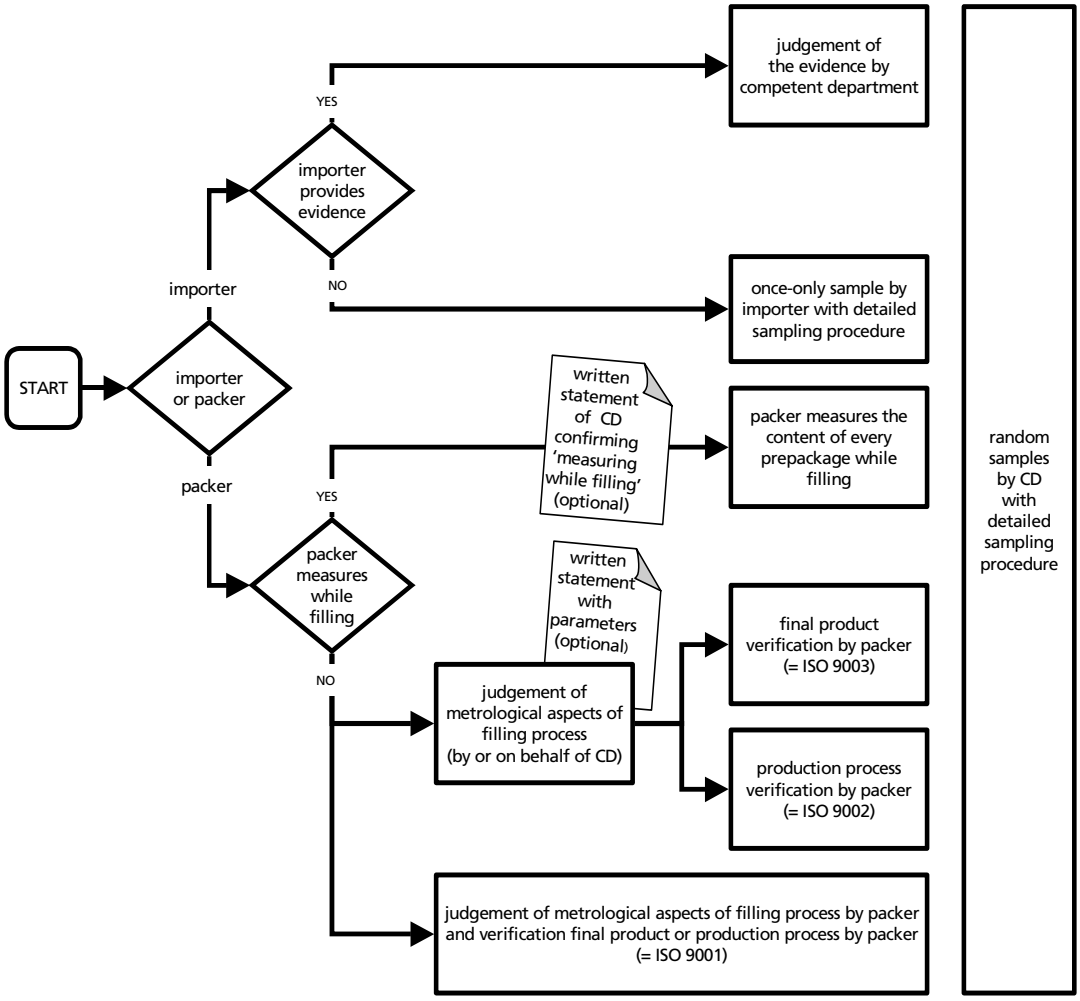

Figure 3-2: Combination of the possibilities of imports, measuring while filling and recognized procedures for e-marked prepackages. CD means 'competent department'

3.4.1.2 desiccating and hygroscopic products: the moment of complying with the requirements

Different views exist on the moment prepackages should comply with the requirements. This is a problem with desiccating and hygroscopic products (and there are a lot of those).

The requirements the prepackages must meet could be one of the following:

1. at the moment the prepackages are closed
2. up to the moment the prepackages are sold (or until the use-by date expires)
3. at all times

At the moment the e-marking Directives give no guidance when prepackages must meet the requirements. Different member states have different philosophies. The moment the prepackages must meet the requirements must be clear in order to avoid unfair competition.

This problem is a trade barrier at the moment. Packers recognize this as such.

The following table sums up the consequences of:

		moment when requirements apply		
		at point of pack	at all times	at moment of sale
change in quantity of product resulting from environmental circumstances	gain	packer may not underfill anticipating on the gain of quantity inspector compensates when sampled after point of pack	packer may not underfill anticipating on the gain of quantity no compensating for inspector	packer can underfill anticipating on the gain of quantity inspector compensates when sampled before point of sale
	loss	packer does not have to overfill anticipating the loss of quantity inspector compensates when sampled after point of pack	packer must overfill anticipating the loss of quantity no compensating by inspector	packer must overfill anticipating the loss of quantity no compensating by inspector when sampled before point of sale

Figure 3-3: effects of the moment prepackages need to comply

According to the Codex General Standard for the Labeling of Prepackaged Foods[30] (part of Codex Alimentarius), article 4.3, the declaration of the quantity of product in a prepackage represents the quantity at the time of packaging.

Comparison with Council Directive 2000/13 (labeling, presentation and advertising of foodstuffs) article 6.5 suggests that the requirements must be met at the moment of packing.

This is different from the 251102 draft of OIML R87 (see 3.4.3).

[30] *CODEX STAN 1-1985 (Rev.1-1991)*

packers can compete more easily when requirements must be met at the moment of packing because uncertainty about future weight loss is transferred to the consumer.

3.4.1.3 the batch size for a packer

In the Directives the batch size is defined for the reference test (that is performed by the Competent Department). In some countries this has led to the conclusion that (in general) the batch for a packer has to be defined in the same manner. In other countries there are no requirements for the batch size for a packer.

When the batch size for a packer is allowed to be bigger than the batch size for the reference test, the result of the judgment of a packer might be different from the competent department (who look at a smaller batch size). In that case the packer is in forced to use a batch size the competent department would do (in general: an hours production).

When the purpose of the reference test would be to judge the records of the packer, the packer might define his own batch size, more in line with more practical sizes (a batch might take a shift, one day or several days to produce).

3.4.1.4 technical differences in implementation

A lot of differences exist with regards to measuring methods. Harmonizing and producing standards on the subjects can only solve these. At the moment WELMEC Working Group 6 functions as the forum for this. WELMEC document 8.3 gives a universal interpretation how to deal with the requirements in the Directives. This document is the expert's opinion how the Directive should have been applied. The Description of the National Implementation as given in Annex E shows the full spread of differences in the EU Member States.

These technical differences lead to technical barriers to trade. packers recognize them as such. Some of them are listed here:

- different interpretation of the term 'sufficiently small' (Directive 76/211/EEC, Annex 1, section 1.2)
- density measurement of carbonated drinks
- how to declare free product (example: '200 g + 10% free')
- density measurement of ice-cream
- g or ml?
- identification of packer or the person arranging for the packing to be done

3.4.1.5 market surveillance

Checks at retailers are not very often carried out due to efficiency reasons: the batch must contain at least 100 prepackages, a number not available in stores for many prepacked products. This number of 100 prepackages is due to the statistical principles to determine the average quantity of product.

Quantity control systems based on the minimum quantity principle (no prepackage with a actual quantity of product less than the nominal quantity) does not require the determination of the average. In this situation only very small number of prepackages should be available for control purposes. Also several prepackages must be bought and destroyed to measure the weight of the packing material. This also requires funding and is an administrative burden.

retailers prefer enforcement to take place at another moment of the distribution chain. That does not disturb customers, no removal and destruction of prepackages for checking, no personnel accompanying enforcement officers and no risk of rejection.

Because there is hardly any market surveillance, prepackages form outside the EU can be put on the market without being subject to metrological control. This gives packers in the EU a disadvantage.

Competent Departments do have the possibility to perform a form of market surveillance: the Directives allow them to perform checks in order to verify if prepackages meet the requirements of the Directives. Because of the batch size limitations only labeling requirements can be checked and suspicion may rise that requires further investigation.

The actual actions are based on the national legalization. Some countries are very easy on the control of the packer's procedures. They rely on the market surveillance (France), other countries like the Netherlands and the Scandinavian countries use quality assurance principles to check in advance the capabilities of packers.

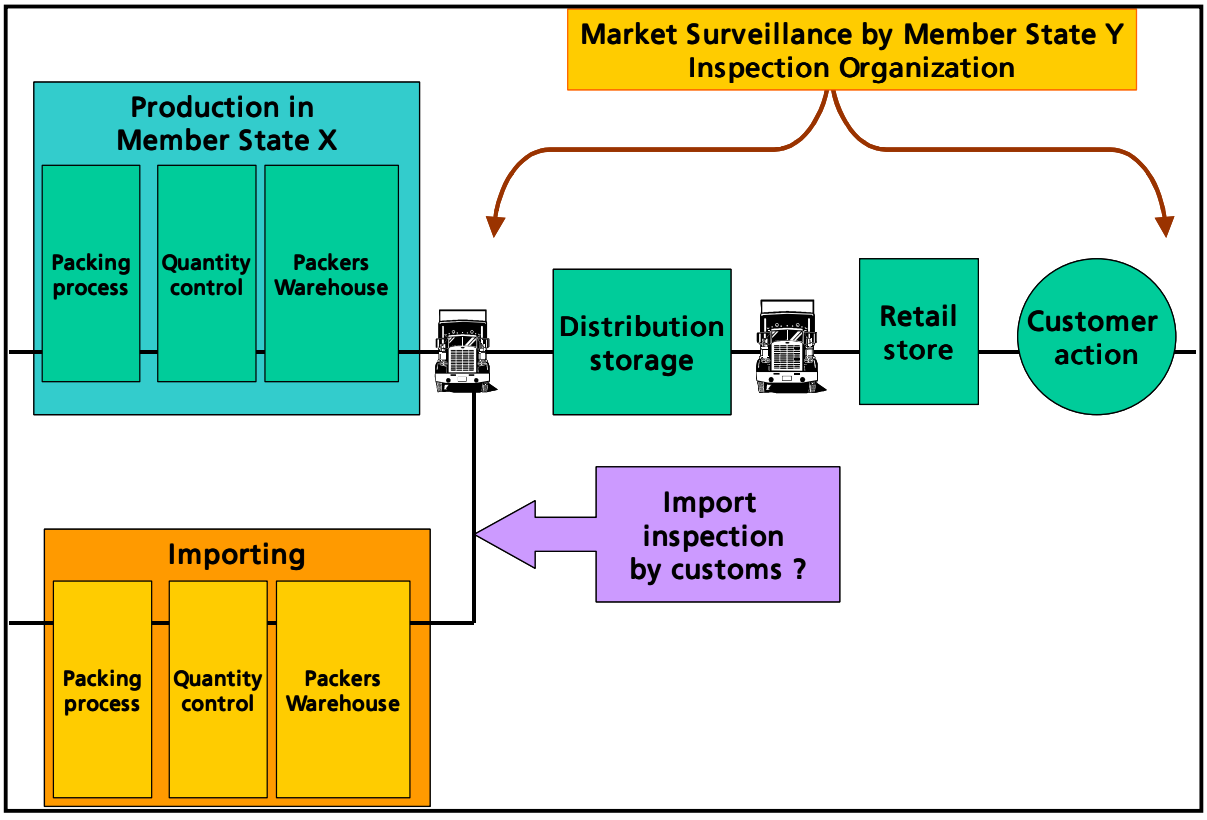

Figure 3-4: Flow of prepackages in the world

Above figure shows the flow of prepackages in the world. A packer can be in any country in the world. Control on prepackages can be done at point of pack, Wholesale and point of sale. A packer can operate in one Member State and his products are put on the market in another Member State. This packer can be confronted with two governmental inspection organizations (GIO's) at this moment.

The GIO in Member State of packing, for example, can perform reference tests at point of pack and control the quantity of product by accreditation principles or by incidental tests. When the product comes on the market in the other Member State, the GIO of that Member State performs either Wholesale, retail storage or point of sale control.

When the packer packs and puts prepackages on the market in the same Member, the GIO of that Member State controls the prepackages in a pre-put on the market and after-put on the market situation. This looks to be a conflicting situation. The same organization (person) is operating as a pre-market official and as a market surveillance inspector. With extended information on a packer this can lead to excessive control on this packer.

These two situations are controlled by Annex I.5 and Annex I.6 of Directive 76/211/EEC.

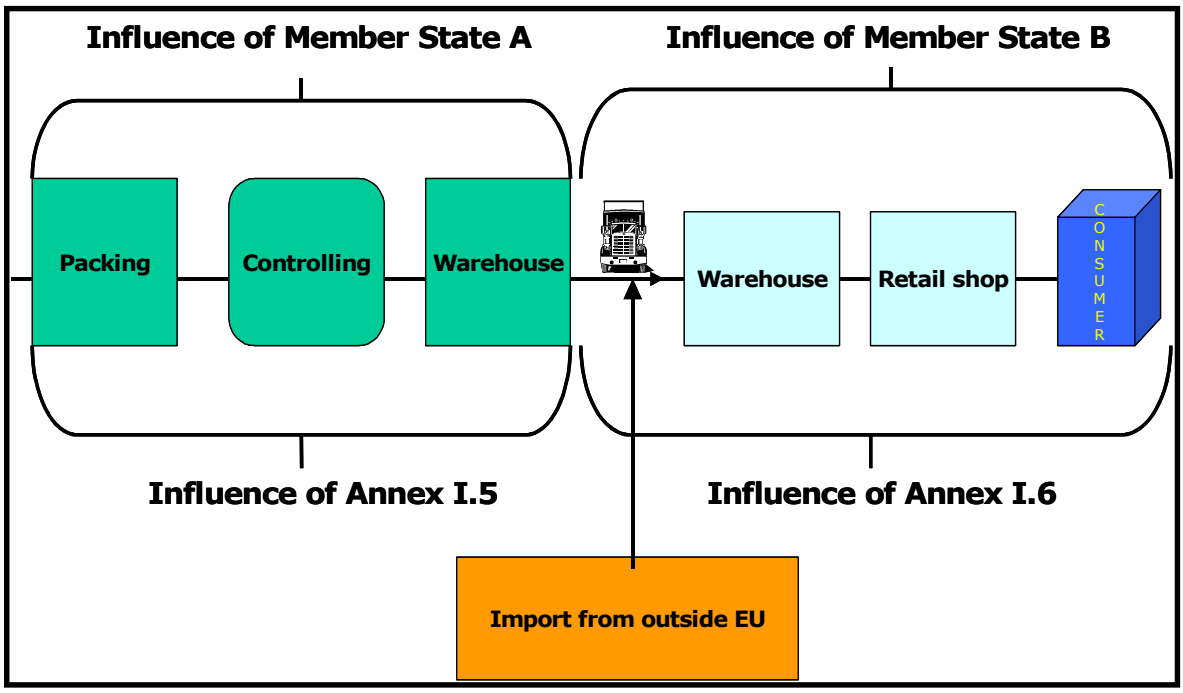

Figure 3-5: Jurisdictional influence on the flow of prepackages

Products imported from outside the EU should be controlled at the point of entrance to the EU. Hardly any Member State is controlling at this point. The consequences are that imported prepackages are only controlled under market surveillance conditions at point of sale. This can lead to an advantage for this packer.

In Great Britain the recognized procedures are laid down in codes of practice. When a packer is required to work according to these codes of practice. The competent department checks if they do so.

3.4.2 Possible future scenarios

3.4.2.1 The module system in European legislation

The New or Global Approach[31] in Europe is based on a number of modules that control the conformity assessment to instruments, equipment, commodities, and all other kind of items under legal control. Prepackages Directives are not based on the Global Approach.

The modules runs from 'self declaration' (module A) of the manufacturer to supervised quality assurance principles (modules D, E and H). An applicable module may be selected by the manufacturer to control the production of the product depending on the complexity and impact of the product on safety, health, consumer protection and environmental protection.

The legislative harmonization is limited to essential requirements that products placed on the Community market must meet.

Depending on the selected modules notified bodies (see chapter 6 of the Guide) play a substantial roll in putting on the market of these products. A notified body is an official, by a EU Member State government, appointed organization. It is the national responsibility to do it proper (see the Guide of the European Commission). A notified body can operate everywhere in the world. In essence any independent organization can apply for the function of a notified body. The government appoints the notified body for a specific functionality. It is like a notified body for NAWI. There will be notified body's in the future for prepackages.

notified bodies are tools for manufacturers to declare their competence in fulfilling the essential requirements. Depending on the context in the particular Directive, notified body's play certain roles. A notified body never takes over the responsibility of a manufacturer to comply with the rules of the particular Directive.

Market surveillance (see chapter 8 of the Guide) is the responsibility of the national surveillance authorities (in this document named governmental inspection organization, GIO). They monitor that products placed on the market comply with the Directives. A GIO can be either a governmental organization, a Department of a ministry, or an independent organization that works under contract on behalf of the government.

The existing national implementation of the e-mark Directives have mixed up the production assessment control on the quantity of product in prepackages with the market surveillance control. In many Member States the same organization and or same people carry out these two activities. This mixture some times lead to the fact that GIO inspectors order packers to implement certain changes in the packing procedures.

[31] *Guide to the implementation of Directives based on the New Approach and Global Approach. http://europa.eu.int/enterprise/newapproach.htm*

3.4.2.2 Understanding module B in the field of prepackages

Module B was originally designed with the (type) testing of instruments and equipment in mind. In the field of prepackages a distinguishable model does not exist. Although the same prepackages are in essence copies of each other, they are not a copy of an 'approved' model. However the characteristics of the filling process (combination of product – machines – man system) predict the outcome. For that reason the concept of process capability is introduced: the characteristics of the filling process can be seen as equivalence to the type approval of a model.

Under module B the manufacturer establishes a technical documentation as regards the design, manufacture and operation of the product. He:

- applies for the EC type-examination,
- places at the disposal of the notified body one (or more) specimen(s), which is (are) representative of the production envisaged,
- informs the notified body of all modifications to the approved product,
- keeps the technical documentation, including a copy of the EC type-examination certificate, at the disposal of the surveillance authorities.

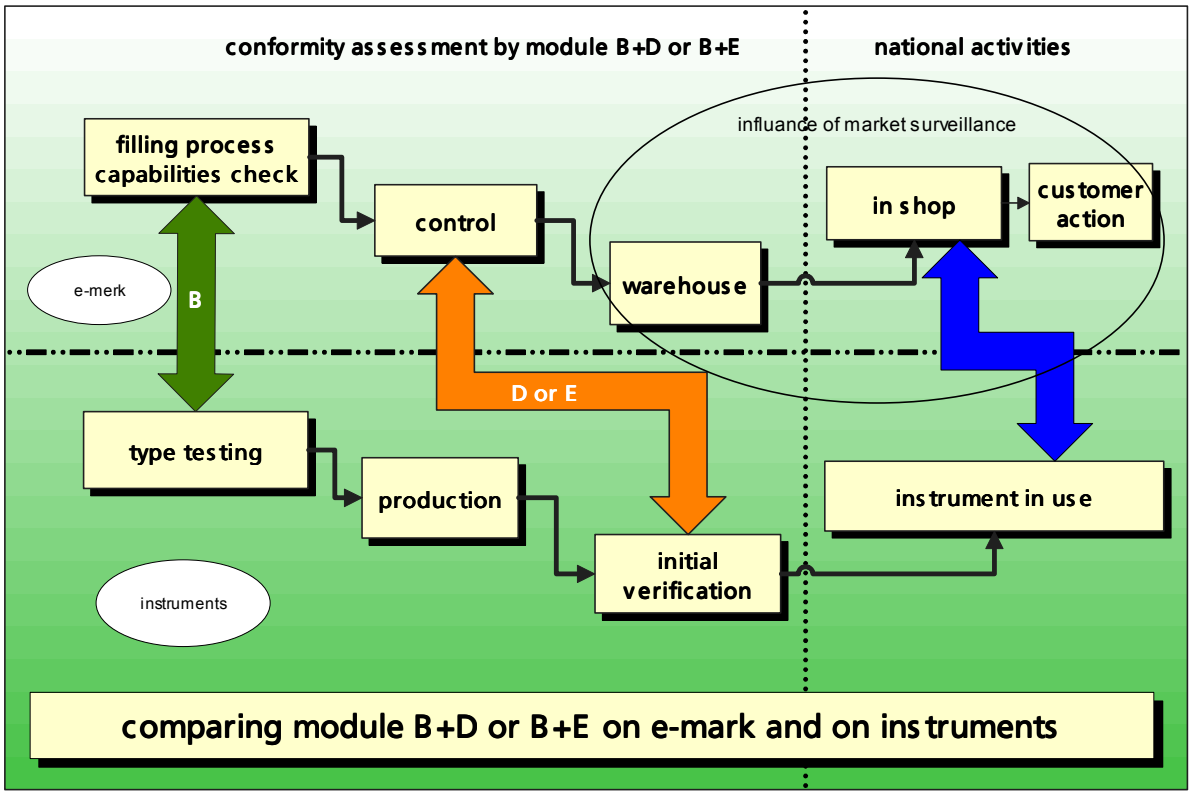

Figure 3-6: Applying the modules on measuring instruments and Prepackages

In the field of prepackages the responsibility of the packer is to keep the characteristics of the filling process within laid down (approved) limits. A change of these characteristics is equivalent to a change of the ' type'. The manufacturer shall document the filling process and its characteristics.

To be able to apply Module B in the field of prepackages, these are the characteristics of the filling process:

- specifications of the equipment used while making up the prepackages
- sample size and sampling frequency
- target settings, rejection and acceptance limits
- product specific measuring methods

They are laid down and enables a packer to judge if his prepackages meet the requirements of the Directives. For the purposes of this study, this combination of these characteristics is called 'process capability'.

Whenever one of the above factors is changed, the 'type' of filling process changes and there might not be a guarantee that the prepackages meet the essential requirements. The packer shall document the complete system by laying down all relevant factors of the process capability.

According to the principles of the new approach the notified body shall:

- ascertains, by performing or having performed examinations and tests, that the specimen(s) meet(s) the applicable provisions and is manufactured in accordance with the technical documentation
- issues an EC type-examination certificate
- keeps a copy of the certificate and a record of other relevant technical information
- communicates to the other notified bodies the relevant information concerning the EC type-examination certificates (on request).

The function of the notified body is to check the capabilities of the filling process. He will during this evaluation check of the system will produce prepackages that comply with the essential requirements. For this he can take samples of produced prepackages and verify the average and TU_1 and TU_2 conditions over suitable periods of time.

This can be translated to prepackages concerning actions of the notified body:

Translation of instrument principles to prepackages principles	
instruments	prepackages
specimen(s) meet(s) the applicable provisions and is manufactured in accordance with the technical documentation	the filling process meets the applicable provisions and is set up in accordance with the process capability (examinations and tests = process capability analyses)
issues an EC type-examination certificate	issues a certificate of approval, containing the process capability analyses description

Figure 3-7: translation of principles that apply to instruments into principles that apply to prepackages

The notified body will issue a certificate that allows the packer to apply the e-mark. The e-mark will carry the identification of the notified body and of the packer.

The actual control during the normal production of the prepackages shall be controlled as under module C, or D, or E. By this interpretation, the production control will have the same position as the initial verification with instruments and equipment.

Next figure gives an overview of various modules as they can be used with prepackages.

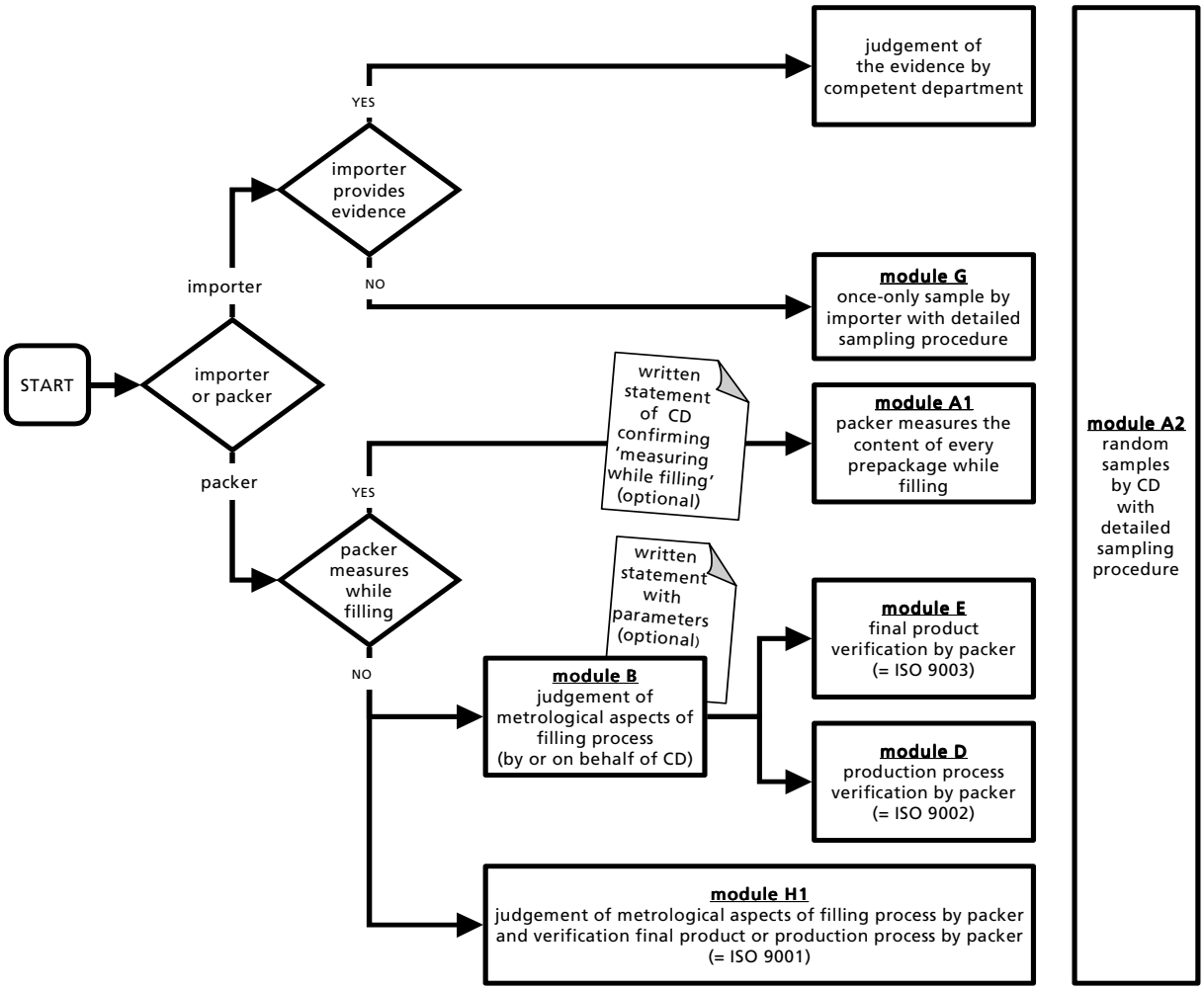

Figure 3-8: e-marking Directives translated into the modules of the new approach (CD means 'competent department')

This figure translates some existing situations into new approach modules:

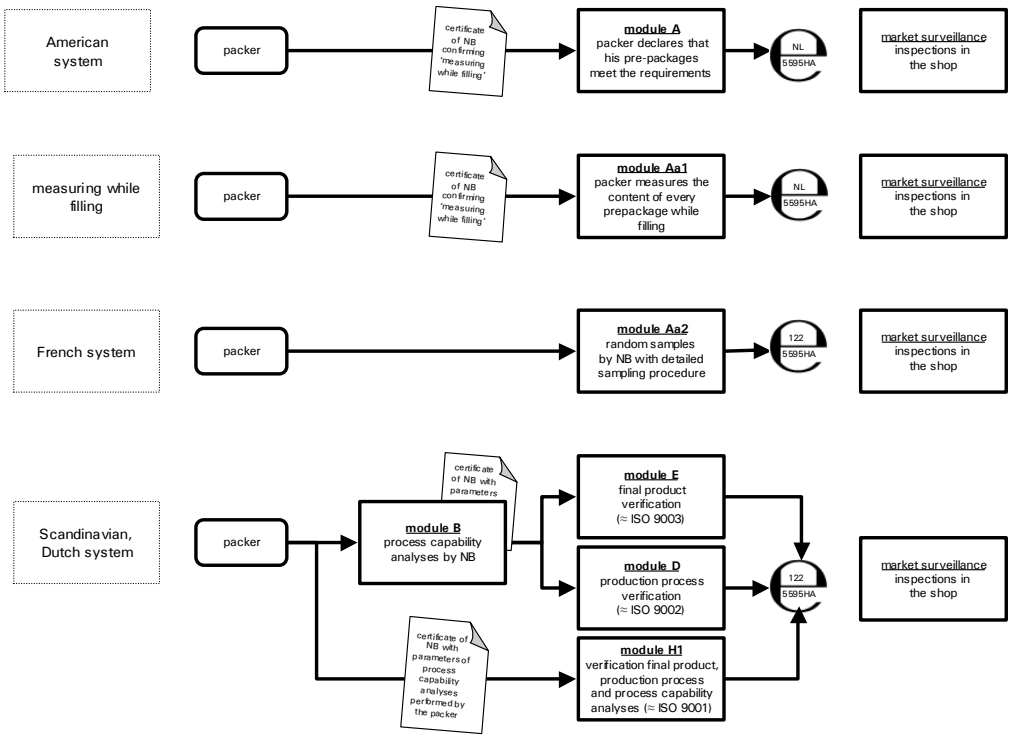

Figure 3-9: New Approach modules applied to the existing prepackages Directives

The current implementation of the e-marking Directives can be translated into the modules of the new approach:

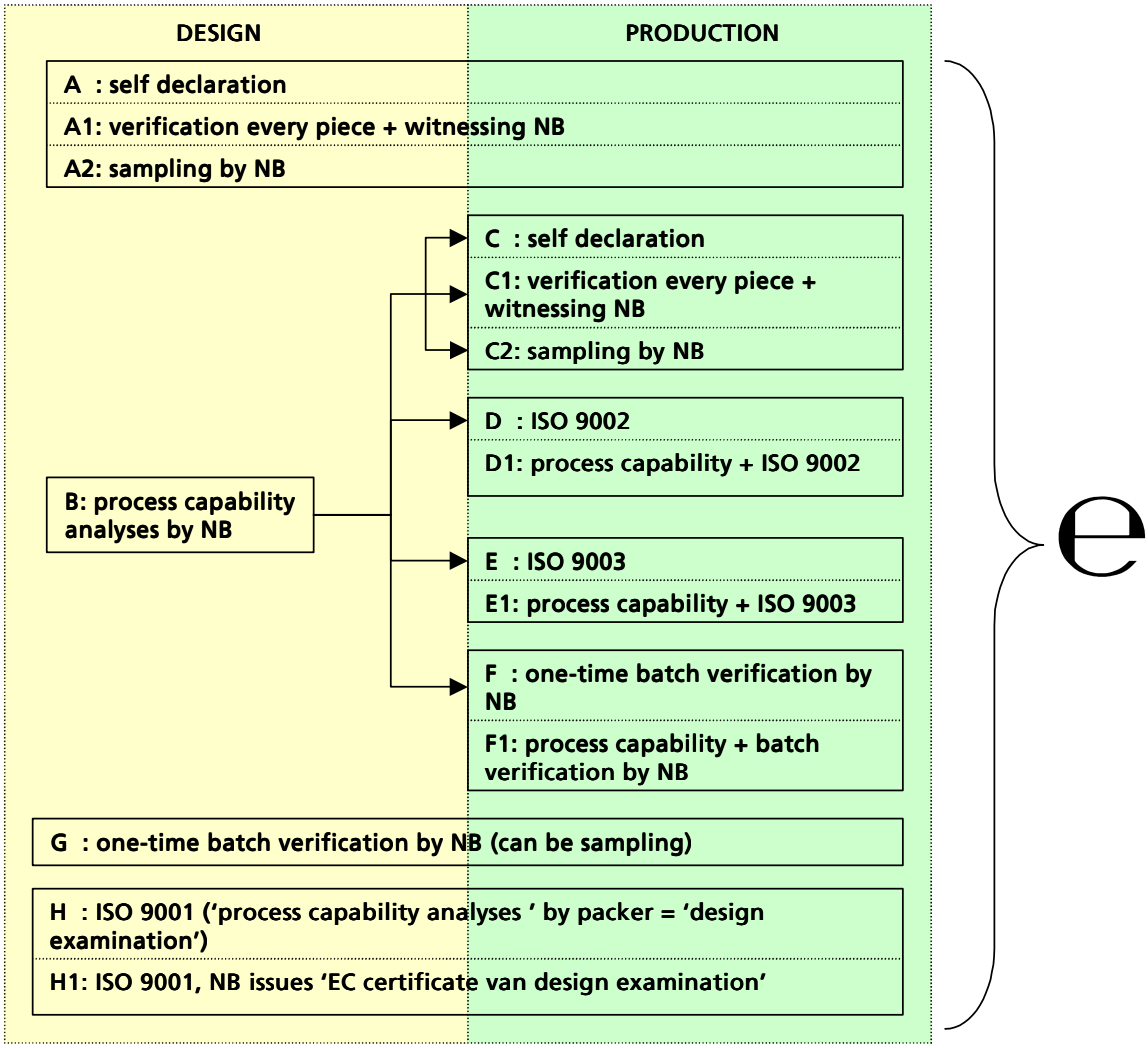

Figure 3-10: Various modules applied to prepackages (NB means 'notified body')

Chapter 4 will apply 4 scenarios with the operational procedures to the field of prepackages.

3.4.3 Drained Weight

Drained weight products are not addressed in the e-marking Directive s. Different interpretations exist. This leads to different requirements for packers and trade barriers:

e-mark applies to drained weight, drained weight + fluids or both

country	e-mark applies to	
	quantity of fluid + quantity of solid items	only quantity of solid items
Austria	x	
Czech Republic	x	
Belgium		x
Denmark	x	x
Finland	?	
France		x
Germany	x	
Norway		x
Hungary	x	
Slovenia	x	
Sweden	?	
Switzerland	?	
United Kingdom	x	
Netherlands	x	

Figure 3-11: e-mark applies to drained weight, drained weight + fluids or both

The Codex General Standard for the Labeling of Prepackaged Foods[32] (part of Codex Alimentarius), article 4.3, requires a declaration of the drained weight of the food in addition to the declaration of the quantity of product in the prepackage. Council Directive 2000/13 (labeling, presentation and advertising of foodstuffs), article 8.4, has the same requirement, since it originates from this Codex.

Application of the chapter on definitions, the declaration of quantity on the label would apply to the drained weight. The Codex and the Directive 2000/13 still require an indication of the quantity of liquid in the prepackage. In future, this last requirement should be removed.

[32] *CODEX STAN 1-1985 (Rev.1-1991)*

Sometimes the product and the fluid interact: product can absorb fluid or loose moisture during time hygroscopic or desiccating products). In contradiction to Directive 2000/13 (labeling, presentation and advertising of foodstuffs) article 6.5 (*the ingredients of a foodstuff must be labeled as recorded at the moment of manufacture*) the 251102 draft of OIML R87 allows a minimum time for these processes to take place:

Product	Period of Time for Checking	
	From	To
Fruit, vegetable and other vegetable foodstuffs (except for strawberries, raspberries, blackberries, kiwis, loganberries)	30 days after sterilization	Tenability
Strawberries, raspberries, blackberries, kiwifruit, loganberries	30 days after sterilization	2 years after sterilization
Products out of salted fish, anchovies, marinades, stewed fish goods, preserved fish; mussels, shrimps and suchlike.	Immediately after pouring on	14 days after pouring on
Marinades of fried fish	48 hours after pouring on	14 days after pouring on
Small sausages and other meat products	5 days after sterilization	Tenability
Other products	14 days after pouring on	Tenability

Figure 3-12: time allowed for interaction between product and fluid

4 Categorize conformity assessment and develop hypotheses on the impacts of choice

4.1 Problems

In the various Member States no harmonized way of conformity assessment of packers and imported is implemented. They vary from:

1. certification of packers procedures by accredited certification bodies and
2. recognition of packers procedures by Competent Departments to
3. self declaration by the packer with inspectors implicit recognizing procedures and
4. self declaration by the packer with inspectors only performing reference tests

In some Member States national legislation forces the packers to pack to the minimum, in others requirements for all prepackages must meet the requirements of the e-marking Directives, weather they are e-marked or not. In some Member States the packer must obtain prior permission. Legislation for importers differs per Member State. This leads to unrestricted imports and thus unfair competition to EU packers.

4.2 Work program

Four new scenarios have been developed and categorized.

4.3 Deliverables

Conformity assessment must be effective. The work has made clear what advantages and disadvantages the different systems of conformity assessment have.

4.4 Discussion and results

The idea is that the new prepackages Directive is mandatory. This means that all prepackages shall comply with the rules about average quantity of product, TU_1 and TU_2. Each prepacked product that will be sold in any shop shall comply. It applies for volume and weight in a certain range (probably 5 gram or 5 ml to 25 kg or 25 liter). The way the quantity of product is guaranteed and controlled can be different. That is why there are four scenarios (options) presented. Selling a prepackage can only be with the e-mark applied.

Four scenarios are developed and described. The range of effect is in the way pre market effort and market surveillance is effective.

On the one side the packer will endure the minimum of actual control by notified bodies but will have the responsibility to control his own system. How a packer ensures that his prepackages meet requirements, is not under supervision. The enforcement on conformity with the rules is by extensive market surveillance. It is up to the market surveillance authorities (in this report called: governmental inspection organizations or GIO's) to organize effective measures against non-complying packers. Because packers are free to organize their own procedures, GIO's cannot interfere at that level. The sanctions shall be at the market level.

On the other side, systems under full quality assurance philosophy apply. The packer is controlled in advance on his capabilities. The expectation of proper performance in the market is high and therefore market surveillance can be limited. Accreditation of packers is the key word. An approved/certified packer will maintain his procedures because his production can be blocked at the very beginning of the production of the prepackages.

Between these two extremes there are two scenarios selected to create a sliding scale of more packer side interaction and probably less GIO interaction.

The next four scenarios are explained as follows. The explanation starts with a very short formulation of the product specifications. For the four scenarios these requirements does not differ much. The variation is due to the participation of the notified body. In the product specifications reference is made to Annexes on Labeling, Testing and Criteria for acceptance of test results. These Annexes are not available now, but will contain the same information as there is now on labeling, testing and accepting results. These Annexes are named in this report as: 'an annex about labels', 'an annex about testing' and 'an annex about criteria'.

Secondly each scenario will be explained about the operational situation. This explanation will outline what happens at the various stages of producing and placing on the market of the prepackages.

The next section discusses the effects of the structure of the scenario, in particular from the Point of packers and importers, the GIO's and the customs.

Finally the report will summarize the comment of the stakeholders and will give conclusions about how useful an scenario can be.

At this moment there is not a link between the four scenarios. The system should be seen as an inquiry to find out which scenario has a preference or a dislike by the stakeholders. At this moment there is no preference for any scenario. The scenarios will be treated as separate items.

4.4.1 Conformity assessment, Scenario 1 (self declaration)

Scenario 1 is based on minimal interaction from legal regulations, no notified body actions and enforced by market surveillance only.

4.4.1.1 product specifications

All prepackages that can be obtained at the EU market shall comply with:

- a certain number of prepackages shall have an average quantity of product of at least the nominal quantity,
- the number of prepackages between the nominal quantity and TU_1 shall be restricted
- the number of prepackages below TU_2 shall be zero,

- the packer (or who takes responsibility for the correct quantity of product) shall put his name and address on the prepackages for traceable corrective actions by a governmental inspection organization,
- all prepackages shall bear the proper information labeled as laid down in an annex about labels,
- market surveillance shall be based on a standard test as given in an annex about testing,
- accepting or rejecting the measured batch shall be based on the criteria given in an annex about criteria.

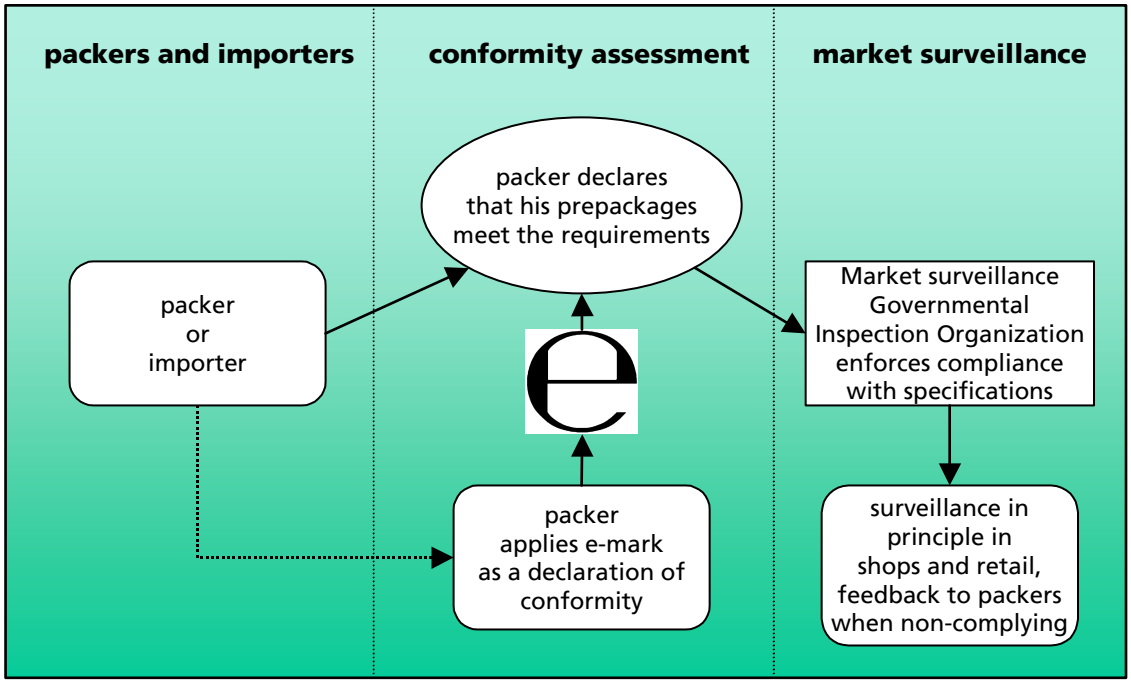

Figure 4-1: Scenario 1, self declaration

4.4.1.2 Operational description

A packer is free to place a prepackage on the market. He does not need any permission. He does neither have any system description, nor a quality assurance system. Any procedure to guarantee the quantity of product can be used by the packer. He only has to comply with the product specifications that the prepackages are part of a larger batch with the quantity of product. He shall place the e-mark on the prepackages to make his declaration of conformity with the product specifications.

The control on the quantity of product is by market surveillance, performed by a GIO. This body is free to control any number of prepackages and checks compliance using tests as given in an annex about testing. If the collected number of samples complies with the criteria of an annex about criteria, the samples are accepted. In the case of non-acceptance, the GIO shall inform the packer and request him to install corrective actions. When a packer consistently not complies with the product specifications the GIO can fine the packer.

4.4.1.3 Expectation of Impact

4.4.1.3.1 Packers and importers

Cheap for packers and importers. This is a very simple system. packers do not apply for any permission. There are no requirements on the packing procedures at the packer site. The packer and importer must comply with the product specifications, but do not need to prove this in advance. Any packer that can put prepackages on the market with the e-mark on, but he is responsible for the proper quantity and labeling.

Applying the e-mark on the prepackage means that the packer declares that the prepackage is in compliance with the new Directive. Prepackages without the e-mark shall not be sold any way. This scenario 1 is a situation where the packer is not controlled by any organization. It is his responsibility to comply. The real control is in the market-by-market surveillance by the GIO. They control the quantity of product in the prepackage. If there is non-compliance the GIO can remove the batch from the market.

4.4.1.3.2 Governmental inspection organizations

The GIO shall control the compliance with the product specifications. Because they do not know the parties involved they will have some difficulty to find the packers and importers.

Difficult to operate with repeating non-complying packers. Large effort required from the side of the GIO. There is a risk that GIO will enforce more stringent requirements because they will want to make market surveillance more effective (for instance: having inspectors implicitly recognizing procedures). Direct costs are only on the side of the government.

4.4.1.3.3 Customs

Difficult to control repeating non-complying imports, because packers outside the EU can easily switch to different or new importers. The cooperation of customs is essential in controlling imports.

4.4.1.3.4 Retailers

The control of the quantity of product at the retailer is limited by the number of prepackages available in the shop. The packer is still responsible for the proper quantity. The retailer remains the Distributor and can not held responsible of the proper quantity. Effectiveness is very limited. Retailers are unhappy with GIO activities in the shop. In daily live the retailer determines which products will be sold. This is not based on quantity of product but on buyers appeal and profitability.

4.4.2 Conformity assessment procedure, Scenario 2 (product validation)

Scenario 2 is based on small interactions from legal regulations, some support from notified bodies and enforced by market surveillance.

4.4.2.1 Product specifications

All prepackages that can be obtained at the EU market shall comply with:

- a certain number of prepackages shall average quantity of product of at least the nominal quantity,
- the number of prepackages between the nominal quantity and TU_1 shall be not larger then n,
- the number of prepackages below TU_2 shall be zero,

- the packer shall put his name and address on the prepackages for traceable corrective actions by a governmental inspection organization,
- all prepackages shall have the proper information labeled as laid down in an annex about labels,
- market surveillance shall be based on a standard test as given in an annex about testing,
- accepting or rejecting the measured batch shall be based on the criteria given in an annex about criteria.

4.4.2.2 Operational description

A packer can place a prepackage on the market either by having all the prepackages he produces, tested on the product specifications by himself under supervision of a notified body who shall issue a certificate of his findings or the notified body shall take samples randomly to test compliance with the product specifications. The packer shall have a system description of the packaging procedures or a quality assurance system. Any procedure to guarantee the quantity of product can be used by the packer.

The packer only has to comply with the product specifications that the prepackages are part of a larger batch with the quantity of product. He may place the e-mark with the notified body identification number or the plain e-mark on the prepackages to declare his conformity with the product specifications.

The control on the quantity of product is by either the tests performed by or on behalf of the notified body or by market surveillance, performed by a GIO. This organization is free to control any number of prepackages and checks compliance using tests as given in an annex about testing. If the collected number of samples complies with the criteria of an annex about criteria, the samples are accepted.

In the case of non-acceptance, the GIO shall inform the packer and the notified body and request the packer to install corrective actions. When a packer consistently not complies with the product specifications the GIO can fine the packer. The notified body can withdraw the test certificate or refuse to give permission to use the e-mark with the notified body identification.

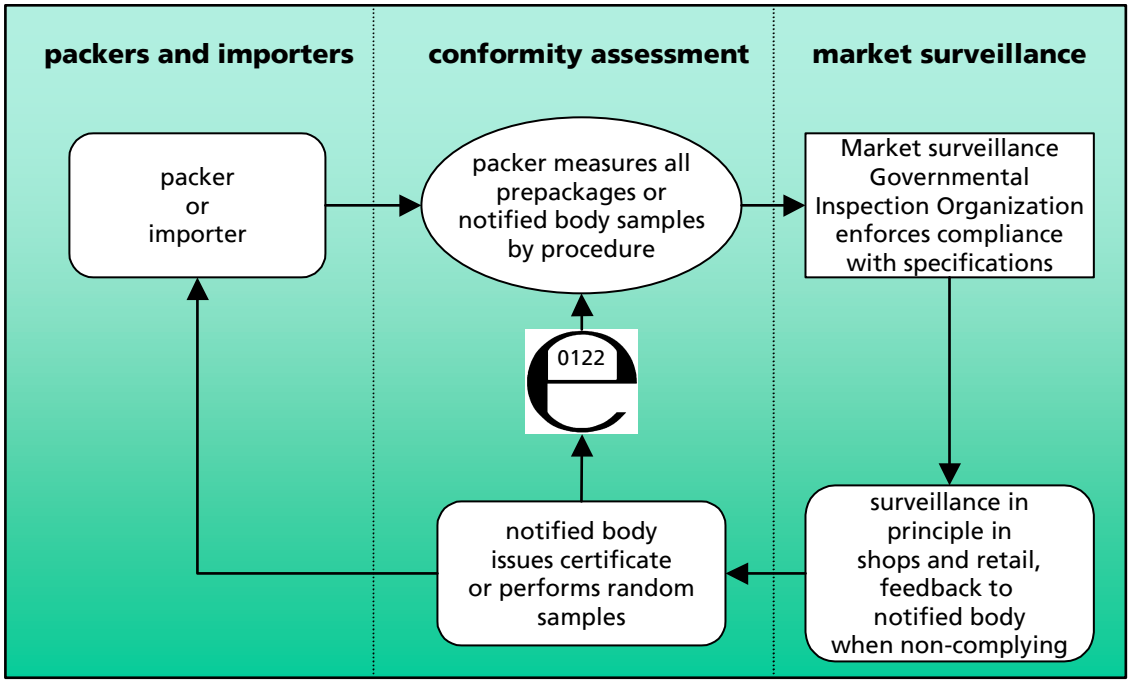

Figure 4-2: Scenario 2, product validation

4.4.2.3 Expectation of Impact

4.4.2.3.1 Packers and importers

Relative cheap for packers and importers. This is a simple system. Packers have to perform either by themselves under witnessing by a notified body tests on all prepackages or shall ask product validation and testing by a notified body. There are no requirements on the packing procedures at the packer site except that the packers shall document the performed procedures. The packer and importer must comply with the product specifications and shall prove this in advance. Packers shall pay the work done by the notified body.

4.4.2.3.2 Notified bodies

Notified bodies shall either witness the tests performed by the packer and issue a certificate of compliance for a approved test session or shall perform themselves tests on samples at random intervals. When the tests are in compliance the packer can place the e-mark with the notified body number on all the prepackages. The work of the notified body is expected to be paid by the packer.

4.4.2.3.3 Governmental inspection organizations

The GIO shall control the compliance with the product specifications. Because they can ask notified bodies the names of packers operating in the countries, it is easier to know the parties involved and find the packers and importers.

Difficult to operate with repeating non-complying packers. Large effort required from the side of the governmental inspection organization. There is a risk that GIO will enforce more stringent requirements because they will want to make market surveillance more effective (for instance: having inspectors implicitly recognizing procedures). Direct costs are at the side of the government and the packer.

4.4.2.3.4 Customs

Difficult to control repeating non-complying imports, because packers outside the EU can easily switch to different or new importers. The cooperation of customs is essential in controlling imports.

4.4.2.3.5 Retailers

The control on the quantity at the retailer is limited by the number of prepackages available in the shop. The packer is still responsible for the proper quantity. The retailer remains the distributor and can not held responsible of the proper quantity. Effectiveness is very limited. Retailers are unhappy with GIO activities in the shop. In daily live the retailer determines which products will be sold. This is not based on quantity of product but on buyers appeal and profitability.

4.4.3 Conformity assessment procedure, Scenario 3 (validated filling process)

Scenario 3 is based on detailed interaction from legal regulations, dedicated participation of notified bodies, use of QA principles and enforcement by market surveillance.

4.4.3.1 Product specifications

All prepackages that can be obtained at the EU market shall comply with:

- a certain number of prepackages shall average quantity of product of at least the nominal quantity,
- the number of prepackages between the nominal quantity and TU_1 shall be not larger then n ,
- the number of prepackages below TU_2 shall be zero,
- the packer (or who takes the responsibility for the quantity of product) shall put his name and address on the prepackages for traceable corrective actions by a governmental inspection organization,
- all prepackages shall have the proper information labeled as laid down in an annex about labels,
- packers shall use the participation of a notified body for process capability acceptance and different levels of quality assurance control
- market surveillance shall be based on a standard test as given in an annex about testing,
- accepting or rejecting the measured batch shall be based on the criteria given in an annex about criteria.

4.4.3.2 Operational description

A packer can place a prepackage on the market under a certain number of conditions. He needs support of a notified body for validation of his filling procedures by process capability principles. He shall have a system description and a quality assurance system if the wants to. The notified body shall supply the packer the permission to apply the e-mark with the notified body number and a packer identification number.

The approval of the filling process gives any GIO a degree of confidence that this particular packer probably will put complying prepackages on the market.

The need for extensive market surveillance activities on products of this particular packer is limited.

Market surveillance on the quantity of product will be performed by a GIO. This body is free to control any number of prepackages and checks compliance using tests as given in an annex about testing. If the collected number of samples complies with the criteria of an annex about criteria, the samples are accepted.

In the case of non-acceptance, the GIO shall inform the responsible notified body and request him to perform corrective actions. When a packer consistently not complies with the product specifications the notified body will withdraw the permission to apply the coded e-mark.

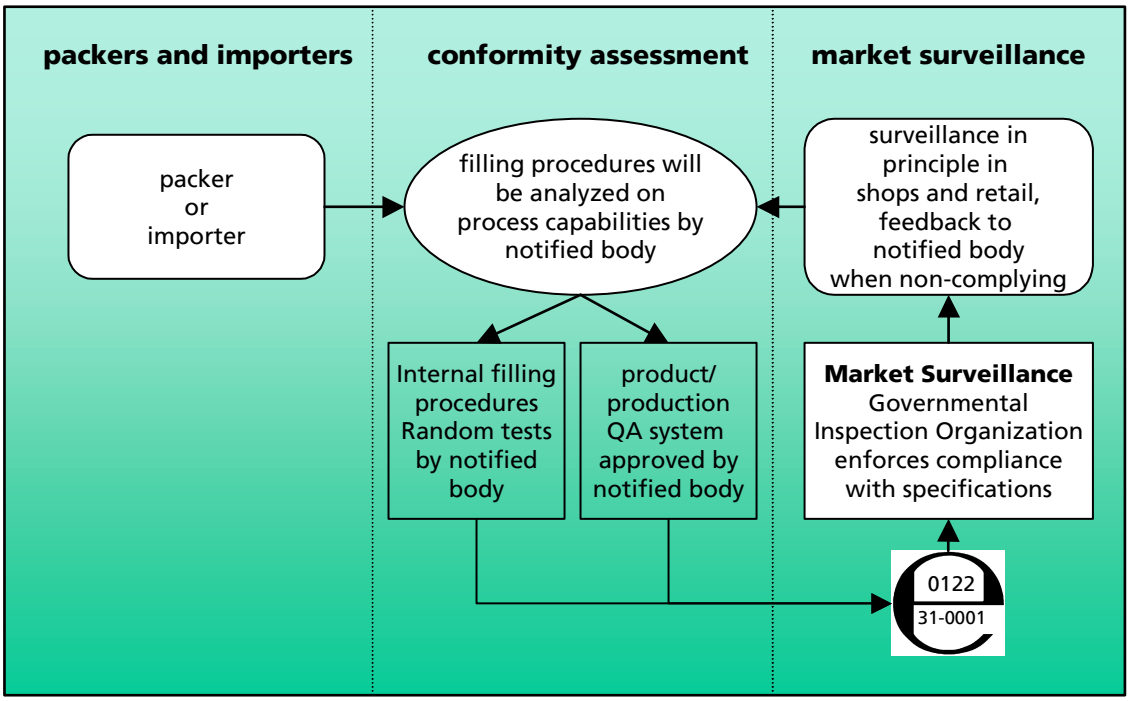

Figure 4-3: Scenario 3, validated filling process

4.4.3.3 Expectation of Impact

4.4.3.3.1 Packers and importers

Packers and importers will have to pay the activities of the notified body. There are requirements on the packing procedures at the packer site. The packer and importer must comply with the product specifications and prove this in advance. The surveillance burden on the packer can be as minimal as possible. Just to maintain confidence in the performance of the packer and considerable less due to a sort of guarantee of proper performance. The approved filling procedures give the packers the option to optimize the average quantity of product as close as possible to the nominal quantity of product. This will lead (certainly with expensive products) to substantial reduction in product costs.

4.4.3.3.2 Notified bodies

Notified bodies control the processes of the packer based on the principle of process capability. The notified body can optimize the control at the packers site by selecting the best sampling spot, either at the filling line or in the warehouse. The target is to let the packer use a filling and control system optimal for that packer. All modern tools of process control can be used to create the guarantee of complying with the Directive. The notified body can operate all over the world and can stimulate the packers to the best filling process.

4.4.3.3.3 Governmental inspection organizations

The GIO shall control the compliance with the product specifications. Because they do know the parties involved they will have no problem to find the packers and importers. Easy to operate because non-complying packers can be controlled by the particular notified body. Substantial reduced effort required from the side of the governmental inspection organization. The GIO can rely on the fact that a controlled packer already has proved to be capable of producing complying prepackages. There is a risk that GIO will enforce more stringent requirements nationally.

4.4.3.3.4 Customs

The effort of customs reduces considerably because the presence of the coded e-mark guarantees the compliance with the Directive.

4.4.3.3.5 Retailers

The control on the quantity at the retailer is limited by the number of prepackages available in the shop. The packer is still responsible for the proper quantity. The retailer remains the distributor and can not held responsible of the proper quantity. Effectiveness is very limited. Retailers are unhappy with GIO activities in the shop. In daily live the retailer determines which products will be sold. This is not based on quantity of product but on buyers appeal and profitability.

4.4.4 Conformity assessment procedure, Scenario 4 (total packing quality)

Scenario 4 is based on detailed interaction from legal regulations, dedicated participation of notified bodies, use of QA principles and enforcement by market surveillance. The packer is allowed to set up his own filling procedures based on his capability of process analyses

4.4.4.1 Product specifications

All prepackages that can be obtained at the EU market shall comply with:

- a certain number of prepackages shall an average quantity of product of at least the nominal quantity,
- the number of prepackages between the nominal quantity and TU_1 shall be not larger then n ,
- the number of prepackages below TU_2 shall be zero,
- the packer (or who takes the responsibility for the quantity of product) shall put his name and address on the prepackages for traceable corrective actions by a governmental inspection organization,
- all prepackages shall have the proper information labeled as laid down in an annex about labels,
- packers shall use the participation of notified bodies for process capability acceptance and quality assurance controls,
- market surveillance shall be based on a standard test as given in an annex about testing,
- accepting or rejecting the measured batch shall be based on the criteria given in an annex about criteria.

4.4.4.2 Operational description

A packer can place a prepackage on the market under a certain number of conditions. He needs support of a notified body for validation of the design of his filling procedures by process capability principles. He shall have a system description and a quality assurance system. The notified Body shall supply the packer the permission to apply the e-mark with the notified body number and a packer identification number.

The approval of the filling process gives any GIO a degree of confidence that this particular packer probably will put complying prepackages on the market.

The need for extensive market surveillance activities on products of this particular packer is limited.

Market surveillance on the quantity of product will be performed by a GIO. This body is free to control any number of prepackages and checks compliance using tests as given in an annex about testing. If the collected number of samples complies with the criteria of an annex about criteria, the samples are accepted.

In the case of non-acceptance, the GIO shall inform the responsible notified body and request him to perform corrective actions. When a packer consistently not complies with the product specifications the notified body will withdraw the permission to apply the coded e-mark.

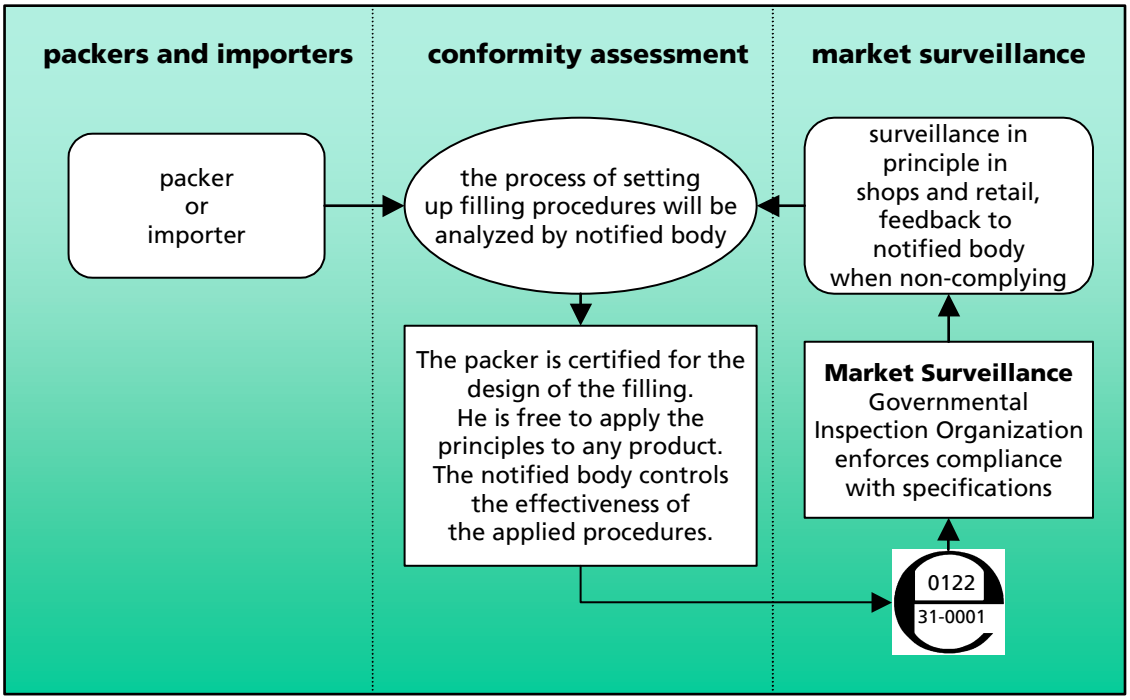

Figure 4-4: Scenario 4, total packing quality

4.4.4.3 Expectation of Impact

4.4.4.3.1 Packers and importers

Packers and importers will have to pay the activities of the notified body. There are requirements on the packing procedures at the packer site. The packer and importer must comply with the product specifications and prove this in advance. The surveillance burden on the packer can be as minimal as possible. Just to maintain confidence in the performance of the packer and considerable less due to a sort of guarantee of proper performance. The approved filling procedures give the packers the option to optimize the average quantity of product as close as possible to the nominal quantity of product. This will lead (certainly with expensive products) to substantial reduction in product costs.

Because the packer has an approval for the design of the filling and controlling process he can apply the principles to any product he likes to prepack. He does not need to ask any approval for the various products. The responsibilities at the packers site are substantial. It needs a very good QA system.

4.4.4.3.2 Notified bodies

Notified bodies shall control the design of processes of the packer based on the principle of process capability. The notified body can optimize the control at the packers site by selecting the best sampling spot, either at the filling line or in the warehouse. The target is to let the packer use a filling and control system optimal for that packer. All modern tools of process control can be used to create the guarantee of complying with the Directive. The notified body can operate all over the world and can stimulate the packers to the best filling process.

4.4.4.3.3 Governmental inspection organizations

The GIO shall control the compliance with the product specifications. Because they do know the parties involved they will have no problem to find the packers and importers. Easy to operate because non-complying packers can be controlled by the particular notified body. Substantial reduced effort required from the side of the governmental inspection organization. The GIO can rely on the fact that a controlled packer already has proved to be capable of producing complying prepackages. There is a risk that GIO will enforce more stringent requirements nationally.

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The effort of customs reduces considerably because the presence of the coded e-mark guarantees the compliance with the Directive.

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5 Inventory of views and conclusions of European Member States stakeholders concerning methods and conformity assessment

5.1 Problems

The views of stakeholders collected in this inventory are essential to the Cost Benefit Analysis principles discussed in chapter 4. For the effectiveness of the Cost Benefit Analyses the scenario methods of conformity assessment developed in chapter 4 have been defined in great detail. Changes in the conformity assessment method after this stage would make further analyses unusable.

The expert on Cost Benefit Analysis has been introduced to the scenario methods of conformity assessment before any interview with stakeholders took place.

5.2 Work program

From the large number of stakeholders dealing with prepackaging a representative group has been contacted for comments on the conformity assessment systems developed under chapter 4. The table below summarizes the work done related to stakeholders that 'deal directly with prepackages' and 'other' stakeholders.

Stakeholders dealing directly with prepackages	other relevant factors	questionnaires	interviews with representing organizations
packers	packing for third parties or not	yes	yes
importers established in the Community and their agents	size of trading area: local, national, EU, global	yes	yes
persons arranging for the packing to be done		yes	no
retailers and supermarkets		yes	Yes
packers in third countries		yes	yes
Consumers	-	no	yes

other stakeholders	other relevant factors	questionnaires	interviews with representing organizations
Competent Departments	private or governmental	yes	yes, WELMEC
inspection organizations	private or governmental	yes	yes, WELMEC
European Commission	-	no	yes, EC
OIML	-	yes	yes

Figure 5-1: Input from stakeholders

The inventory has collected the views of stakeholders on the scenario methods of conformity assessment to be able to perform the Cost Benefit Analysis.

This has sets the goal of the inventory: the target of the inventory is to obtain information from the views of the stakeholders to supply input to the Cost Benefit Analysis.

5.3 Deliverables

The purpose of the work was to produce an overview of the opinions of the stakeholders on the scenario methods of conformity assessment of chapter 4 and to rubricate all data to enable the Cost Benefit Analysis.

5.4 Discussions and results

Throughout the world legislation of prepackages has three reasons: to open markets, fair trade and consumer protection.

The most important reason for new legislation is consumer protection while fair trade is very important as well. The comments of packers and consumers are therefore of major importance. All EU consumer organizations (in all the various Member States and coming Member States, that are listed by 'Consumers International') have been addressed by the questionnaires, as well as the branch organizations at the European level (mailing lists in Annex N). Only 2 organizations had reacted on the invitation to participate in the questionnaires. With two consumers organization some discussion took place.

About 74 packers had answered the questionnaire. 8 packers have been interviewed.

Further more all the Competent Departments in Europe have been asked to support the work carried out, by sending a special mailing to the packers in their country. Thirteen Competent Departments have filled in the questionnaire.

The relevant organizations in the USA had been visited and talked to. For detailed information see chapter 6 and Annex G.

Annex J gives an overview of the Competent Departments in EU Member States and some other European countries.

The table below gives a quick overview of received reactions

	packers		retailers		Consumer		Competent Departments	
countries	EU	USA / Japan / S. Africa	EU	USA / Japan / S. Africa	EU	USA / Japan / S. Africa	EU	USA / Japan / S. Africa
questionnaire	74	0	3	0	2	0	13	0
interviews	8	4	0	0	0	0	WELMEC WG6	8

Figure 5-2: Overview of reactions

5.4.1 Set up of research in the field

Based on the analysis in chapter 5, crucial elements of the circumstances include:

Type of circumstances	Crucial variable
Packer specific	The size of the packers
	The cost price of the product per unit size prepacked
	Type of product
	Production process
	Batch sizes
	Percentage of operational costs within the cost price
Country specific	Number of packers
	Number of retailers
	Distances between stakeholders
	Importance of quantity control
Elements of choice	Number of testing

Figure 5-3: Variables determining the preference of a quantity control system

Questionnaires were sent out to all relevant stakeholders, i.e. packers, retailers, Competent Departments and consumer organizations. The following elements are incorporated in the questionnaires:

- Current activities concerning quantity control
- Attitude towards quantity control
- Preferences on the scenarios
- Packer and retail specific characteristics

Note that not all stakeholders are asked about their opinion on efficiency and the effectiveness of the four scenarios. In some cases the answer would be obvious or irrelevant. For packers and retailers, the answers are only used for finding relations between the characteristics of packers or retailers and their preferences.

Cost Benefit Analysis starts with a baseline: the current situation. Competent Departments are asked about the system in their country and characteristics of the performance of the system applied. Also, they were able to show their preferences on the scenarios.

As representatives of consumers, questionnaires were sent to consumer organizations, asking the attitude of consumers towards quantity control, their current activities and their preferences on the scenarios.

For the packer, the packer specific elements were asked, along with the current activities on quantity control and their preferences on the scenarios.

The elements in the questionnaire for the retailer are similar to the questionnaire of the packers. The relevant information needed includes characteristics of the retailer, the attitude towards and current situation of quantity control and their preferences on the scenarios.

The questionnaires for Competent Departments, consumer organizations, packers and retailers can be found in annex K. The questionnaires were also put on the Internet at http://www.prepackages.org.

The only type of stakeholder that is not being questioned is the importer, because he falls outside the scope of the European Union. However, he is being questioned in interviews.

The following analysis of the stakeholders is based on the expected effects of the different scenarios in chapter 4, the interviews of importers in the United States in chapter 5, the questionnaires and interviews. stakeholders are more likely to provide insight through personal interviews, because of the limitations of questionnaires.

5.4.2 Stakeholder analysis

5.4.2.1 Consumers

The response of consumer organizations is very low; only 2 out of the ca. 35 approached consumer organizations filled in the questionnaire. Additionally, the two organizations that filled in the questionnaire are relatively small.

The conclusion seems to be that quantity control is not really an issue. The number of complaints is low, organizations are unaware of the quantity control system that is currently applied in their country and their preferences are contradictory.

Naturally, when being asked, markings that guarantee the quantity of product in a prepackage are important for consumers. In first instance, preferences towards quantity control are as much control as possible at zero cost. But both organizations state that the trust in packers is high and they have great confidence in the system applied. ‘More control of government and laws cost more than it corrects the situation.’ The willingness to pay within the cost price of the prepackage is zero.

'Consumers would not expect to have to pay anyone other than a public body to guarantee correct quantity, any more than they would expect to have to pay someone to guarantee the safety of the State, or the safety of their own property.' The organizations are also contradictory in their answers to where in the prepackage chain the control should take place and the number of controls.

5.4.2.2 Retailers

Retailers value the e-mark highly and put high effort in their quantity control. All retailers perform random testing, most also perform a reference test and do non-destructive testing. Quantity control is part of a complete test in which the prepackage is tested also on items like quality and safety. Performing measurements themselves is less expensive than quantity control by a notified body, but the notified body has the benefit of being independent. In both cases, a lot of packers can be checked at once, because of the large number of suppliers.

Additional to the tests performed, retailers demand of their suppliers to have an e-mark as well. Although indicated of high importance, quantity control is ranked lower than brand name, price of products, quality of products and service. Being the mouthpiece of the consumer, the retailer seems to rank the objectives of the consumer, indicating the quantity of less importance, because of the unawareness. However, as indicated by one retailer: 'The consumer expects that the actual quantity of product to be equal to the nominal quantity and not the nominal quantity with a manufactures tolerance.' For most products, a consumer would not mind to buy a prepackage with an actual quantity of product that exceeds the nominal quantity, but probably would mind if the actual quantity of product were less.

Self-declaration with a lot of market surveillance is clearly preferred in the Northern part of the European Union. 'Independent checking at zero cost for the retailer provides certainty of measure and a level playing field.' However, these retailers have great confidence in the current system, which resembles more to scenario 3 and expressed concern if the changes were to produce variable controls that gave rise to inconsistent measure.

The picture in Southern Europe seems to differ completely. A retailer from Southern Europe indicates the first scenario as 'poor', though their current system mainly resembles this scenario. His preferences are towards as much quantity control at the point of pack as possible, pointing at scenario 4.

5.4.2.3 Packers

The number of packers can differ considerably per member state. In the Netherlands approximately 700 packers are registered, while the Germans claim they have far more than 20.000 packers and the UK indicated to have a number between 50.000 and 250.000 (see Annex M, minutes of WELMEC WG6 meeting in November 1995). Some of the differences can be explained partly by the number of inhabitants and economic activity, but inevitably there are also major differences in the size of packers across the European Union. In the Netherlands, all packers have been approached to fill in the questionnaire, in other countries however, it was impossible to approach all, not only the number of packers is too large also the network lies mainly in the Netherlands. An overview:

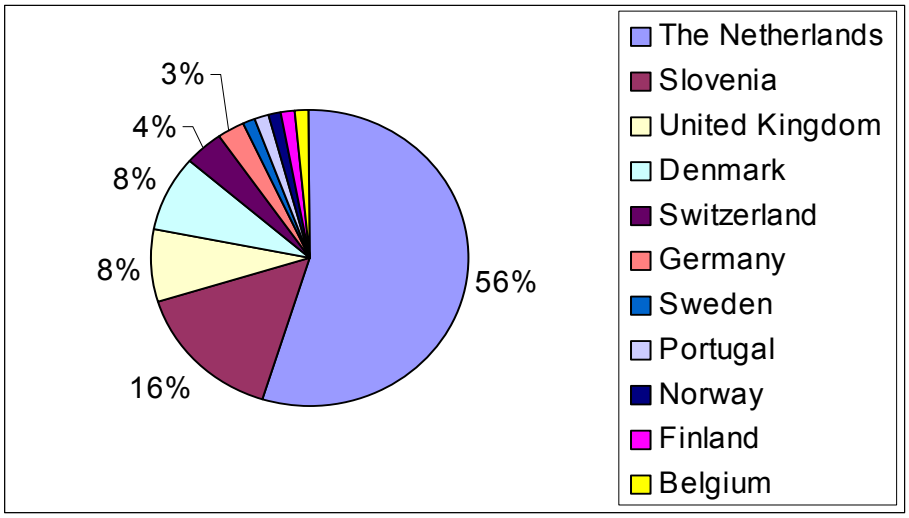

Figure 5-4: Overview of the responses of packers

Retailers indicate the e-mark as being of high importance and most demand an e-mark of the suppliers. Naturally, the demand of the retailers can be traced back in the arguments of quantity control by the packers. For 70% of the packers quantity control is a condition to ensure sale, 19% name the argument to avoid the risk of no sale at all, while 10% states no arguments. Other arguments are more sale (promotional item), legal obligation, avoiding overfilling, quality and safety. Over 95% of the packers have activities on quantity control, mainly checking the weight (61%), product validation (54%) and measuring while filling (35%). Still 20% of the packers do not use any markings, although Slovenian packers might influence this percentage. Almost 50% of the packers are controlled once a year, 31% less than once a year and 6% have never been controlled. On average the Dutch, Danish and Swiss are controlled just above once a year.

Looking at the procedure for the scenario systems. In scenario 1 a packer is not controlled by any organization, as it is his responsibility to comply. This means the packer is free to decide his cost-efficient quantity control system or just to overfill and will have no additional costs. However, a packer also has the possibility to not bother at all, because market surveillance is not a real threat. In the other scenarios packers are controlled by a notified body and need to pay for their activities. These scenarios have increasing costs for the packer as the effort of the notified body is also increasing. Scenario 2 is the cheapest, only product validation is needed, performed or witnessed by the notified body, in the third scenario the filling process is controlled, while in scenario 4 a whole quality assurance system on his production process is needed. Despite the increasing costs to obtain a certification production can be cheaper, because a more detailed control can optimize the production process by getting closer to the nominal quantity. Especially with expensive products and large production applying a complete quality assurance system can be very interesting.

In the questionnaire, most packers state they are satisfied with the current system. 'Change would add significant costs to our operations with no benefit to consumers or us.' And 'more legislation and rules (and a complete controlling army) the more and more products will cost.' That is probably why some packers even indicate the first scenario as being more costly to them. Only 38% of the packers do see a cost reduction in scenario 1. Possibly, there are also some social barriers for change, because packers feel the current system works well. Small enterprises argue that a complete quality assurance system is too expensive and is irrelevant to their customers. For products that are prepacked in small numbers the batch size is relatively large. Finally, some packers doubt the benefit of the e-mark, because the law enforces the actual quantity of product to comply with the nominal quantity. Other (West European) packers feel their e-mark and thus their more strict system, being a competitive advantage.

Overall, self-declaration is the only scenario that is perceived being somewhat less costly. The other scenarios are perceived as increasingly more costly. Surprisingly, almost 58% of the packers would prefer the law to allow quality assurance systems, 42% would (also) want to allow manufacturer self-declaration and 16% indicates the notified body control. In their arguments of their preference, keeping the current system is named often. Quality assurance would protect the consumer as much as possible, self-declaration is seen as flexible for the packer and efficient because of market mechanism, while notified body control not too costly and the benefit of control being done by an independent body.

5.4.2.4 Competent Departments

Thirteen Competent Departments of which nine are situated within the European Union filled in the questionnaire. That is a large response since twenty Competent Departments were approached.

Competent Departments control either all prepackages or only e-marked products. (See Annex J) Across the European Union Competent Departments are funded differently. The costs for the packer vary from none, to all remaining costs are carried by public funding.

The involvement of notified bodies increases through the four scenarios. In case of the first scenario there is no control at the point of pack, while in the fourth scenario a whole quality assurance system is set up. Contrarily, the activities of GIO are diminishing, from a lot in scenario 1 to hardly in scenario 4.

As the intensity of market surveillance is the responsibility of the Member State, governmental inspection organizations will enforce more or less stringent requirements nationally. Additionally, quantity control is not a real issue compared to quality and safety within market surveillance.

Scenarios 3 and 4 are easy to operate for governmental inspection organizations, because non-complying packers can be found and controlled by the particular notified body. Additionally, the GIO can rely on the fact that a controlled packer already has proved to be capable of producing complying prepackages. The effort of customs reduces considerably because the presence of the coded e-mark guarantees the compliance with the Directive.

Whatever their current system is, almost all Competent Departments are having difficulties in doing their activities. Overall, there are too little inspectors to perform all controls they supposed to do. The number of inspectors differs, but is in most countries approximately 3. Another point, independent of any scenarios is the legislation, the differences between countries are only mentioned once, and the main problem of the legislation is its lack of clarity. Also, there is a desire for similar legislation for not e-marked prepackages.

Because there is no notified body in the first scenario, governmental inspection organizations do not know all parties involved and will have some difficulty to find the packers and importers. It would be very difficult to deal with packers that keep on producing non-complying prepackages. This requires a large effort from the governmental inspection organization. It is also difficult to control imports; cooperation of customs is essential in controlling imports. The Competent Departments in the questionnaire carry this view and a worldwide register of packers is proposed. The other disadvantage that is mentioned is the large number of inspectors that is needed to perform the market surveillance. Choosing a one-sided system in which only retailers are tested would be too costly. Advantages include only one body, no costs for packers and fair competition also for Small and Medium Enterprises.

The argument for a focus on control at the point of pack is that the process of prepackaging can be adjusted more effective and efficient. However, a quality assurance system is also perceived as being more costly, especially in countries with a lot of packers. A quality assurance system is in the focus of quantity control the opposite system of self-declaration, most effort is being done only at the packer.

From the questionnaires, Competent Departments have a cost preference for the scenarios that combine control at point of pack and point of sale. Self-declaration or a total packing quality would be much more costly especially in countries with a large number of packers or retailers. Regarding effectiveness, the confidence increases with the control at the point of pack, indicating at a total quality system. Again, there is a preference for the current system.

country	percentage below average	Percentage below TU1	percentage below TU2	percentage wrong labeled	percentage total rejections
Norway	5,0%	5,0%	0,0%	5,0%	-
Sweden	0,0%	0,0%	0,0%	10,0%	-
Netherlands	-	-	-	-	12,0%
England	5,0%	2,0%	1,0%	1,0%	-
Finland	5,0%	1,0%	0,0%	10,0%	-
Germany	1,8%	0,8%	1,4%	0,1%	-
Slovenia	8,0%	6,0%	0,0%	50,0%	-
Austria	5,7%	5,8%	5,3%	-	-
Belgium	10,0%	4,0%	5,0%	1,0%	-
Denmark	3,0%	3,0%	2,0%	0,0%	-
France	10,0%	10,0%	no control, under TU_2, it is an offence	5,0%	-

Figure 5-5: Rejection percentages of reference tests in various countries

Transposing the percentages to an overall EU wide percentage is not possible due to the fact the participating countries don't know the total number of packages produced. As Annex M shows for the EU Member States, some do have a well-defined number of packers (e.g. The Netherlands with 750, UK some were between 20.000 and 250.000 and Germany much more than 20.000) and others don't know.

None of the Member States could indicate their criteria for acceptable rejection rates.

The acceptable percentage of non-complying prepackages will be a country decision. The percentage of prepackages below TU_2 are quite high in some countries. These percentages should be not more than 0,1% or so.

5.4.2.5 Conclusions

- Consumers and consumer organization are unaware of the quantity control system in their country. When confronted, today's willingness to pay more for a (change in) system equals zero, because quantity control is not really an issue. Also the retailer, being the mouthpiece of the consumer, indicates that quantity control is not really an issue compared to price, quality, service and brand name. In first instance, consumers obviously would want as much control as possible at zero cost, but are unaware of the impacts arising from the implementation of one of the scenarios. They do have a clear preference for a truly independent notified body control, because they have no possible financial or other influence between the parties involved.

- Retailers, packers and Competent Departments rate their own system very high. Gearing the national systems to one another is perceived as a lesser benefit than the cost for changing the current national systems. Besides economic barriers, there could also be some social barriers in a (possible) change of quantity control system. Quantity control is not really an issue to undertake any changes in the system. However, there could be made some technical adjustments to legislation to ensure fair trade.
- Retailers value quantity control high, most demand e-mark, but also perform tests themselves.
- In Western Europe there exists only a few, very large retailers. Packers have no other choice than to comply with the standards set by the retailer. More stringent legislation for the packer makes the e-mark stronger and can imply a competitive advantage, as the retailer needs less control.
- Heavy reliance on market surveillance results in difficulties finding non-complying packers and importers. Additionally, there is less regulation on compliance for the packer. It is also difficult to control imports; cooperation of customs is essential in controlling imports.
- Performing quantity control is practically a problem in the one-sided scenarios in which there is heavy reliance on control at the point of pack or point of sale. Self declaration and quality assurance systems are perceived as too costly and time consuming, while Competent Departments claim they already have too much work and too little inspectors. Therefore, they have a cost preference for 'Product validation'. Competent Departments think the effectiveness is increasing along with the scenarios.
- The overall conclusion is that harmonizing the technical elements of a quantity control system is perceived as more important than the choice for conformity assessment and the prescribed intensity of market surveillance, which eventually is decided nationally

6 Describe, compare and make conclusions on the situations in main extra-EU trading partners.

6.1 Problems

Import of 'prepacked' products from third countries is not well controlled. Many importers do not report their imports to the Competent Departments (sometimes because this is no requirement in national legislation, sometimes because no enforcement takes place). Complaints from extra-EU trading partners are based on inconsistency of the legislation in the Member states. Although the e-marking Directives facilitate imports from third countries, very few importers 'go by the rules'.

OIML Recommendation 87, dealing with prepackaging, did not lead to harmonized legislation due to the following problems:

- the document is sometimes '*basis for regulations of many countries but it is often modified to meet local needs'* (as presented by the secretariat of OIML Technical Committee 6, dealing with the revision of the document)
- at the moment the recommendation is in revision: Drafts 2 and 3 have received more than 600 comments, also proving that there is no large agreement amongst experts from different countries. The final (251102) draft is voted on in 2003.

Trade with and trade from third countries will be easier when prepackaging systems look alike.

6.2 Work program

The volume trade of **prepackages** from and to third countries is not known. According to the World Trade Organization the total volume of **food** (food is often transported as prepackage, figures are exclusive of raw material) is divided as follows:

		North America	Latin America	C+E Europe, Baltic's,	Africa	Middle East	Asia	total
exports to	Billion Dollars	10,15	3,09	8,08	6,33	5,26	10,53	43,44
	% of total	23,4	7,1	18,6	14,6	12,1	24,2	
imports from	Billion Dollars	10,33	19,6	4,54	10,6	1,34	12,37	58,78
	% of total	17,6	33,3	7,7	18,0	2,3	21,0	
import + export	Billion Dollars	20,48	22,69	12,62	16,93	6,6	22,9	102,22
	% of total	20,0	22,2	12,3	16,6	6,5	22,4	

Information retrieved from WTO: International Trade Statistics 2000 (ISSN 0072-064X, ISBN 92-870-1216-4).

Based on this information, covering legislation of North America, Latin America and Asia would cover 64,6% of total trade with the European Union.

The main extra-EU trading partners have been chosen on the basis of trade volume in this table, and will include USA and Japan. Investigation has excluded countries in Eastern Europe, as most of them will implement new legislation relating to prepackaging, as they become part of the European Union.

National legislation relating to prepackaging in the different regions of the world is not harmonized, but usually has a similar philosophy due to similar cultural background. To get understanding of and to be able to compare legislation we studied two procedures:

1. The first and preferred procedure (taken in the financial figures) leads to quick and good understanding of legislation of leading countries and regions the European Union imports and exports to. A desk study highlighted the situations in general in the selected countries. Real interviews supplied for the necessary details to under stand the differences and similarities. Also understanding the developments of new legislation was taken into account.
2. Desk study lead to understanding of current legislation of nine important countries. Disadvantage: less understanding of regional developments and new legislation.

In the case of procedure 1, after investigating the legislation, interviews have been held with representatives of:

- the Asia-Pacific Legal Metrology Forum (APLMF) and the Metrology Institute of Japan (MIJ)
- the Inter-American Metrology System (SIM) for North and South America, the North American Cooperation in Metrology (NORAMET) for USA, Canada and Mexico and National Institute of Standards and Technology (NIST), for the USA[33]

Visits to the representatives of SIM and NIST have been combined with interviews with the secretariat of Technical Committee 6 of OIML, as it is one of the important stakeholders (as mentioned in paragraph 2.3).

South Africa has legislation[34] similar to the European Union. A comparison of legislation did not needed an interview and has been a desk research.

6.3 Deliverables

The work resulted in a description of legislation relating to prepackaging and an overview of resemblances and differences in philosophy, definitions, methods of metrological control and conformity assessment

6.4 Discussion and results

The choices have been to analyze the system in Japan, South Africa and the United States of America. Japan has been selected representing the Asia Pacific region. South Africa recently started with a system that can be seen as a copy of the European e-mark system. The USA is selected as one of the larger trading partners.

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[33] *relevant documents: Handbook 133, Checking the Net Contents of Packaged Goods and Handbook 130, Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality*

[34] *SABS 1841:1998*

Latin America has not been selected because the fact that the e-mark system not yet functions in line with the EU system.

Central and Eastern Europe is not selected because countries there are harmonizing with EU legislation (and will be in the future too).

All other regions are not of large importance to collect information from.

6.4.1 Operational system in the USA (see also Annex G)

The control on prepackages in the USA is organized in about 750 individual Regions. Each region is a jurisdictional independent entity. The general rules concerning the control of quantity of product is based on the regulations given in NIST Handbook 133, Checking the net contents[35] of packaged goods, fourth edition, January 2002. This federal document is used more or less by all Regions. The scope of the control is the USA is given as follows:

'Routine verification of the net contents of packages is an important part of any weights and measures program to facilitate value comparison and fair competition. consumers have the right to expect packages to bear accurate net information about the quantity of product. Those manufacturers whose products are sold in such packages have the right to expect that their competitors will be required to adhere to the same standards.

The procedures in this handbook are recommended for use to verify the net quantity of contents of packages kept, offered, or exposed for sale, or sold by weight, measure (including volume, and dimensions) or count at any location (e.g., at the point of pack, in storage warehouses, retail stores, and wholesale outlets).'

Maximum Allowable Variations (maximum permissible deviation from the average) are given for products declared in weight, volume, count, length, width and area.

Besides a number of large, US wide operating, packers the overwhelming number of manufacturers are local packers. None of the participants in the meeting were able to give percentages of large and small packers. There were indications that manufacturers of products like toilet paper are large and of dairy products small.

Any information about how much prepackages are shipped is not available. No one could confirm that products are transported more as bulk products than as prepacked products. There are reports on the fact that for products with short shelf live, the average quantity of product is lower on Saturday and Sunday than on weekdays.

All participants expressed that routine verification of the net contents of packages is an important part of any weights and measures program to facilitate value comparison and fair competition. consumers have the right to expect packages to bear accurate information about the quantity of product. Those manufacturers whose products are sold in such packages have the right to expect that their competitors will be required to adhere to the same standards. In essence the level of the regulations are not important as long as there are applicable to every manufacturer.

The philosophy of Small Business Assumption does not work. 'Being small' cannot be an excuse to be under less enforcement than the others.

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[35] *for the purpose of clarity the wording 'net content' is used in this paragraph as it is the US equivalent of 'quantity of product'*

There is no control on imported prepackages at the Point of import. Because 99% of the control is at point of sale, the imported products will be selected automatically.

Packers behave in general properly. They don't like to get a bad name and publicity. The largest costs are from disruption of the business, not the fines from the government. To get and maintain customer satisfaction is the most important issue.

American customers are seen as grown up. They know how and were to complain. In general the retail manager and the toll free numbers are the entry points. The most problems are due to negligence and indifference, not only with the small packers. The know-how at the packers could be improved in relation of the advantages of the prepackages procedures to proper content control.

Retailers are responsible for the proper quantity in prepackages. They are the target of the control and will be fined.

Market surveillance (point of sale control) is really important. It leads to fair competition and a level playing field for all packers.

There is about 2% rejection for products sold by weight and volume. The total rate of rejection is about 10% to 15%, depending on the type of product. Especially construction products have difficulties to comply. Food products score much better. The equipment used by the packer and the price of the product influence the rejection rate as well.

Although the type of product (strong hygroscopic) can influence the possibilities to control the filling process, none of the stakeholders were in favour of different Maximum Allowable Variations for different products.

There is no discussion how effective the control on prepackages is. There are no criteria how much tests shall be done and what rejection percentage is acceptable.

Packers are familiar with the procedures. They prefer to have no factory visits. They claim to behave correctly and don't need any control.

6.4.1.1 Reactions on Scenario 1

It should be clear that scenario 1 is in principle the way the USA is performing the control on prepackages. The big difference is the number of governmental inspection organizations (750 in the USA and about 25 in Europe). A further difference is the fact that Regions in the USA do not work together. They operate only in their own region. The Retail control is well established and effective due to the fines addressed to the Retail owner. It is the retailer to get things organized.

The American stakeholders do not have any reservation to this scenario.

Scenario 1 is very easy for exporters to Europe. Packers are not confronted with governmental inspection organizations (GIO's) from European Member States. The importer may get control. But the time frame for doing tests is limited and the control therefore not very effective.

6.4.1.2 Reactions on Scenario 2

All the stakeholders don't see any advantage of the function of the notified body. The credibility of the notified body is ranked not very high. The stakeholders don't see the notified bodies as an organization capable of accrediting packers for the various activities.

Introduction of an extra layer of control is seen as not effective and not improving the structure to work more efficient. Another point to be skeptic to the scenario 1 is the fact that notified bodies can be private organizations. They are afraid that the transfer of financial resources from GIO to the private sector will be effective.

The final conclusion was: Scenario 2 is not better and more expensive.

6.4.1.3 Reactions on Scenario 3

The conclusions about the function of the notified body in Scenario 2 hold in scenario 3 also. In this case the functioning of effective not controlled organizations is even more under discussion. The fact that Competent departments are not controlled by a European accreditation organization nor by a governmental organization is the basis of the doubt.

The stakeholders see this scenario as more cost effective that scenario 1.

6.4.1.4 Reactions on Scenario 4

In general there was a good acceptance of scenario 4. But the statement is that what is allowed under scenario 4 is allowed under scenario 1. Scenario 4 is more expensive in comparison to scenario 1.

6.4.2 Operational system in Japan (see also Annex H)

6.4.2.1 Basic structure

While the Measurement Law requires measurement in general to be as accurate as possible, it provides for tolerances for specific products (specified in a Cabinet Order). Other products are not legislated.

The tolerances only apply for the quantity of product of individual prepackages. There is no requirement for the average quantity or product. This means that a packer on average may fill below the nominal quantity as long as quantity of product of individual prepackages is more than the nominal quantity minus the tolerance. *Effectively Japan incorporated the minimum quantity principle with tolerances below the nominal quantity.*

The legislation also applies to imported prepackaged products.

6.4.2.2 Legislation

Requirements for legislation is laid down in:

- Measurement Law (article 10 through 15)
- Cabinet Order Concerning Measurement for Sales of Specified Commodities
- Ministerial Ordinance Concerning Measurement for Sales of Specified Commodities

The Ministry of Economy, Trade and Industry (METI) is responsible for the overall implementation of the legislation. Prefectures (= provinces) and designated municipal governments are responsible for the inspection of sellers, packers and importers.

Japan is considering adopting OIML R87 and R79 into its legislation.

Although no requirements exist what language to use on prepackages, Japanese is supposed to be used. Other languages are allowed.

The Ministerial Ordinance requires that the print size, positioning and color must be easily recognizable by consumers. The following information is required: name and address of packer/importer, net content and the proper legal unit so that the nominal quantity is expressed in four or less digits.

Japan uses the metric system, other units are allowed.

Products that loose weight after packing (desiccating products) have broader tolerances.

For measuring 'drained weight products', excess water is removed at the point of pack. The Japan Agricultural Standards Law and related ordinances state detailed methods of measuring, including frozen foods.

No declaration of the identity of the product is required on the prepackage.

Japan does not know the concept of the 'principle display panel'.

Terms like 'content', 'weight' as part of the declaration of the nominal quantity is allowed.

While the Measurement Law requires measurement in general to be as accurate as possible, it provides for tolerances for specific products (specified in a Cabinet Order). Other products are not legislated.

The tolerances only apply for the quantity of product of individual prepackages. There is no requirement for the average quantity or product. This means that a packer on average may fill below the nominal quantity as long as quantity of product of individual prepackages is more than the nominal quantity minus the tolerance. *Effectively Japan incorporated the minimum quantity principle with tolerances below the nominal quantity.*

The legislation also applies to imported prepackaged products.

For the purpose of metrological control Japan is divided up into 103 perfections. With around 16 million people the Tokyo Metropolitan Government is the largest.

6.4.2.3 Type of controls

The perfections are responsible for verifying measuring instruments and the quantity of product of prepackages.

Checks take place at the packer and at the retailer.

6.4.2.3.1 At the packer

Japan does not check prepackages at the packer.

The inspection institute of the prefecture may recognize packer's procedures. The Inspection Institute of Weights and Measures of the Tokyo Metropolitan Government has recognized the procedures of 16 manufacturers of food products.

packers whose procedures are recognized are audited every five years.

These procedures are subject to recognition:

- organization chart + structure of the company
- incorporation of relevant parts of Measurement Law
- measuring instruments
- sample sizes and sample frequency
- records of calibration of measuring instruments, samples

- training/exams
- tare instructions
- rejection

The Inspection Institute of Weights and Measures of the Tokyo Metropolitan Government must be kept informed of changes of the procedures.

When samples at the retailers contain more than 10% overfill, the procedures are considered to be non-conforming.

Packers who have their procedures recognized, perform better than packers who do not have their procedures recognized.

Also importers and oversees packers can have their procedures recognized.

6.4.2.3.2 At retailers

When available, the sample size is 32. When not available the sample size is 3. A non-conforming packer is a packer of whom more than 5% of the samples is rejected (this means: quantity of product in individual prepackages is less than the nominal quantity minus the tolerance).

In the summer of 2002 17.324 prepackages of 365 packers were checked. Out of them 49 packers were non-conforming (13,5%). This means that probably more samples were rejected, but not recorded (the percentage reflects only the packers with more than 5% rejected samples).

At the Inspection Institute of Weights and Measures of the Tokyo Metropolitan Government on a yearly basis 8 fte's are involved in checking the quantity of product of prepackages (divided over 13 people).

6.4.2.4 Conclusion

The Japanese legislative system for prepackages is not harmonized with the European because of the lack of requirements for the average quantity of product. This means that Japanese legislation does not guarantee that Japanese prepackages comply the EU average requirement. EU products comply easily with the Japanese 'average' requirement.

The two sets of tolerances (A and B) from Japan are never larger that the EU NTE (negative tolerable error) and usually smaller.

6.4.3 Operational system in South Africa (see Annex I)

6.4.3.1 Basic structure

Next to national legislation, South Africa has implemented EU Directives 75/106/EEC and 76/211/EEC into South African Standard SABS 1841 (edition 1.1 of 2000).

A packer or importer that complies with the legislation may apply the e-mark (which is identical to the European e-mark). Whether or not a packer or importer complies with the legislation has to be established by SABS through auditing of procedures.

Differences with EU legislation:

- every six months a surveillance
- nominal quantities above 10 kg or l

- the type of records to be kept by the packer is specified:
  - verification and calibration of measuring instruments
  - production control
  - process control
  - non conformances
  - evidence and effectiveness of corrective action
  - disposition of non conforming product
- several types of rectification of rejected batches are listed:
  - blending
  - sorting
  - re-labeling
  - topping up
- several options of disposal of rejected prepackages are listed:
  - destroying
  - returning to the previous 'owner'
  - giving them away

The purpose of this voluntary system is to enable easy access on the European market. No agreements with EU competent departments exist.

6.4.3.2 Conclusion

The South African legislative system for prepackages is almost harmonized with the European. This means that European prepackages always meet the requirements of the South African legislation.

South African prepackages meet requirements of EU legislation except for nominal quantities above 10 kg or l.

7 Assess the theory of Costs Benefits Analysis of only mandatory harmonized metrological methods.

7.1 Problems

The number of scenario methods of conformity assessment resulted from the work mentioned in chapter 4 are numerous. The selection of examples to be analyzed on Cost Benefit Analysis has been based on the fact of mandatory legislation. No non-mandatory scenarios have been analyzed.

7.2 Work program

There is no standard description of Cost Benefit Analysis available, although the Dutch Ministry of Economic Affairs is in the process of constructing a set of criteria. For the purpose of this report we formulated the work as follows.

Cost Benefit Analysis is the systematic comparison of the involved stakeholders for the relevant costs and profits of prepackaging policies.

The following questions have been answered for a proper analysis of the scenarios:

- What are the basic assumptions of Cost Benefit Analysis
- Which costs and profit factors are effective
- Who are the stakeholders
- Which costs and profit factors are relevant for the particular stakeholder

For the comparison of the scenarios the following question has been answered:

- What are the understandings concerning positive and negative effects of the various scenarios

7.3 Deliverables

The purpose of the work was to provide an overview of the Costs and the Benefits of four promising scenarios. The results have been expressed in quantitative terms. As far as possible the results have been expressed in financial terms. Non-quantifiable components have been expressed in descriptive terms.

7.4 Discussion and results

7.4.1 Cost Benefit Analysis

7.4.1.1 Introduction

All effects of proposed regulations are identified and mapped in a Cost Benefit Analysis. Cost Benefit Analysis is a comparative analysis, two or more scenarios are weighed often against a null scenario in which nothing has been done or against each other. In order to compare benefits and costs, they should be expressed in monetary values if acceptable estimates are possible. Costs and benefits that are realized on different time scales are made comparable through calculating all effects for one specific time by adjusting future effects with a discount rate. Cost Benefit Analysis is not restricted to a comparison of scenarios, ideally the net benefit for the society, as a whole has to be calculated. Cost Benefit Analysis also has its limitations, mainly in evaluating certain effects for which no quantitative or monetary data are available and setting the discount rate.

Generally, Cost Benefit Analysis accounts for all (negative and positive) effects of policy measures, on society as a whole as well as individual stakeholders (e.g. business, consumers, etc.) and provides insight in the type of effects, the crucial differences between the scenarios and uncertainties that comes along in the decision. In this way the decision-makers have an integral view of all possibilities and can weigh all pros and cons against each other.

Elements of any Cost Benefit Analysis are an objective, a scope of the analysis, a selection of the scenarios, an identification of all impacts and finally an analysis in order to explore the crucial differences between the scenarios. These elements will be discussed below for conformity assessment in prepackages.

7.4.1.2 Key objective

The main objectives for conformity assessment in prepackages are similar to having a quantity control system at all: consumer protection, free trade and fair trade. consumers have the right to expect prepackages to bear accurate information about their quantity, while manufacturers whose products are sold in such prepackages have the right to expect that their competitors will be required to adhere to the same standards. The current situation, which is the null scenario in the Cost Benefit Analysis, is that every EU-member country has a quantity control system. However, the systems are not mandatory and show national variation in legislation.

National variation in legislation can result in a competitive (dis)advantage for international packers in specific countries due to different costs or number of control. The (dis)advantage can lead to national variation in cost prices and/or actual quantity of product of the prepackage and can thus affect fair trade and consumer protection. Harmonizing the different regulations within the European Union sets the same standards for every stakeholder and reduces the risk of fair trade and consumer protection being affected. However, the intensity of performing quantity control cannot be regulated by the European Union and is decided nationally.

Within the European Union free trade and fair trade is already legislated. Therefore, the analysis is mainly based on consumer protection. However, in some cases where fair trade can be affected, the effects will be mentioned. The protection of consumers on the actual quantity of product can be formulated as follows.

Consumers are more protected when the quantity of product in a prepackage, at the point of buying, complies with the nominal quantity on the prepackage. A visible e-mark must guarantee the consumer that a prepackage bears the accurate information. Packers can put an e-mark on their prepackages according to a prescribed quantity control system. Naturally, the costs of the control system should be reduced to a minimum.

7.4.1.3 Scope of the analysis

In order to comply with consumer protection, prepackages (with an e-mark) need to be checked on their quantity of product. The quantity of product in prepackages can be tested at different places of the prepackage lifetime. The lifetime of a prepackage until it has arrived at the consumer is visualized in figure 7.1, which presents the prepackage chain.

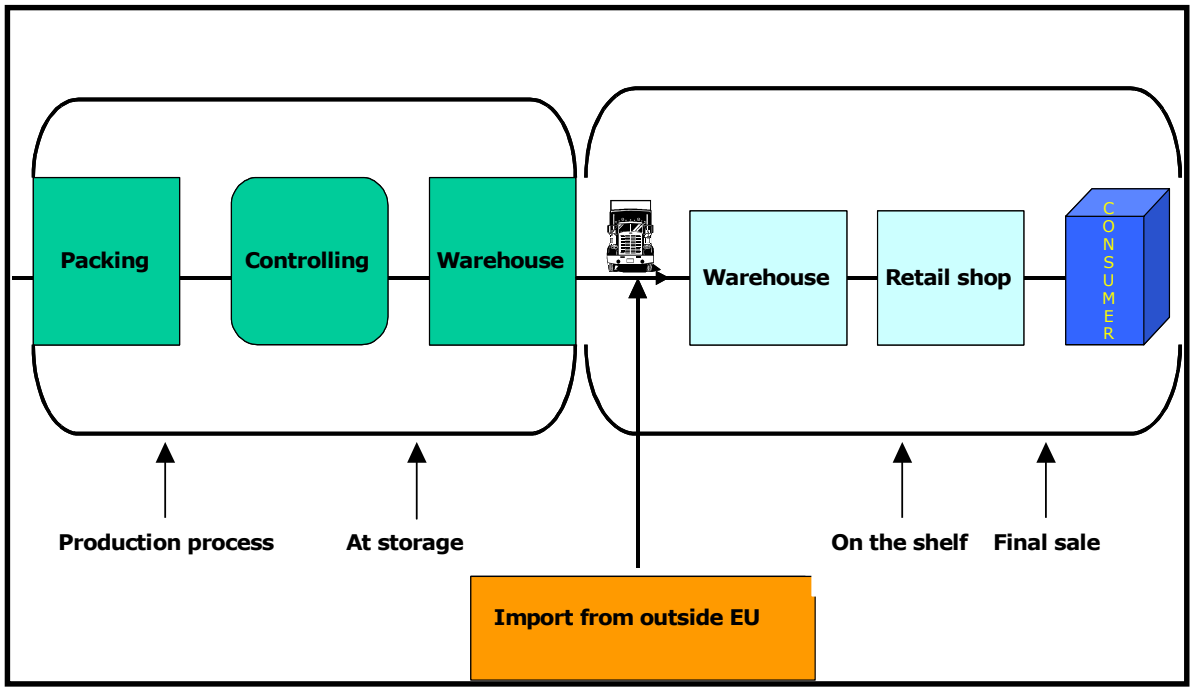

Figure 7-1: the prepackage chain

The chain of a prepackage starts at a packer, as a product becomes a prepackage when it is packed. After production, the prepackages are stored at a warehouse, from where the prepackages are waiting to be transported to a retailer. Finally, the retailer puts the prepackage on the shelf until it is sold to the consumer. The chain is more complicated due to imported and exported prepackages, whether outside the European Union or not. The prepackage can enter, leave or re-enter at different places in the (national) chain.

In the Cost Benefit Analysis it is assumed that the prepackages are tested according to the average principle. This requires testing several prepackages at the time. Prepackages are controlled in a batch, which is produced in the same production process. A batch is rejected when it does not comply with certain requirements.

The current requirements for the batch are that: the average quantity of product meets or exceeds the nominal quantity, a small number of prepackages may contain less than the TU_1 limit and no prepackages are allowed below the TU_2 limit. Also certain labeling requirements apply[36]. Limits are defined in percentages of the nominal quantity and depend on the batch size.

Batches can be rejected because of different reasons. Possible failures in the prepackage chain are:

- under filling
- filling process failure
- mishandling
- moisture loss
- mixed batches[37]

Packers may underfill the prepackages in a batch on purpose or just being negligent. When the packer does have a proper filling process, batches could become rejectable due to a failure in the packaging process. However, a correct filling process does not assure acceptable batches that are tested at a later point of the chain. The average quantity of product of the batch could fall below the tolerable limit due to mishandling or moisture loss. Finally, batches could also be mixed due to rotate stock management, where by coincidence the prepackages with the lowest quantity of product are put together.

The possibilities of performing quantity control are restricted to controlling at the point of pack, in storage or at the retail. At the point of pack, quantity control can be done during the production process by monitoring the filling process or checking the machinery. Sampling can be done just after the production process at the packer, in storage or at the retail. Quantity control can be performed by the possessor of the prepackages or by an independent party[38]. Note that there is a difference between control at the point of pack or point of sale in the executive independent party. A Competent Department recognizes the procedures of the packer, while a governmental inspection organization (GIO) performs control at the retailer, which is called market surveillance.

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[36] *Theoretically, the average principle can also have other standards, but the presented essential requirements are assumptions for the Cost Benefit Analysis. Besides the average principle there also is a minimum quantity principle, in which the actual quantity or product in each single prepackage meets or exceeds the nominal quantity.*

[37] *The quantity control system does not work when:*
- *a mixed batch is rejected while the original batches are OK, or*
- *a mixed batch is accepted while (one of) the original batches are not OK*

[38] *independent party: notified body or governmental inspection organization*

In case of consumer protection, already two considerations can be made for the proposed quantity control. Applying the average principle, prepackages that are overfilled within a batch can compensate under filled prepackages. This implies consumers could end up buying under filled prepackages, which is acceptable to the quantity control system[39]. Secondly, a batch should meet the standards set by the quantity control system until the final sale is made, which implies market surveillance is desirable to check possible failures of mishandling and moisture loss. However, controlling a batch by market surveillance increases the probability of system failures due to mixed batches.

7.4.1.4 Scenarios

The required information on the prepackage, the testing procedure and rejection criteria are the same for all four scenarios. Governments control the prepackages by market surveillance and possibly at the point of pack. An independent party (notified body) can check the average quantity of a batch at any place of the prepackage chain. If the checked prepackages meet the prescribed requirements, the batch is accepted. In case of non-acceptance at the retailer, a governmental inspection organization may:

- fine the packer and/or
- perform checks at the packer to verify if a constant error causes the non-acceptance (in that case: prevent placing on market)

The four scenarios differ on conformity assessment, the (prescribed) accompanying intensity of market surveillance and the corrective actions taken. In practice, the conformity assessment in combination with the intensity of market surveillance indicates the emphasis of the point of control, at point of pack or point of sale.

Theoretically, stringent regulations for packers will need less market surveillance than no regulation at all, as failures at the point of pack are reduced to a minimum. However, setting stringent regulations for the packer has its disadvantages. As already mentioned in the key objective, the intensity of performing quantity control can only be prescribed by the European Union and is eventually decided nationally. National variation in the intensity of performing quantity control could affect fair trade as the accompanying costs differ. Also, quantity control cannot be obliged to imported prepackages, which could also affect fair trade.

Scenario 1: Self declaration

Scenario 1 is based on minimal interaction from legal regulations. A packer declares that the prepackages apply to the prescribed requirements. governmental inspection organizations control the prepackages by a lot of market surveillance. Corrective actions are the responsibility of the packer and need no approval. The first scenario bears a close resemblance to the current control system in the United States. A crucial difference between the US system and the first scenario is the responsibility of rejected batches. In the United States the retailer is responsible, while in the first scenario and the current system within the European Union the responsibility lies at the packer or importer.

[39] *Note that the under filled prepackage contains is at least the TU_2-limit.*

Scenario 2: Product validation

A packer can place prepackages on the market after:

- every prepackage is checked by the packer, under supervision of a notified body that issues a certificate or
- sampling of batches by the notified body, two times per year

The packer shall have described packing procedures and/or a quality assurance system. The packer can use any procedure that guarantees compliance to the proper quantity of the product. The packer declares that the prepackage is part of a larger batch that meets the product specifications by placing the e-mark on the label.

Corrective actions are the responsibility of the packer. When not effective, the notified body can withdraw the certificate and/or can demand to remove her identification of the prepackages.

Scenario 3: Validated filling process

A packer can place prepackages on the market when a notified body:

- validates the (described) filling process of the packer by process capability analyses and
- certifies the quality assurance system of the packer or performs random checks of the production

The validation of the filling process by the notified body together with the certified quality assurance system provides any GIO confidence that this particular packer will place complying prepackages on the market. Therefore, there is no need for a lot of market surveillance for prepackages of this particular packer.

Corrective actions are the responsibility of the packer and need validation/certification of the notified body, who can withdraw the validation/quality assurance certificate and/or can demand to remove her identification of the prepackages.

Scenario 4: Total packing quality

A packer can place prepackages on the market when a notified body:

- certifies the ability of the packer to validate his own filling process by process capability analyses and
- certifies the quality assurance system of the packer

The certified quality assurance system (that includes the validation of the filling process by the packer) provides any GIO confidence that this particular packer will place complying prepackages on the market. Therefore, there is no need for a lot of market surveillance for prepackages of this particular packer.

Corrective actions are the responsibility of the packer and need validation of the notified body, who can withdraw the certificate and/or can demand to remove her identification of the prepackages.

The scenarios show a decreasing need for market surveillance and an increasing effort at the point of pack. The scenarios chosen are extreme possible systems. Some countries more or less apply one of the above-mentioned scenarios. Scenario 1 bears a close resemblance to the American system, while the system of Scandinavia and the Netherlands looks like scenario 3. Although in practice, the applied quantity control systems are less biased. The next figure shows the current system for several countries.

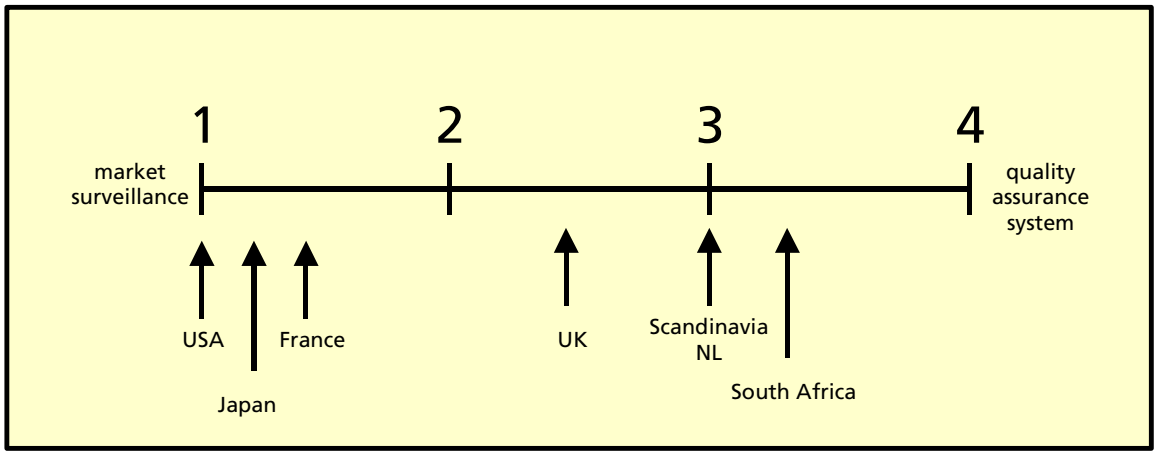

Figure 7-2: an overview of systems in different countries, the numbers represent the four scenarios, not a scale

7.4.1.5 Relevant impacts

The relevant costs of a quantity control system consists of operational costs, i.e. the costs that are made to do any quantity control at all, the cost of overfilling and the accompanying costs of a rejection. Operational costs and the cost of overfilling are made to comply with the requirements set by the control system. An overview of the operational costs and the costs of rejected batches are presented in table 3.3. In this table the affected stakeholder that carries the cost is also mentioned. In order to compensate these costs the affected stakeholder mostly calculates these costs within the cost price, when the affected stakeholder is a packer or retailer, or in taxes, in case the notified body (NB) or governmental inspection organization (GIO) carries the costs.

overview of the relevant impacts

	Costs and benefits	Remarks	Affected stakeholder	Calculated within
Operational costs	Production process	Costs include the full time employment (fte) and production time loss in: Monitoring the filling process Checkweigher Sampling	packer	Cost price
	Quantity control	Fte of the performing body and actor where the control takes place	packer / retailer / NB / GIO	Cost price / tax
	Overfilling	The value of the amount that on average is overfilled	packer	Cost price
Costs of a rejection	Sunk costs[40]	Sunk costs of the rejected batch	packer (or retailer)	Cost price
	Lost benefits	Lost benefits of the rejected batch	packer (or retailer)	Cost price
	Fines	Fines paid to a GIO	packer	Cost price
	Corrective actions	Costs of failure detectness and taken corrective actions on failure and reusability	packer / retailer	Cost price
	Reusability	Benefits of the rejected prepackages in reusing them	packer / retailer	Cost price
	Future lost benefits	Future lost benefits due to bad publicity and/or image loss	packer / retailer	-

Figure 7-3: an overview of the relevant impacts

Operational costs include the costs in the production process, like monitoring, checkweigher or sampling and the costs of performing the quantity control, mainly fte of the performing body and actor where the control takes place. The overfilling cost cannot be assigned (fully) to operational costs as overfilling can also include strategic behavior to decrease the probability of rejected batches. The costs of a rejection include the costs of the rejected batch (sunk costs and lost benefits), the costs of non-complying (fines and corrective actions), the net benefit of reusing the rejected batches (corrective actions and reusability) and costs due to image loss (future lost benefits).

[40] *Sunk costs are all costs already made accountable for a product or prepackage. In case of quantity control, the sunk costs depend on the number of prepackages within a batch.*

The only benefit in table 7.3 is the net benefit arising from reused rejected prepackages. These benefits are part of the costs of a rejection, because the net benefit of reusing the rejected batches will never fully level up the costs of the rejected batch, i.e. sunk costs and lost benefits. Note that the possibility of compensating the costs of a rejected batch is decreasing when the failure is detected at a later stage of the chain, i.e. when more costs are already made, corrective actions are more expensive and/or the profit margin of the reused prepackages is lower.

Not every cost caused by quantity control is relevant. Relevancy depends on the objective of the Cost Benefit Analysis. Therefore, costs need to be sorted out. Important distinctions of impacts are its affected stakeholder and whether the impact is direct or indirect, priced or un-priced, redistributive or efficient. Costs can be incurred directly from applying a quantity control system like sampling or the machinery used. These costs are operational costs, which are discussed above and are recurring over time. Indirect costs are costs that are made as a response to the system or the costs after a rejection. Some costs can be quantified in monetary terms, at least on the individual level, while other costs cannot, because they are surrounded with uncertainty like future lost benefits. Finally, costs can be assigned to being redistributive - an interchange between the stakeholders -, like fines, or as an inefficiency as the costs will only increase the cost price.

Costs mainly incur at stakeholders in the prepackage chain, the packer and retailer. Eventually, the quantity control system is paid by the consumer as a part of the market price and/or by the citizen in subsidizing the independent parties by taxes. Although there is a subtle difference for an individual, in the analysis this distinction is not taken into account. In order to compare the scenarios on all relevant costs, it is assumed that all incurred costs are calculated within the cost price[41]. Therefore, consumers, citizens, notified bodies and governmental inspection organizations are left out of the classification of the costs to avoid costs are assigned twice. The Cost Benefit Analysis could also be based on the consumer and citizen, but choosing these stakeholders is less logical as the costs are made at the stakeholders within the prepackage chain. Moreover, the packer and retailer make their own decisions regarding quantity control. In section 5.4.2, attention will be paid to the decision making of the packer and the retailer.

The next figure gives a classification of the different effects arisen from a quantity control system. Except for costs in the European Union, there could also be costs involved for non-European Union countries. In view of consumer protection, only imported prepackages are incorporated in the next table[42].

[41] *Currently, there is also national variation in calculating the costs made by Competent Departments. Within the European Union some countries fully subsidies their Competent Departments, in some countries these costs are fully paid by the Packer who will calculate these costs within the cost price, but also a combination currently exists. This national variation affects fair trade, which in the European Union will disappear when the systems are harmonized.*

[42] *When fair trade is the objective for the analysis, also exported prepackages should be incorporated in analyzing fair trade outside the European Union.*

Classifying the costs

		European Union				
		Priced effects		Un-priced effects		
		Redistribution	Efficiency	Efficiency	Redistribution	Import
Direct effects	packer	Fines	Monitoring Checkweigher Sampling FTE of packer and NB			
	retailer		Market surveillance Sampling FTE of retailer and GIO			Market surveillance Sampling FTE of retailer and GIO
Indirect effects	packer	Overfilling	Sunk costs (A+B) Lost benefits (A+B) Reusability (A) Corrective actions (A+B)	Future lost benefits (A+B)		
	retail		Sunk costs (B) Lost benefits (B) Reusability (B)	Future lost benefits (B)		Sunk costs Lost benefits Reusability Future lost benefits

Figure 7-4: Classification of the relevant impacts[43]

The costs of rejected batches depend on the stakeholder where the batches are rejected. Batches can either be rejected at the packer by a notified body (case A) or at the retailer by a governmental inspection organization (case B).

Important for the Cost Benefit Analysis is that some priced effects are simple exchanges between two stakeholders. Fines are an exchange between packers and notified bodies, while overfilling is an exchange between the packer and consumer[44]. Only efficiency costs need to be included, as these 'real' costs eventually have to be net paid by the consumer for the quantity control system.

[43] *This classification is based on Eijgenraam, Carel J.J., Carl C. Koopmans, Paul J.G. Tang, A.C.P. Verster. (2000) "Evaluatie van infrastructuur projecten, leidraad voor kosten-batenanalyse" CPB/NEI*

[44] *Of course, the consumer pays more because of overfilling, but - at least on average - he also buys more. The question whether this overfilling is desirable is not discussed in this analysis.*

Table 7.3 gives an overview of the costs by applying and performing a quantity control system. The total cost of a specific system would imply adding up the costs made at every packer and every retailer. However, there is no overall cost structure of a packer or retailer, the number of packers and retailers is unknown and very large and the accounted costs are made internally and possibly not registered by the packer or retailer. Therefore, quantification of the current situation or null scenario is impossible. Available data is restricted to the information from provided by independent parties across the European Union. Information that can be obtained includes the costs of the organizations, the number of tests and rejection percentages. However, the applied systems show national variation. Every EU-member country likely chose a quantity control system based on their country-specific characteristics. Comparing these systems based on costs and rejection percentages is rather invaluable, as within the data there are country specific differences. Moreover, the European Union as a whole has another structure. Thus, analyzing national data cannot be accounted for the European Union and provide no insight in the crucial circumstances when one system is better than the other. Besides, the choice for a specific quantity control system is made in the past and circumstances changes over time. Today, another quantity control system could be 'better' than a current system applied in the same country.

The impacts of a quantity control system consist mainly of costs to ensure a public benefit, consumer protection, as fair trade is more or less guaranteed when the system is the same for any packer. Theoretically, the analysis made could also be defined as Cost Effectiveness Analysis. Cost Effectiveness Analysis concentrates on a single type of benefit, in this case consumer protection, excluding others, eventually offering a ranking of regulatory options on the basis of comparative ‘cost per unit of effectiveness’ of each measure. Scenarios are ranked such that a certain level of effectiveness should be obtained as efficient as possible, i.e. minimizing all costs that are not redistributed. Besides a Cost Benefit Analysis, in the analysis of quantity control a ranking of effectiveness at a certain level of costs would also be interesting. Either way, for quantity control systems quantification of all costs seems impossible, a clear-cut ranking of scenarios based on effectiveness or net costs is inconceivable.

Ideally, the four scenarios should be quantified for the European Union. Some scenarios are more or less applied in a specific country, but the European Union has a quite different structure than a single country in which the system is applied. An estimation of the costs per scenario is not possible either, because the scenarios are only specific about the legal part of the system and do not mention anything about the responsible stakeholders, the intensity of market surveillance, the fine payment, etc[45]. Besides, for an estimation of the total costs per scenario in the whole European Union an overview of the number of packers and retailers is needed[46] as well as insight in the costs made internally at all packers and retailers[47]. Obtaining this information is practically impossible with millions of packers and retailers within the EU. However, the individual stakeholder can be analyzed in qualitative terms in order to get an idea about which variables influence the choice of the scenarios. Therefore, individual decision-making regarding quantity control will be discussed in the next section.

7.4.2 Individual decision making

7.4.2.1 Introduction

The key objective of the Cost Benefit Analysis regarding quantity control is consumer protection. In the former section the goal of consumer protection is discussed and can be formulated as 'as much accurate information about the quantity of product for consumers as possible at a minimum cost'. The goal results in an effectiveness and efficiency problem. In this analysis the effectiveness is formulated as a low percentage of rejectable batches, while efficiency is a minimized calculated percentage of quantity control within the consumer price. Except for a minimum cost and trustworthy prepackages, two other considerations can be incorporated in the analysis of the scenarios: a sound quantity control system[48] and easy failure detectness. These objectives are indirectly linked to the efficiency and effectiveness of a quantity control system. An unsound quantity control system is ineffective, as rejectable batches can be accepted and can be inefficient when acceptable batches are rejected, unnecessarily increasing the sunk costs and lost benefits. Failures of rejected batches that can be tracked down easily decrease the costs made for corrective actions and can prevent future rejections by repairing the failures[49]. The next figure lists the criteria of efficiency, effectiveness, soundness and failure detectness.

Analysis criteria:

- Efficiency: minimizing all costs arising from quantity control that are not redistributed
- Effectiveness: maximizing the prepackages that meet the prescribed requirements

[45] *Information would be incomparable, as the costs of quality control have different explanatory variables (e.g. different distances, different applied systems, different geographical borders different amounts and sorts of Packers and stakeholders, cost structure of labour, different costs to be paid to Competent Departments).*

[46] *There is no information about who the stakeholders are.*

[47] *It is very likely that the information needed is not available for individual packers or retailers, e.g. who could state its costs for performing quantity control, when quantity control is done within a system of control (e.g. quality).*

[48] *A sound quantity control system means that rejectable lots are rejected and acceptable lots are accepted.*

[49] *Normally, the kind of failure is visible on the prepackage.*

- Soundness: rejecting rejectable batches and accepting good batches
- Failure detectness

Figure 7-5: Criteria of efficiency, effectiveness, soundness and failure detectness

The analysis focuses on efficiency and effectiveness such that soundness and failure detectness is incorporated. Efficiency and effectiveness is often a trade-off decision. On behalf of the consumers, the government indirectly makes a decision in choosing the quantity control system and the number of inspectors at the independent parties. Based on these decisions packers and retailers make their decisions regarding quantity control. Insight in their decision making process is therefore valuable.

Ideally, it would be nice if individual stakeholders have an incentive to comply with the quantity control system as much as possible at a minimum cost. A stakeholder has a large incentive when complying is (financially) important and the cost of complying or low. According to economic theory stakeholders see this as a cost minimization problem, where the costs of quantity control and costs arising from rejection are minimized. The structure of such a minimization problem is structured as follows:

$$\text{Min } TC_{\text{Quantity control}} = C_{\text{control}} + \rho * C_{\text{rejection}}$$

where

$TC_{\text{Quantity control}}$	Total costs arising from a quantity control system
C_{control}	Costs incurred by ex ante activities on quantity control
ρ	Probability of rejection
$C_{\text{rejection}}$	Costs incurred by rejection

The formula is based on costs that incur through time. At the point of control, costs already have incurred because of ex ante activities, costs are made because of performing the control, and possibly there are some costs to be made in case of rejection. The probability of rejection (ρ) depends on the number of control and the characteristics of the quantity of product of the batches. Within the formula, there is a relation between the costs of control ($C_{control}$) and the probability of rejection (ρ). In order to decrease the percentage of rejectable batches and therefore the probability of rejection (ρ) a stakeholder can put more effort in quantity control, thereby increasing the costs of control ($C_{control}$). Because of this relation an individual stakeholder has to make a trade-off between the recurring costs of performing quantity control ($C_{control}$) and the threat (ρ) of the contingent costs of a rejection ($C_{rejection}$). The second term of the function ($\rho * C_{rejection}$) determines the pressure on complying. The individual stakeholder will make a decision on the operational cost based on this pressure. In order to comply more to the applied requirements the stakeholder will put more effort in quantity control and as a consequence the consumer price will increase.

7.4.2.2 The individual packer

The packer has a decision on the real quantity put of a prepackage sent in the chain, by setting the average quantity of product, the accuracy of the filling process and product validation. Combining the general minimization function above with the costs out of table 5.1, the packer's minimization function can be further specified:

$$\text{Min } TC_{\text{Quantity control}} = (C_{\text{operational}} + C_{\text{overfilling}}) + \rho * C_{\text{rejection}}$$

where:

$$C_{\text{operational}} = C_{\text{monitoring}} + C_{\text{checking machinery}} + C_{\text{sampling}} + C_{\text{CD}}$$

$$C_{\text{rejection}} = C_{\text{sunk costs}} + C_{\text{lost benefits}} + C_{\text{fines}} + C_{\text{corrective actions}} + C_{\text{future lost benefits}} - P_{\text{reusability}}$$

The operational cost can include sampling, monitoring the filling process, checking the machinery and the declaration of the Competent Department. The choice on the intensity of quantity control depends on the pressure, the cost of a rejection. The cost of a rejection includes the sunk costs, lost benefits, fines, the reusability of the rejected prepackages, corrective actions and future lost benefits. Note that there is a difference in the cost of rejection by the possessor or an independent party, i.e. the notified body or governmental inspection organization. In general, the costs of a rejection by the independent party are higher due to higher declarations and possible fines and future lost benefits.

Elements of choice

A packer has no influence on the number of tests being done on his prepackage and the system applied. However, he has a choice in the intensity of paying attention to the accuracy of the quantity of product. This choice is a cost-effective decision in which a trade-off is made between recurring operational costs and the pressure by the threat of incidental costs when batches are rejected. The incidental costs are uncertain, not only because it depends on an unknown or estimated probability of rejection, but also because of the potential fine and unpredictable future lost benefits. The cost of rejection depends on several characteristics of the product packed and the quantity control system. In order to clarify these characteristics, the elements of the cost of rejection will be analyzed first. With this insight in the intensity of the pressure, the choice on quantity control will be further analyzed.

Pressure

The amount of sunk costs is at least the cost price of the product per unit size when it is sold plus the cost of packaging multiplied by the batch size. Furthermore, the final amount of sunk costs depends on the point of rejection. Rejection at the retailer might increase the sunk costs with other costs made by packer like transportation and retailer when he can claim his expenses. The pressure is increasing with the amount of sunk costs, i.e. when the cost price is higher, batch size is larger, rejection is at a later stage of the prepackage chain and retailers are more powerful. The amount of lost benefits is calculated by the profit margin per prepackage times the batch size. Lost benefits and sunk costs can be quantified quite accurately, the packer can only estimate the remaining impacts. The estimation of the fine depends on the threat and height of the fine, which can differ among the member states. The cost of corrective actions mainly depends on technological product and production process in combination with the applied quantity control system. However no general conclusions can be drawn on relations with the estimation of costs on corrective actions. Some relations can be found in reusability and future lost benefits.

Reusing rejected batches at all depends on the type of product, e.g. in case of prepackaged food there is often not enough time. The profitability of reusing the batches is related to the value of the prepackage at the market, which is equal to the sunk costs and lost benefits. If the market price is low, it is more likely that the costs of corrective actions are larger than the benefit of reusing them. The future lost benefits depends on the extent that a rejected batch would cause loss of image. The image of the packer decreases when the rejected batch is made public and is perceived as being an important signal for the image of the packer by the consumers. The image loss has greater consequences when the packer is large, competes on quality and the retailer is powerful, putting a lot of (future) earnings at risk. Table 5.3 gives an overview of important characteristics and its relation to the pressure[50] imposed on the packer.

[50] *pressure: the pressure for the packer to do quantity control to make sure that prepackages meet the requirements, comes in the form of public opinion, enforcement by government, enforcement by customers, costs of waist etc.*

packer's pressure on quantity control

Cost	Characteristic	Low pressure	High pressure
Sunk costs	Cost price of the product packed per unit size for the packer	Low cost	High cost
	Cost of packaging	Low cost	High cost
	Batch size	Small batch	Large batch
Lost benefits	Profit margin for the packer	Low margin	High margin
	Batch size	Small batch	Large batch
Fines	Probability of getting fined when a batch is rejected	Low threat of getting fined	Any rejection means a fine
	The height of the fine	Low fine	High fine
Future lost benefits	Status of mark	C-mark	A-mark
	Power of retailers	Little	Great
	Size of the packers	Small	Large

Figure 7-6: packer's pressure on quantity control

Effort on quantity control

In general, the higher the pressure caused by the threat of rejection, the higher the effort on complying. For minimizing the probability of rejection the packer has a choice between several solutions. Within the analysis the solutions are limited to four distinct actions: monitoring the filling process, checkweigher, sampling and overfilling. The eventual (combination of) action(s) taken depends on the cost and the effectiveness of the four solutions in relation to the pressure on complying. The cost of overfilling will be a cheap solution if the cost price per unit size is (very) low. Overfilling is highly effective if the variation of the actual quantity of product is small, which for example is usually the case when the product of the prepackage is liquid. In general, monitoring the filling process is a relatively cheap action, however the effectiveness differs.

Batches are monitored on total quantity of product, which is more effective when the batch size and/or the variation is small. A checkweigher is more expensive, but can be very accurate on the actual quantity of product per prepackage. Even without a regulated control system this solution can be very valuable for expensive products as the packer can minimize the usage per prepackage. This accurate solution is relatively effective when the batch size is large. A checkweigher is more useful when the packer is competing on quality and/or high profit margins.

The cost of sampling is low and effective when prepackages can be checked rather quickly when there is reliable reference material. Proper quantity control is more credible when the control is certified. However certification will increase the cost of control. The calculated cost of the notified body depends on the applied quantity control system and the declared percentage. In the analysis the cost of control per prepackage is relevant. The total cost of control should be divided by the production number.

Conclusion

The conclusion is that incentives for paying more attention to the accuracy of quantity of product are regular control by the governmental inspection organization, high market prices, large batch sizes, high fines, large size of the firm and great power of the retailer. The preferred action(s) on quantity control depends on the characteristics of the product and production process, the variation of the actual quantity of product, batch size and the cost price of the product.

7.4.2.3 The individual retailer

In the former section the pressure on the packer caused by a quantity control system is discussed. In practice also retailers exert pressure on the packer for example by their buying behavior. The intensity of this pressure depends on the market forces in the chain. Furthermore, the retailer has a decision on performing quantity control himself, thereby deciding on behalf of the consumer about the quality of the prepackage. Like the packer, the minimization function of the retailer is based on the general function and can be further specified with the relevant costs for the retailer as presented in table 5.1.

$$\text{Min } TC_{\text{Quantity control}} = (C_{\text{sampling}} + C_{\text{market surveillance}}) + \rho * C_{\text{rejection}}$$

where

$$C_{\text{rejection}} = C_{\text{sunk costs}} + C_{\text{lost benefits}} + C_{\text{corrective actions}} + C_{\text{future lost benefits}}$$

At the retailer costs incur by performing quantity control through sampling, which is performed by him, and market surveillance performed by the governmental inspection organization. The probability of rejection (ρ) depends on the number of control and the characteristics of the quantity of product of the batches. Note that the characteristics of the batches at the retailer can change in comparison to the characteristics of the batches at the packer due to mishandling, moisture loss and mixed batches (see 5.4.1.3) on the way to the retailer. The cost of rejection consists of sunk costs, lost benefits, corrective actions and future lost benefits. If the retailer is powerful, sunk costs and lost benefits can often be declared to the packer.

Elements of choice

The retailer can influence the characteristics of the batches at the packer by his buying behavior. Additionally, he can control the quantity of product by sampling himself at the point of entrance. Finally, the failure of rejected batches can be found in mishandling and mixed batches. The probability of rejection would also reduce if the retailer is more focused on these failures. Again, the intensity of action depends on the pressure on the accuracy of the quantity of product.

Pressure

The imposed pressure on the retailer depends on the cost of rejection and the threat of rejection. The cost of rejection for a retailer can include sunk costs, lost benefits, corrective actions and future lost benefits. Compared to the cost of rejection of the packer, A retailer does not have to pay fines and has no profit of reused batches due to legislation. Legally, the retailer is not responsible for the rejection and therefore cannot be fined. Therefore, the retailer is also not authorized to resell the rejected batches. The cost of corrective actions is limited to the effort after a batch is rejected. The amount of sunk costs depends on the cost price of the prepackage plus the costs made by the retailer multiplied by the batch size. Like the packer, the amount of lost benefits depends on the profit margin and the batch size. Sunk costs and lost benefits might be recalculated to the packer, depending on the agreement made and/or the relation with the packer. Recalculation would imply no pressure. Normally, the largest part of the pressure would be accounted to future lost benefits. Future lost benefits are higher when the retailer is large, competes on quality and consumers are sensitive for rejection.

The next table summarizes the characteristics of the imposed pressure on the retailer.

retailer's pressure on quantity control

Cost	Characteristic	Low pressure	High pressure
Sunk costs*	Cost price of the prepackage at entrance	Low cost	High cost
	Incurred costs after entrance	Low cost	High cost
	Batch size	Small batch	Large batch
Lost benefits*	Profit margin for the retailer	Low margin	High margin
	Batch size	Small batch	Large batch
Future lost benefits	Focus of retailer	Low budget	Quality
	Power of consumers	Little	Great
	Size of the retailer	Small	Large

Figure 7-7: Overview of the characteristics of the pressure on the retailer

Effort on quantity control

The incentive for the retailer to assure that the prepackages sold to the consumers contain accurate information about the quantity of product, can lead to two possible actions. Intensify the pressure on the packer to deliver acceptable batches or sampling at the point of entrance. Note that exerting effective pressure on the packer is only possible if the retailer has enough market power. Furthermore, there is (financial) space for sampling at the point of entrance is if the profit margin is large enough and/or the retailer has a quality focus. Using his market power would imply no cost for the retailer. The cost of sampling per prepackage decreases when the number of prepackages entering the retailer's warehouse increases. The cost of sampling is probably only marginal, just like the cost of drawing more attention to avoid mishandling or mixed batches. However, when there already is market surveillance, sampling doubles the cost of control.

Conclusion

The focus on quantity control depends on the pressure. Pressure mainly depends on the future lost benefits, which increases as the retailer is larger, focuses on quality and consumers are more sensitive for rejectable prepackages. When quantity control is an issue a retailer has a preference for no market surveillance. The retailer would prefer taking is own actions and the market would solve the problem. Intervention would only imply an increase in consumer prices and taxes. When the pressure is low, theoretically there should be market surveillance to protect the consumers. However, one important reason of a low pressure is that consumers are rather careless about the quantity of product in prepackages. Fair trade is also not affected as retailers are competing on price.

7.4.2.4 Quantity control

There is no minimization function for the performers of the quantity control system, the notified body and governmental inspection organization. Within the decision making process of an individual packer and retailer the threat of quantity control and the legislation of the quantity control system plays an important role. These issues will be further analyzed below.

Performing quantity control

The number of control is one on one related to the pressure for the packer and the retailer. A system also puts pressure on the packer due to the cost of a fine. Theoretically, higher fines for packers would need less control at the point of pack. The total cost of one separate control decreases when the time needed for control decreases, the number of packers or retailers increases and the distances between the stakeholders diminishes. To ensure fair trade the cost of control by the notified body should be fixed and need not be dependent on geographical differences. There is a crucial difference between the number of control and the threat of control. The pressure for the packer is increasing when quantity control is performed more often, not announced and at more places in the prepackage chain.

Legal system

In this chapter four scenario systems are considered. The need for notified bodies increases through the four scenarios. In case of the first scenario there is no control at the point of pack, while in the fourth scenario a whole quality assurance system is set up. Contrarily, the activities of governmental inspection organization are diminishing, from a lot in scenario 1 to hardly in scenario 4. Effectiveness and efficiency of the scenarios for the individual packer and retailer depends on the characteristics. These characteristics determine the pressure and the efficient action taken. There is a cost preference for a flexible system as the efficient action differs per individual. However, the pressure and therefore also the intensity of complying differs. The intensity of a complying increases with the scenarios. However, scenario 4 is more inefficient compared to a flexible system as individual packers cannot perform their efficient action. Again, the analysis leads to a trade-off between effectiveness and effectivity. The first scenario can be indicated as most efficient, while the fourth scenario focuses on effectiveness. Additionally, fair trade might be affected more in the fourth scenario. However, the key objective in the analysis is consumer protection. The trade-off between effective and efficient legislation depends on the consumer.

7.4.2.5 The individual consumer

No minimization function of the individual consumer is analyzed. However, some preferences can be drawn from the former sections and the key objective. Controls are most effective at the point of sale as failures can occur at all places in the prepackage chain. Furthermore, applying the average principle seems inefficient. From an individual consumer point of view, it is rather strange that a single prepackage whose actual quantity is less than the nominal quantity is acceptable due to the overfilling of the remaining prepackages in a batch. Although not incorporated in the scenarios, it would imply a preference for the minimum quantity principle over the average principle.

So far, the analysis assumed a preference for trustworthiness over cost price. In practice however, it seems highly unlikely that correct information about the quantity of product is an issue for most consumers. Research in the United Kingdom shows that consumers hardly look at the information about the quantity of product, let alone (the meaning of) the e-mark. Mostly, consumers compare prepackages by looking at the packing material, while a minority compares by looking at the price per product unit. The responses to the questionnaire specify this unawareness. When non-complying, consumers will assume that 'someone' is responsible, and that whatever the system may be, it works 'properly'. consumers rather look at intervention by public brought up by the media, rather than private bodies. The question rises if the government should protect the consumers, if accurate information about the quantity of product is not an issue.

7.4.3 Conclusions

It is impossible to quantify any costs in the different scenarios. The Cost Benefit Analysis of several scenarios on quantity control systems demands a complete structure of packers and retailers in all countries of the European Union. Explanations for being unable to quantify are:

- No information in full about the structure in the EU concerning the number of Prepackages, packers and retailers and the time needed to do one test
- No insight in internal costs of packers and retailers
- Costs decision differs strongly per individual packer and retailer
- Scenarios are too vague on the way and number of control

The 'optimal' system of quantity control depends on the characteristics of packers and retailers and country specific differences. What can be done is give insight in the consideration of the (individual) relevant stakeholder. From the analysis done, the following conclusions can be formulated:

- The effort of an individual packer or retailer to comply depends on the perceived pressure, i.e. the threat and cost of rejection. The individual packer or retailer regards the intensity of the pressure as given and chooses his cost-efficient action.

- The pressure of an individual packer depends on many variables like its size, unit price, profit margin, batch size, fine, status of the packer and power of the retailer. The cost efficient action of the packer depends on the characteristics of the product and production process, the variation of the actual quantity of product, batch size and the cost price of the product. The preference of scenarios differs per individual packer. For example, regarding size, Small and Medium Enterprises would have a preference for self-declaration, because quantity control per prepackage is relatively more expensive. Therefore, the efficient solution is self-declaration or to offer a flexible system in which the packer is able to choose his cost-efficient solution.
- The pressure of an individual retailer increases as the retailer is larger, focuses on quality and, most importantly, consumers are more sensitive for rejectable prepackages. When a retailer has power the market would choose the most effective solution at a minimum cost. Market surveillance would be a waste of money. Intervention is necessary when accurate information about the quantity of product is important for consumers, but the market offers no choice.
- The most effective quantity control system is the fourth scenario, 'Total Packing Quality' along with a lot of, not announced market surveillance. However, this system is inefficient for individual packers and retailers with high-level pressure. The first scenario, 'Self declaration' is sufficient for such packers and retailers. Again, there is a trade off between effectiveness and efficiency. Regarding the key objective, consumer protection, the optimal choice depends on the consumers.
- Consumer protection would implicate a preference for the minimum quantity principle and control at the point of sale such that every consumer would never buy an accepted prepackage with an actual quantity that is less than the nominal quantity. However, research shows that an e-mark is not an issue for consumers. Accurate information about the quantity of product is taken for granted.
- The scenarios do not differ enough to come to a clear conclusion. The structure of the European Union regarding quantity control is too complex. The 'best' scenario depends on the region, the packers and retailers within this region, the sort of product, e.g. food or medicines and most importantly the power and preferences of the consumer market.

In the European Union as a whole there is a trade off between market mechanism and governmental intervention. In some cases any governmental intervention is a waste of money as retailers and/or packers perform their quantity control properly, a law, which allows self-declaration, would be efficient. However, in other cases governmental intervention by enforcing a law for Quality Assurance systems is needed to protect the consumer if accurate information about the quantity of product is an issue.

The above is summarized in this effect matrix:

	Self declaration	Product validation	Validated filling process	Total packaging quality
packer	Chooses his own cost-effective control system: overfilling for small packers and low cost product or quality assurance. Incentives needed from consumer (e.g. A-mark) or retailer or market surveillance	Cost of control by notified body. Carries cost of transferred risk of retailers.	Cost of control by notified body. Possible SME-burden. Firms with low cost product and small firms prefer overfilling.	Cost of control by notified body. Possible SME-burden. Firms with low cost product and small firms prefer overfilling
retailer	Carries the cost of market surveillance.	Carries the cost of market surveillance.	Low costs on average. Especially reduced costs for retailers competing on quality	Low costs on average. Especially reduced costs for retailers competing on quality.
notified body	No role in this system	Not very effective role in this system: witnessing packers' checks or sampling.	Has a great deal of work to do: validating filling procedures + judgment limited QA system	Has a great deal of work to do: judgment complete QA system
market surveillance organization **(governmental inspection organization, GIO)**	Has a lot of work. Effective of overfilling packers, Difficulties to retrieve responsible packer, especially outside the EU	Has a lot of work. Effective of overfilling packers, Difficulties to retrieve responsible packer, especially outside the EU	Limited work to do. The control at the packer by is effective.	Limited work to do. The control at the packer by is effective.

Figure 7-8: effect matrix