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METROLOGICAL REQUIREMENTS OF PREPACKAGES

Working document

This is a consultation document by DG Enterprise and Industry of the European Commission. It is published in conjunction with an interactive survey on Your-Voice-in-Europe.

The aim is to collect opinions on the issues raised in the document with a view to formulating the policy as regards metrological requirements in pre-packaging. The Commission is expected to adopt a proposal early in 2006.

The consultation of stakeholders is part of the Commission's impact assessment and complements a study on impacts finalised by an external consultant in November 2003. A report on the views received in this consultation, including a list of respondents, will be made available in June 2005.

This Consultation document commits only the Commission services involved in the preparation of the proposal.

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1) Introduction

Consumers very often buy products that have been packed elsewhere and cannot be opened without altering the product. Traditionally, therefore, in order to protect consumers all Member States have regulation imposing the control of the quantity contained in order to ensure that consumers indeed get the quantity that is indicated on the package. The European Community also has adopted regulation on the accuracy of the contents to ensure that consumers are correctly informed and to allow products to freely circulate in the Community.

The first such EU legislation for metrological requirements for pre-packaged products dates from 1975 for liquids[1] and a year later, in 1976, similar metrological requirements for non-liquids were regulated[2]. Prepackages which conform to the metrological requirements of the directives may be marked with the e-mark and benefit from free movement ensuring a level playing field for businesses. Next to the harmonised legislation, parallel national legislation has continued to exist.

After over 20 years of implementation of this legislation, a team in the framework of the SLIM-IV exercise (Simpler Legislation for the Internal Market), comprising of members designated by Member States and independent experts proposed by the Commission, advised to simplify the current legislation[3].

As regards metrological requirements the SLIM team recommended the following:

- combine the metrological requirements laid down in Directives 75/106/EEC and 76/211/EEC in a single piece of legislation,
- retain the average system (i.e. the contents of each prepackage in a batch must on average be equal to the indication on the package) and make current optional provisions mandatory,
- review other provisions of Community law on quantity indications for pre-packaged products with a view to integrating them into a new single directive.

It also suggested adapting the scope of the Directives as follows:

- in recognition of emerging market patterns, the scope of existing legislation should be extended to include nominal quantities up to 25 kilograms/litre and consequently, a number of questions relating to the implementation of metrological checks on these larger quantities should be addressed,
- extend metrological checks for determining net drained weight while recognising that an agreed Community method for determining net weight is needed,
- when reviewing the existing provisions, the opportunity should be taken to clarify definitions that give rise to problems of interpretation.

The Commission commented that it welcomed the advice and committed itself to further study the issues brought up. At a meeting with stakeholders in December 2000 it was decided

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[1] Council Directive 75/106/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain pre-packaged liquids

[2] Council Directive 76/211/EEC 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 pre-packaged products

[3] COM(2000)56 final, pp 9-11 and 21-22 the SLIM exercise considered both metrological requirements in pre-packaging as well as ranges of sizes; the latter are not the subject of this document.

concentrate first on the issue of ranges of sizes in prepackaging and to further study the issue of metrological requirements. At a meeting with national authorities in March 2003 specific elements in relation to metrological requirements were further discussed and in November 2003 a study on the impacts of a review of metrological requirements was finalised.[4] This working paper by the Commission services builds on these inputs and gives an overview of the issues to be treated in potential regulation.

2) Reasons to regulate

a) Community context

In accordance with established case-law by the Court of Justice of the European Community[5], Article 28 EC Treaty prohibits obstacles to the free movement of goods coming from other Member States, where they are lawfully manufactured and marketed.

However, obstacles to intra-Community trade resulting from disparities between provisions of national law must be accepted in so far as such provisions are applicable to domestic and imported products without distinction and may be justified as being necessary in order to satisfy overriding requirements, such as consumer protection and the fairness of commercial transactions. In order to be permissible, such provisions must comply with the principle of proportionality. They must therefore be confined to what is actually necessary to ensure the safeguarding of the legitimate public interest of consumer protection and fairness of commercial transactions. Furthermore, they must be proportional to the objective thus pursued which cannot have been attained by measures that are less restrictive to intra-Community trade.

As regards prepackaged products, national rules concerning the correct filling of prepackages and the test methods to verify this are in principle of a nature such as to ensure effective protection for consumers and the fairness of commercial transactions. As national rules currently diverge, common rules are required in order to allow the free movement of products.

b) International context

Worldwide most countries have regulation concerning metrological requirements. In order to reduce barriers to trade countries cooperate internationally.

The Organisation Internationale de Métrologie Légale (OIML) has a membership 60 countries and another 50, which follow its activities as observers. The Community as such is not a member of OIML, but most of its Member States are. Despite that fact, under the terms of the WTO/TBT agreement, it could be argued that OIML qualifies as an international standardising organisation. Therefore, its recommendations should in principle form the basis for regulation by its members (national authorities).

In November 2003 OIML updated Recommendation 87 (OIML R87) concerning the "Quantity of products in prepackages" and the update is in line with the existing EU

[4] W. Frankvoort, J. Hogendoorn, J. Rommerts: Business impact analysis on conformity assessment in prepackages, study for DG Enterprise, October 2003 (simultaneously published with this document)

[5] Case C-3/99 of 12 October 2000, Cidrerie Ruwet SA v Cidre Stassen SA and HP Bulmer Ltd. (points 46 and 50) and Case C-293/93of 15/09/1994, Houtwipper (point 14)

legislation[6]. Also relevant is OIML Recommendation 79 (OIML R79) "Labelling requirements for prepackaged products" for the manner in which the prepackages should be marked with information.

Independently from any institutional considerations regarding participation in OIML, the updated OIML recommendation will lead Member States to update their legislation. Although the basis is common there is no assurance beforehand that differences of interpretation and implementation may not occur on substance. Also for this reason a Community legal framework is needed.

In line with the WTO/TBT agreement, the Community is committed to take OIML recommendations as the basis for its regulation. Consequently, Community legislation will provide a legal framework allowing OIML recommendations to be implemented uniformly throughout the Community.

The EU's main trading partners are members of the OIML and are expected to follow its recommendations in national law.

c) Trade and turnover

The case for regulation of metrological requirements is reinforced by the size of the market. Regulation aims to ensure that there is a level playing field and that potential trade barriers are eliminated.

For example, turnover of retail trade of foodstuffs is around € 600 billion. Assuming that two thirds is sold in prepackages, turnover would amount to € 400 billion or 4% of GDP of the European Union. To this should be added the turnover of non-foodstuffs sold in prepackages which may amount to a figure of a similar order. In total, turnover in prepackages could amount to 6-10% of GDP.

3) Elements of potential regulation

The following is an outline of the issues that would need to be addressed in the framework of the current legislation. It is proposed to base EC regulation on both OIML R79 and OIML R87[7].

a) Scope

The current directives concern contents ranging from 5g (5ml) to 10kg (10L) and this could be extended from 0 up to 25kg (25L) according to the SLIM team's recommendation or to 50kg (50L) according to OIML R 87. The latter maximum ties in with worker protection rules that require the indication of gross weight for heavy loads which are manually handled.[8]

The current directives concern prepackages that are automatically filled in equal sizes or individually filled. Other elements that could be added to the scope are measuring containers

[6] Notably Chapter 4.5 of OIML recommendation R87 provides offers enough statistical information to be equivalent to paragraph 5 of directive 76/211/EEC.

[7] OIML Recommendation 79 (OIML R79) "Labelling requirements for prepackaged products" , 1997
OIML Recommendation 87 (OIML R87) on the "Quantity of products in prepackages", 2004

[8] Directive 90/269/EEC 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 requires that employers must among others offer "precise information on the weight of the load".

(Dir 75/107) and automatic packaging of differently sized products (catchweighing). These issues will be discussed in more detail further on.

Another question is whether the Community provisions should apply to packages sold to the final consumers only or cover all commercial transactions including business-to-business transactions?

b) Units of measurement

The question comes up whether legislation should define precise rules per product or group of products, or whether only weight and volume would suffice? For instance, should, or could, the scope be extended to include number (e.g. matches, nails, candles) or more units of measurement, which should be verifiable, such as indications of length and area, e.g. m^2 for textiles and, or indication of volume, e.g. m^3 for compost, or indications of quality, e.g. number of washes of washing powder, burning time of candles, the area covered by paints?

Some of these elements are already part of OIML R87, but there may be a problem of choice, e.g. should biscuits be indicated by count or by weight? OIML R79 gives guidance for some types of product on the most appropriate quantity to be declared on a label.

c) Definitions

The SLIM team advised that, when reviewing the existing provisions, the opportunity should be taken to clarify definitions that give rise to problems of interpretation in the current Community rules.

i) Content = quantity of product

A prepackaged product is the combination of a product and the packing material in which it is packaged. The prepackaged product is packaged in predetermined quantity without the purchaser being present and it cannot be altered without the packing material being opened or undergoing a perceptible modification. This definition is currently in the directives and follows OIML R87 (points 2.10 and 2.11).

In the current directives there is no definition of packaging material and this has given rise to unclarity, notably whether the wrappings around sweets and chocolates (pralines) are included in the weight mentioned on the prepackage or not. In order to remain consistent, a choice must be made, namely that all elements of packing material should be excluded from the quantity of prepackaged product indicated. Packaging therefore is everything of the prepackage that is meant to be left over after use of the product, except for items naturally in the product. This is coherent with OIML R87 (point 2.9).

As the consequence of the two definitions above, the content of a prepackage can now be defined in a clear-cut way as the quantity of the product in the prepackage excluding the packaging, i.e. the quantity of product that is meant to be used, i.e. consumed, or subjected to a treatment, e.g. cleaning products or candles[9]. This also clarifies the concepts of nominal quantity of product which is mentioned on each prepackage (OIML point 2.8) and the actual quantity that the prepackage in fact contains, which can be checked by measurement (OIML point 2.1).

[9] This definition is coherent with that in Article 3.1 of Directive 94/62/EC on Packaging and Packaging Waste

ii) Drained quantity

Drained quantity is currently not defined in the directives although it is referred to in Directive 200/13[10]. It is suggested to define this as follows in conformity with OIML R87 (point C.1). Drained quantity products are products that are preserved in a liquid medium. The drained quantity is the solid part of the product that is meant to be used minus the liquid medium in which it is preserved.

Depending on whether the liquid medium can be consumed or not, there are three cases:

- The liquid medium is an integral part of the product, e.g. 'spirits with raisins' or 'fruit juice with pulp' or 'poire williams' where the pear has grown in the bottle, in which case drained weight is not relevant. The content is a summation of both the solids and the liquid medium.
- The liquid medium is a second product which can be consumed, e.g. 'fruits in juice' or 'cheese in olive oil', and its quantity should also be mentioned separately as well on the prepackage. There will be two content declarations.
- The liquid medium is not consumed, e.g. 'anchovies in brine' or 'green peas in water' where the liquid is discarded, in which case the drained weight is the only indication required. The content is just the quantity of solids.

iii) Frozen products

Frozen products should follow the same principles as for drained quantity. This conforms to OIML R87 (point D). The water used as the liquid medium should be excluded from the quantity indicated on the prepackage. The legislator may establish specific limits, e.g. frozen poultry meat[11].

iv) Packer and importer

A packer and importer are not defined specifically in the current directives (nor in OIML recommendations) although under the directives both have legal responsibilities[12]. It is suggested to add these definitions.

Over the last 30 years there have been changes in the way product is packed. Multi-stage packing is carried out for some products with one organisation filling the prepackage and another applying the label. As the prepackage is not completely formed until the last operation and the last person to make a change to the package and its contents could therefore be considered to be responsible for the quantity declared. This could be one solution but would need refining to include the importer.

An alternative definition could be: a natural or legal person responsible for the conformity of the prepackage with the Directive with a view to placing it on the market.

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[10] Directive 2000/13/EC on the labelling presentation and advertising of foodstuffs, Article 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 labelling. 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."

[11] Regulation EEC/1538/91 on marketing standards for poultry meat, Annex VI point 6.4, allows the addition of extra water when freezing poultry meat the quantity of which could be mentioned on the package.

[12] Annex I.4 of Dir 76/211/EEC

d) Quantity requirements for prepackages

Based on these definitions a number of requirements can be formulated which are necessary to guarantee correct filling of prepackages.

i) Automatically filled batches

The current legislation concerns products that are filled by automated machines, which have a known standard deviation. The controls can then be of a statistical nature for quantities above a certain number.

An automatically filled batch is defined as the quantity of prepackages produced at one time under conditions that are presumed uniform. It is suggested to maintain the reference test[13] which is in the current directives and conforms to OIML R87 (points 3 and 4).

As innovation allows quicker filling, the size of batches increases and the current rules require numerically large samples for the reference test that make it expensive. Current rules reflect international standards on statistical testing[14]. It could be considered, as an option, to include simpler tests in the Directive, if these tests can be proven to be statistically relevant[15].

Minimum filling could be an option to packers filling automatically. Filling low-value products to over the minimum is a trade-off to the simpler testing involved. Allowing to test on the minimum quantity (see below under iii) would reduce the costs currently associated with the reference test when high speed filling is applied.

ii) Glass bottles as measuring containers (Dir 75/107/EEC)

Glass bottles are measuring containers in the sense that they will contain the nominal quantity for which they have been designed when filled to a specific height. They will have slight variations and therefore the above-mentioned statistical methods of samples are equally applicable to the production in batches of such bottles.

Currently such bottles are defined in Directive 75/107/EEC[16] which is optional and allows national rules to coexist. It follows existing international standards[17]. EC legislation should also become total and no differing national rules should continue to exist.

iii) Individual (manual) filling and the option of minimum filling

Individual filling of pre-packages is currently covered in the harmonised directives[18]. However, data collection in order to perform the reference test is often complex in practice and so minimum filling becomes an option. Where individual filling is used, each pre-package should at least contain the quantity indicated on the package, i.e. it is prohibited to under-fill.

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[13] Annex I.1 of Directive 76/211/EEC gives as objectives for the reference test on a sample of prepackages from a batch:
-No prepackage may have an error of twice the allowed tolerable negative error (TU2).
-Only a small portion of prepackages may have contain less than the nominal quantity minus the allowed tolerable negative error (TU1).
-On average, the quantity of product must be at least equal to the nominal quantity indicated on the prepackage

[14] ISO standards 2854, 2859 and 3494.

[15] A. Duran : « Les principes statistiques du contrôle métrologique du contenu net des préemballages fixé par la directive CEE 76/211 », expert report OIML E4, 2004, see: http://www.oiml.org/download/docs/e/E04-f04.pdf

[16] Directive 75/107/EEC relating to bottles used as measuring containers

[17] OIML Recommendation 96 concerns measuring container bottles (1990)

[18] Annex 1 paragraph 4 of Directive 76/211/EEC : "… the product shall be measured ..."

The minimum filling could be tested on a single package by checking whether it contains the quantity indicated minus the tolerated error, if suitable legal measuring equipment had been used.

Minimum filling could be distinguished from the average filling by an indication of the word 'minimum' before the quantity indication on the label.

iv) Filling differently sized products (catchweighing)

Automatically filling differently sized products, e.g. cuts of cheese or meat, is not covered currently by the harmonised directives. One option could be that each prepackage is considered to be individually filled and that the minimum quantity is indicated (see point iii above).

An alternative would be to indicate which class of automatic catchweighers as defined in the Measuring Instruments Directive gives the presumption of conformity[19].

e) Labelling requirements for prepackages

The current directive contains labelling requirements that concern only the indication of the quantity and the type of unit to be used depending on the nature of the product[20]. It is limited to the aspect of metrological requirements. Other labelling requirements are treated by separate general directives and sometimes by specific product regulations. In the following, suggestions are made that concern labelling but these do not prejudge the Commission's choice to treat these elements in other pieces of legislation or for standardisation bodies to take these suggestions on board in their documents.

i) Deceptive packaging

Deceptive packaging is meant to mislead the consumer. There are a host of factors that may lead to such deception, one of which one may be the packaging. However, it may be difficult to objectively establish whether a package is deceptive. OIML R87 gives guidance on what misleading practices should be prohibited[21].

The general practice of misleading practices is already the subject of a Commission proposal which also applies to packaging. At this stage, therefore, there seems to be no need to regulate deceptive packaging specifically[22]. On the other hand, OIML R87 could offer a basis for standardisation by means of which to comply with the aforementioned draft proposal.

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[19] Automatic catchweighers are described in Annex MI-006 of Directive 2004/22/EC where it is indicated that the X category instruments specifically produce to the requirements of Directives 75/106 and 76/211.

[20] Directive 76/211/EEC, Art 4.2: "Prepackages containing liquid products shall be marked with their nominal volume and prepackages containing other products shall be marked with their nominal weight, except in the case of trade practice or national regulations which provide otherwise and which are identical in all Member States, or in the case of contrary Community rules."

[21] OIML R87 Edition 2004, mandatory Annex E and OIML R79, point 6.

[22] COM(2004) 753 final of 16. 11 2004: Commission Communication on Council Common Position, on COM(2003)356 final, of 18.6.2003: Proposal for a Directive of the EP and of the Council concerning unfair business-to-consumer commercial practices in the Internal Market and amending directives 84/450/EEC, 97/7/EC and 98/27/EC. See also the DG SANCO Unfair Commercial Practices portal

The quantity indication should be on the primary display panel on the front of the package[23] and the phrase that the quantity indication should be legible and visible 'under normal conditions of presentation' (Annex I, point 3 of directive 76/211) could be refined to "The quantity indication should be on the primary display panel on the front of the package"; which conforms to OIML R79 (point 5.5.2).

Non-functional surplus packaging material (i.e. non functional slack fill and packages with false bottom, sidewalls, lid or covering) is already prohibited by the Packaging and Packaging Waste directive[24]. Where slack fill is functional, the consumer should be informed of the percentage of the filling, which could be indicated on the label next to the quantity indication.

Issues of minimum fill and maximum fill which impinge on safety requirements, such as is the case for aerosol dispensers, should be dealt with in the in the specific legislation, e.g. the Aerosol Dispensers directive[25].

ii) Quantity declaration of free offers

Quantity declaration of free offers[26] is of the type "175g plus 25g free". In some member states only the indication of the total is accepted and it is not clear under current rules whether only total contents may be indicated. In terms of metrological requirements it is important that consumers should be informed by the mention of the total nominal quantity (content) and that any indications on the quantity given for free could be mentioned but not as part of the overall content indication nor in the same type settings.

Such a definition would allow to unambiguously establish the unit price as being the price of the package divided by its quantity (expressed in kilo or litre)[27].

iii) Identification of importer or packer on the label

Currently labels of food products must contain an indication of the name or business name and address of the manufacturer or packager, or of the seller established within the Community[28] . The cosmetics directive requires the name and address of the manufacturer or the person responsible for marketing the product who is established within the Community[29].

These practices could be extended to all non-food products thereby allowing the authorities a quick and efficient means of tracing the packer or the importer or person placing the product on the market (see 3.c.iv above) [30].

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[23] OIML R79, point 2.4 defines Principle display panel as: the part of the package that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display.

[24] Minimisation of packaging by volume or weight is required by Article 9 and Annex II of Directive 94/62/EC on Packaging and Packaging Waste

[25] Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers

[26] Neither OIML R79 or OIML R87 offers any guidance on the issue of declaration of free offers

[27] Article 2 of Directive 98/6/EC on consumer protection in the indication of the prices of products offered to consumers

[28] Article 3.1.7 of Directive 2000/13/EC on the labelling presentation and advertising of foodstuffs

[29] Directive 76/768/EEC on cosmetic products, Article 6.1.a. This article also allows Member States to require that the country of origin be specified for goods manufactured outside the Community.

[30] OIML R79, point 4: The label of a pre-packaged product shall specify conspicuously the name an place of business of the person responsible for any of the following: manufacturing, packing, distributing, importing or retailing the product. When the product is not manufactured or packaged by the person whose name appears on the label, the name may be qualified by a phrase that reveals the connection such person has with the product, for example: manufactured for …", "distributed by …", "marketed by…", imported by …" or "sold by …"

iv) Minimum size of the quantity declaration

Appropriate information of the consumer also depends on the legibility of the markings. With populations growing older the access to this information should be reconsidered. Currently the 'e'-mark is required to be a minimum height of 3mm, there seems no reason why the minimum height of the nominal quantity should be any less than this.

Current legislation defines the size of the quantity from 2mm to 6 mm depending on the size of the package[31]. As 2mm is deemed to be quite small, it is suggested to indicate the quantity in at least 5mm[32].

v) Desiccating products

Desiccating products dry out over time and therefore weigh less as time passes[33]. The weight of the content at the point of sale will tend to be less than at the time of packaging. By how much will depend on the rate of desiccation which will also depend on circumstances such as the type of packaging, temperature and humidity at the point of sale. If desiccation cannot be prevented by means of packaging, it would seem to be correct to place a warning on the prepackage explaining that the prepackaged product may be prone to desiccating and may weigh less than indicated. This warning would not need to be placed on prepackages that can be guaranteed to prevent desiccation, thereby offering an incentive to develop such packaging.

This implies that market surveillance of desiccating products is best carried out at the packer's premises immediately after packaging. If checked elsewhere and found deficient, the packer or importer must be able to show that the contents in the prepackages were correct at time of packing and justify that any deficiency found is due solely to the product desiccating.

At present, according to the general interpretation by the authorities of the directives, at any place in the distribution chain any prepackage containing a desiccating product should not have a quantity less than twice the allowed tolerable negative error (see point d)-i above). This and labelling requirements can be checked at any time[34].

f) Conformity assessment (manufacturer, packer, importer)

The current legislation states that the packer or importer (in the case where the packer is outside the Community) are responsible for prepackages meeting the requirements of the directives.

- The packer can either check the actual contents using a suitable legal measuring instrument (prescribed by national law) or organise checks in such a way that the quantity of contents is effectively ensured. In this latter case there is a difference between the two pieces of legislation[35]: for liquids (Dir 75/106) he must follow procedures recognised by the authorities, while for other products (Dir 76/211) 'this condition is deemed to be fulfilled if his checks are in accordance with a procedure recognised by the competent department of the Member State'. In both cases he must

[31] Dir 75/106 and 76/211, Annex 1, point 3.1
[32] see also OIML R79, Annex B
[33] Neither OIML R79 or OIML R87 offers any guidance on the issue of desiccating products
[34] Mutatis mutandis, this interpretation would apply to the minimum quantity indication, if it would be allowed.
[35] Dir 75/106, Annex 1, paragraph 4 stipulates that packers must carry out production checks in accordance with recognised procedures, whilst Directive 76/211, Annex 1, paragraph 4 that the packers fulfils his obligations by following recognised procedures and leaves open other routes to conformity.

keep documents at the disposal of the competent department in order to be able to show that the checks are correctly carried out.

As regards the first option of checks using automatic filling instruments, more clarity may be needed on what is suitable, for instance: maximum verification unit in relation to nominal quantity and software requirements.

As regards the second option, national practices as regards the recognition of procedures are quite different and there would seem to be four categories of recognition:
- Explicit in some sort of certification scheme
- Implicitly by the inspector
- Implicitly by means of codes of conduct
- In some member states there is no formal recognition

The Commission is not aware that the absence of harmonised packing procedures leads to problems on the market and, unless information to the contrary would be forthcoming, does not see a need to harmonise the procedures. The question arises whether there is a need for formal recognition of packing procedures by Member States in order to ensure a uniform application of the various options of recognising procedures available to the packers and importers?

- An importer has three possibilities: to measure, to organise checks or to provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility.[36] This responsibility should remain.

g) Enforcement (national authorities, competent departments)

As regards the national authorities, the competent department shall perform the reference test or tests which are equivalent at each packer's and importer's premises (see note 12 above for a description the criteria of the reference test contained in the directives)

The current directives also contain provisions that allow the national authorities to conduct further enforcement[37]. This includes additional tests to check the conformity of packages and regular in-service verification of pre-packaging machinery.

According to the study (see point 4d below), competent authorities consider that market surveillance may be insufficient as regards imports from third countries and at the point of sale, if the average-filled prepackages do not belong to a same batch[38]. More work would be needed to identify the rules by which to establish proper control of imported products, e.g. shop tests, identification of importers and the passage of information by Customs at the external borders to Competent Departments. Competent departments in WELMEC WG6 are invited to inventory current national practices as regards imports from third countries.

[36] Directive 76/211/EEC Annex 1 paragraphs 4 and 5
[37] Directive 75/106 and 76/211/EEC Annex 1 paragraph 6
[38] No such surveillance problem occurs in the case of minimum filling that can be tested on a single package.

h) Innovation and tolerances

Processes are continuously being improved and filling machines are becoming more precise. This enables packers to guarantee better filling and also to better track activities so that quality assurance becomes feasible.

Technically the currently established tolerances could be refined further. It would, however, decrease the tolerances to be stricter than those in international standards. Furthermore, it could incur costs and reduce the price competitiveness of EU prepackaged products on the world market.

i) Nature of regulation

Harmonisation should be mandatory and total, i.e. no additional national rules are allowed. This would conform to the advice by the SLIM team. The current e-marking, which currently distinguishes the average system from other national systems, could disappear. In future no indication would mean that the average filling method has been used, while 'minimum' would indicate that the option of minimum filling has been applied. Each system will have its own tests.

As regards the recommendation of the SLIM team to review other provisions of Community law on quantity indications for pre-packaged products with a view to integrating them into a new single directive, the Annex indicates the legislative texts which would need to be reviewed. The Commission will examine whether by means of an 'interpretative communication' a coherent implantation can be ensured.

4) Views of stakeholders

In the second half of 2002 for the study commissioned by DG Enterprise, stakeholders were asked about their views concerning the types of conformity assessment[39]. The possibilities proposed were:
1. declaration of conformity by the packer
2. validation of conformity by the packer with a check by a third party (notified body)
3. validation of the filling system by a third party (notified body)
4. certification of the quality system by a third party.

While some or all these options may currently be available to packers depending on the member state, it should be noted that they do not prejudge the discussion on this consultation document.

The results gathered for the study were mainly from Slovenia and the Netherlands and are not representative in a statistical sense but nonetheless they would seem from the perspective of the Commission services to represent widely held opinions.

a) Consumers

Consumer organisations consider that there should not be any under-filling. Their preference is for a minimum filling of each pack. However, in the study consumers were not confronted with the consequence that this could cost more, i.e. the difference between the current average system and the minimum system. On the other hand, many packers of cheap products already

[39] W. Frankvoort, J. Hogendoorn, J. Rommerts: Business impact analysis on conformity assessment in prepackages, study for DG Enterprise, October 2003 (simultaneously published with this document)

fill up to well over the minimum because it is cheaper to overfill than to invest in more precise packaging machinery.

b) Packers

For packers a declaration of conformity by the packer without interference by a third party would be cheapest. However, less ardent controls by the competent authorities could lead to retailers fearing the consequences of non-law-abiding packers rebounding on them and over time it is probable that retailers will demand packers to install quality assurance mechanisms which are the most expensive in terms of investment in human resources.

c) Retailers

Retailers would not want the burden of conformity assessment to shift to them because this would increase their costs. Checks on the packer by a third party or the competent authorities exonerate retailers and give the best guarantee of quantities being correct.

d) Competent departments (authorities)

Competent departments are currently annually controlling 'good' packers and believe that the established system has proved to be efficient and effective, given the low level of complaints[40]. Intra- EU trade is controlled by the departments in the country where packing is done, so, in their view, the only grey area is imports from third countries.

5) Policy alternatives

Within the regulatory framework, possible policy alternatives lie mainly in the area of conformity assessment and enforcement. The objective is to make the EC legislation exhaustive, but within this context there are two alternatives.

a) Maintain current approach

Under the current approach conformity assessment is carried out by packer or importer and enforcement by the competent departments (=national authority). National authorities consider the system is to be efficient and there are few complaints, be it from packers, importers, consumers or other stakeholders. The system could be maintained as it is and be made total. However, a number of aspects enumerated above could be improved, e.g. scope, units, definitions, minimum filling, catch weighing and possibly other labelling issues.

b) Possible alternatives

The apparent cause of the success of the current approach is its emphasis on conformity assessment at the premises of the packers and importers. While this element should be maintained, it is conceivable to look for improvements to guarantee its continued good functioning in future.

There would seem to be three options for possible improvements of conformity assessment:

1. Third party verification should be possible by bodies other than competent departments and these could be authorised to operate beyond the national scale, which would lead to efficiency gains[41].

[40] As an example, 1 UK Competent Department carried out 88 tests in 2003/4 of which 7 (8%) failed the reference test. During these visits 2 problems relating to equipment and 14 relating to records were also detected.
[41] OIML D9 Principles of metrological supervision, 2004

2. The recognition of packers' procedures could be harmonised in order to promote a level playing field.
3. The use of automatic packaging machinery specified in the Measuring Instruments Directive could give a presumption of conformity.

c) Costs and benefits of the alternatives

In order to calculate the costs and benefits it is useful to define a methodology. The starting point is the current situation which is partly mapped out in the table below. Member states' authorities have been requested to check and add the relevant information for their country.

Table 1. Current situation of conformity assessment and enforcement (reference test, recognition of procedures, other checks) in member states, accession states, EEA states and Switzerland:

		recognition of procedures	**reference test**	**other checks**
packer	pays	CZ, DE, EE, FI, HU, NL, NO, SI (maybe in future), SE, SK	AT (if bad), CZ, DE, DK, FI, NO, SE, HU	DK, DE, HU
	free	AT, DK, MT, SI (now), UK	AT (if good), BE, BG, EE, FR, MT, NL, SI (if good), SK, UK	AT (if good), BE, BG, CH, CZ (if good), MT, SE, SI (if good) UK
retailer	gets refund for product	(not applicable)	AT (if good), BG (after complaint), DE, FI, HU (?), UK (if good)	AT, DE, HU (?)
	must supply product for free	(not applicable)	BE, CH, DK, EE (if bad), FI, FR, NL, SI (if good), UK (if bad)	BE, CH, DK, FI, NL, SE, SI

Source: *Oral communication by members of WELMEC WG 6 on 10 June 2004*

The costs of recognition of procedures may vary from zero to an hourly rate of over one hundred € and a maximum of €5,000, depending on the member state. Such differences, although less pronounced also exist for the reference test; which may cost up to € 1,000.

Stakeholders are requested to provide quantifications in order to allow the Commission services to evaluate the impacts of the policy alternatives.

6) Conclusions for comment

In this document the Commission services suggest a number of conclusions on which they invite stakeholders to give their comments.

As concerns the definitions:

- ‘quantity’ and ‘packaging’ should be defined in coherence with international standards
- ‘drained quantity’ and ‘liquid medium’ should be indicated separately
- ‘frozen products’ should be treated as ‘drained quantity’
- 'packer' and ‘importer’ can be defined as the person responsible for placing the package on the market.

As concerns the scope:

- scope of the directive should be increased from 0g (0ml) to 50k (50L)
- units, length and area could be included as units of measurement
- other claims (washes, burning hours, painted m^2) should be verifiable

As concerns the quantity requirements:

- the average filling for batches should be based on OIML and be made exhaustive
- current glass bottle regulation (Dir 75/107) must be made exhaustive
- individual filling according to the minimum filling must be added
- minimum filling of differently sized products (catchweighing) must be included
- tolerances should remain as they are, i.e. in line with international standards

As concerns labelling requirements:

- labelling of ‘minimum’ quantity to distinguish it from average filling
- if there is slack fill, percentage of filling needs to be labelled
- the quantity indication must be on the front of the package and at least 5mm high
- if part is offered for free, the total of the quantity of the package must be indicated
- address of the person placing the product on the EU market must be on the label
- ‘desiccating products’ should be labelled as such if desiccation can occur

As regards conformity assessment (manufacturers, packers, importers):

- responsibility for compliance lies with the person placing the package on the market
- packers’ procedures require verification by a third party
- a choice of national (non-harmonised) procedures should be available to packers
- current reference tests for automatically filled batches must remain mandatory and be performed at packers and importers premises for efficiency and effectiveness.
- procedures of conformity assessment should be harmonised
- third party verification outside the national borders should be possible
- the use of suitable legal measuring instruments gives presumption of conformity

As regards enforcement (national authorities, competent departments):

- enforcement should remain obligation for national authorities
- (shop) testing of 'minimum' minus the tolerance of a suitable instrument

An interactive policy making (IPM) survey is foreseen during the public consultation.

Annex 1: Metrological terms in EC directives and regulations

Identification of Directive	Description of the content of the Directive	Does the wording pre-package, pre-packaging, pre-packing packaging e-mark appear in this directive	Does the wording conformity assessment, metrological requirement, metrological control appear in this directive	Is there a reference to 75/106/EEC?	Is there a reference to 76/211/EEC?	Interpretation and comments on this Directive in relation to pre-packages
Directive 75/106/EEC	(making-up by volume of certain prepackaged products)	Yes	Yes	n. a.	no	Base document regulate wine, beer, spirits, milk, fruit juice, vinegar, oil, waters
Directive 76/211/EEC	(making-up by weight or by volume of certain prepackaged products)	Yes	Yes	Yes, article 1	n. a.	Base document additional to 75/106 for all other pre-packed products
Directive 2000/13/EC	(labeling, presentation and advertising of foodstuffs)	yes	no	no	no	No references
Regulation 1538/91	(marketing standards for poultry meat)	yes	no	no	yes	Poultry meat shall comply with the e-mark directive
Directive 94/62/EC	(packaging and packaging waste)	no	no	no	no	No relation with the e-mark field
Directive 75/324/EEC	(aerosol dispensers)	no	no	no	no	No relation with the e-mark field
Directive 73/437/EEC	Sugar for human consumption	yes	no	no	no	No relation with the e-mark field

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<u>Annex 1</u>: Metrological terms in EC directives and regulations (continued)

Identification of Directive	Description of the content of the Directive	Does the wording pre-package, pre-packaging, pre-packing packaging e-mark appear in this directive	Does the wording conformity assessment, metrological requirement, metrological control appear in this directive	Is there a reference to 75/106/EEC?	Is there a reference to 76/211/EEC?	Interpretation and comments on this Directive in relation to pre-packages
Directive 79/373/EEC	Compound feeding stuff	yes	no	no	no	No relation with the e-mark field
Directive 88/388/EEC	Flavourings for use in foodstuff	yes	no	no	no	No relation with the e-mark field
Directive 76/768/EEC	Cosmetic products	yes	no	no	no	Nominal content shall be stated
Directive 89/107/EEC	Additives for use in foodstuff	yes	no	no	no	Net quantity shall be stated
Directive 89/108/EEC	Quick frozen foodstuff	yes	no	no	no	Net quantity shall be stated
Regulation 2200/96	Fruits and vegetables	yes	no	no	no	The net weight shall be stated
Regulation 554/95	Description and presentation of sparkling wine	yes	no	no	no	No relation with the e-mark field
Regulation 3201/90	Description and presentation of wine	yes	no	no	no	no

Source: W. Frankvoort, J. Hogendoorn, J. Rommerts: Business impact analysis on conformity assessment in prepackages, study for DG Enterprise, October 2003