ORGALIME

Position Paper

Brussels, 25 June 2007

Proposal for a Decision of the European Parliament and of the Council on a common framework for the marketing of products COM(2007)53 final

Executive summary

Orgalime welcomes the draft Decision COM(2007) 53 on a common framework for the marketing of products. It sets up a model legislation based on the New Approach to technical harmonisation which we hope, in combination with the draft Regulation COM(2007) 37 on market surveillance and accreditation, will serve as a benchmark for all forthcoming changes that may affect product legislation. For the companies which Orgalime represents – engineering companies whose total output in 2006 was estimated at 1779 billion euros (27% of the EU manufacturing output) - product legislation based on the "New Approach" is the core legislation regulating our products.

The New Approach legislation has successfully been applied to millions of engineering products for more than 20 years and has been instrumental in the success of the EU internal market with its key benefits: free movement of products and a high level of safety for both consumers and workers everywhere in Europe. In our view, the Decision therefore constitutes a step forward to simplify the increasingly complex legal environment of European engineering manufacturers.

We particularly welcome the broad scope which addresses all product related aspects of Community interests, i.e. not only health and safety, but also environmental protection, energy efficiency, worker or consumer protection, etc... In the face of globalisation, we are pleased to see the rebalancing of manufacturers' obligations with those of other market operators, such as the importer.

Although we believe that it would have been simpler to incorporate a common framework in the Regulation (rather than in a Regulation and a Decision), directly applicable without deviations by all Member States, we are confident that this model legislation will serve as a standard for all planned and other possible upcoming changes that may affect existing product legislation.

While we support the text as a whole, we provide hereafter suggestions of improvement on some provisions, which mostly aim at ensuring that conformity assessment requirements will remain as simple and as clear to understand as possible by companies, especially SMEs, and by authorities. We believe it is important to minimise bureaucratic requirements that only impede the competitiveness of our companies, without providing any additional protection to consumers or workers arising from the placing on the market of unfairly traded products which are not in conformity with EU regulation.

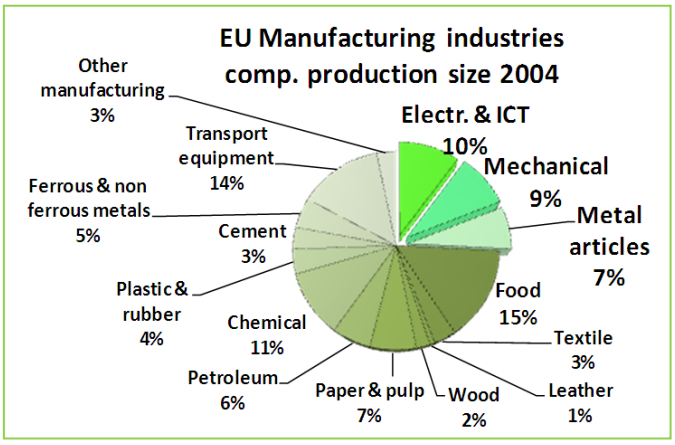
Orgalime, the European Engineering Industries Association, speaks for 35 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.6 million people in the EU and in 2006 accounted for some €1,779 billion of annual output. The industry not only represents more than one quarter of the output of manufactured products but also a third of the manufactured exports of the European Union.

www.orgalime.org

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

The engineering industry supplies one quarter of EU products

The engineering industries are the enabling industries: they provide the technology, equipment and services for all industry and service sectors. Our clients include: our suppliers - the energy and primary transformation industries; the transport industry - the automotive, aeronautics and rail equipment producers; all the process industries - agro-industry and food industry in general, the chemical, petrochemical and plastics industries; consumers in the form of ICT products and household appliances; our own industry, our principal client.



The engineering industries are also the suppliers of the equipment and technology for the health, social and leisure sectors and for the area of the environment: water, wastewater, air treatment etc. equipment which are essential to the creation and maintenance of a safer environment.

And if capital goods are the main engineering products, a large part of what our industry manufactures is destined to the consumer market: household appliances, telephony equipment, electrical and consumer electronics products.

In brief the engineering industries are at the core of Europe's industrial fabric: all other production and service sectors depend on the equipment, technology and innovations of our industry to flourish and to develop.

The New Approach to technical harmonisation has an over 20-year record of successes in meeting EU requirements

All stakeholders have an interest in ensuring that products placed on the Internal Market comply fully with the essential requirements of all applicable Community legislation. The principles of the New Approach legislation which provide for CE marking are based on confidence: confidence that manufacturers are only placing compliant products on the market and confidence that authorities fulfil their task of ensuring efficient market surveillance.

The overwhelming majority of engineering products is covered by harmonised legislation under the New Approach, such as the directives on machine safety, the low voltage (electrical safety), electromagnetic compatibility, etc.. Around 80% of these products are intended for professional users while the remaining 20% are intended for household use and are covered by the General Product Safety Directive which provides a complementary protection for consumers. Over the past years, the New Approach has brought many significant benefits for the development of the Internal Market while ensuring a high level of safety for both professional users (workers) and consumers.

We are confident that the common definitions and standards articles provided in this draft model legislation will further contribute to meet this objective. We provide hereafter suggestions of improvement on some provisions, which mostly aim at ensuring that conformity assessment

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

requirements will remain as simple and clear to understand as possible by companies, especially SMEs.

Areas of possible improvement

On Article 1 - Scope

Orgalime supports the use of a broad scope which addresses all aspect of Community interests, i.e. not only health and safety, but also environment protection, energy efficiency, worker or consumer protection, etc... Having well-known and similar procedures for all product-related aspects covered by Community measures will certainly help manufacturers to fulfil their legal obligations when designing, testing and manufacturing their products. It will also effectively enact better regulation by providing simple and standardised procedures.

On Article 3.1 - Manufacturers should have the choice between product conformity assessment procedures

The wording of Indent "(c)" refers to an alternative between "quality assurance" and "product certification". Because certification usually refers to the involvement of a notified body, such wording is misleading as it seems to set out a restrictive alternative that exclude the possibility for the manufacturer to choose, where the legislation allows, it the route of internal production control (module "A") that does not require the involvement of a notified body.

On Article 3.2 - Conformity assessment procedures

Orgalime supports bringing coherence in the procedures of conformity assessment to various aspects of Community legislation (safety, environment protection, energy efficiency...), which apply to the same product. However, it should be made clear that coherence of the "conformity assessment procedures" of the different directives should not be ensured by all means, regardless of the risks covered by the legislation, as it might lead to imposing procedures which are not proportionate to the product requirements. Therefore, in the effort of aligning the conformity assessment procedures of different Community legislation, legislators should avoid imposing unnecessarily modules (as set out in Annex I).

Consequently, we suggest making a reference to Article 3.1 indent "(d)" which recalls the principle of proportionality in applying the criteria for the choice of the most relevant conformity assessment modules.

On Article 4 - EC declaration of conformity

Simplicity in conformity assessment means "one product; one EC declaration of conformity", even if the product is covered by more than one directive. If the "EC declaration of conformity" contains all relevant information to identify the Community regulation to which it relates, it would be burdensome for the manufacturer to mention the "publication references of the acts concerned" and could lead to confusion: such reference varies from one to another Member State, depending of national laws. If it is up to manufacturers to know which Community legislation applies to their products, it is up to national enforcement authorities to know which national legal provisions transpose the Community legislation.

On Chapter 1 – Definitions

On Article 6 – Definitions

One should take into account that any product is more and more subject to a range of different directives each of which have their own scope and obligations, for example: environmental conscious design, product safety, waste disposal, proof of conformity, contact point for the authorities, reporting of unsafe products… Over the years, different definitions have been used to

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

address the same concepts in different product legislation. This is causing confusion for stakeholders, especially when different directives apply to the same product.

Therefore, Orgalime supports the introduction of common definitions for all New Approach and other EU product directives in order to convey the same understanding of the concepts that trigger obligations for the various market operators throughout the supply chain (design, manufacturing, import, distribution, installation, use, maintenance and disposal). We believe that these common definitions will provide more consistency across the board in the regulatory framework and will facilitate the application and enforcement of applicable EU legislation.

Furthermore, in order to make sure that the conformity assessment system which is proposed in the Decision COM(2007)53 is understood at international level, we feel it necessary to insert additional definitions for "*conformity assessment*", "*conformity assessment body*", "*designation*", "*notification*", "*notified body*" and "*national accreditation body*" and to apply these definitions consistently throughout the provisions of the text, as was initially intended by the Commission (Cf. Working paper SOGS 560-1 of 6 September 2006).

We believe that the definition of "*authorised representative*" should be introduced as well because the definition of "economic operator" refers to it.

The definition of "*CE marking*" should be set out in order to clarify its meaning and significance as to symbolize the single conformity marking of a product with the levels of protection of collective interests imposed by Community law. We strongly recommend to use the definition provided by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives - Official Journal L 220, 30/08/1993 P. 0023 – 0039.

On Chapter 2 – Orgalime welcomes the rebalancing of obligations between all market operators

Over the past 20 years, the New Approach directives contributed to remove internal barriers to trade, while ensuring a high level of safety and equity before EU law for all. Nowadays, the situation has been almost completely inverted with the globalisation of both markets and manufacturing processes: about 40% of all engineering goods are manufactured outside the EU and imported: as such compliance to any conformity assessment procedure, with or without the assistance of notified bodies, which apply to the products or their manufacturing processes are out of control from Member Sates authorities. Therefore, Orgalime welcomes the proportionate rebalancing of obligations between all market operators according to their respective role in the supply chain as set out in Chapter II of the Decision:

- *manufacturers* to design safe and otherwise compliant products to all EU requirements (health and safety of both consumers and workers, environment protection, energy efficiency requirements etc...)
- *importers* to verify that the product was intended for the EU market and accordingly designed to meet all EU requirements
- *distributors* to facilitate the task of market surveillance authorities in tracing back the original manufacturer, authorised representative or importer of the product.

Orgalime has however some suggestions for improvement to the draft provisions, mostly to ensure proportionality and effectiveness of the proposed model legislation, especially bearing in mind that

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

conformity assessment provisions should remain clear, simple and easy to apply for manufacturers, the overwhelming majority of which are SMEs less than 10 employees.

On article 7: Obligations of manufacturers: proportionality should prevail

The natural or legal person having affixed or been responsible for the affixing of the CE marking should verify that the product conforms to all the Community provisions which apply to it and has been the subject of the appropriate conformity assessment procedures before placing the product on the market. Any supplementary requirement that would require manufacturers to carry out tests or keep registers on products already placed on the market, places a disproportionate administrative burden on businesses, especially SMEs, without any added value as regards compliance of products placed on the market. Therefore, Orgalime suggests deleting the last sentence of Article 7 paragraph 4, since this requirement imposes a disproportionate burden on the manufacturer to monitor the market after having placed the product on the market. This sentence takes up a requirement from the General Product Safety Directive (GPSD) that provides additional protection for consumers. Consumer products represent about 20% only of engineering products placed every year on the market. For the remaining 80% of professional products concerned, the proposed model legislation enshrined in the present draft Decision will restrict the freedom of contract which regulates customer relationships between businesses; manufacturers and their professional customers.

Orgalime supports enhanced traceability of the product placed on the market, provided that it does not add administrative burden to lawful market operators without providing a corresponding assurance of an efficient control by authorities: otherwise it becomes a new hurdle for the competitiveness of lawful manufacturers in the face of unfair trade practices. For instance it seems to us disproportionate to request the affixing of the address of the manufacturer on the product itself, as required in Article 7.6. In our view it would be more proportionate and efficient to request any relevant information on means to reach the manufacturer and/or his authorised representative in the accompanying documentation (such as e-mail addresses, web-links, phone numbers etc).

Similarly, Orgalime believe that the requirement in the 2nd sentence of Article 7, paragraph 7 is taken from the General Product Safety Directive (GPSD) and applies to safety aspects of consumer products, in order to provide an adequate protection to un-informed customers. Extending the significance of this requirement for all aspects of public interest to all professional products would be disproportionate, especially for SMEs.

On Article 9 – Obligations of importers. Proportionality should prevail

Article 9, paragraph 3 requires importers to put their name and address on the product. This requirement is disproportionately burdensome and costly as it would imply that the importer obtains from the manufacturer that he should affix his name on the product (on top of the manufacturer's own address as required by Article 7 paragraph 6). Otherwise the importer would have to open all product packages in order to affix his name and address on the product. Besides, this requirement leads to several undesirable legal consequences:

- It would automatically and disproportionately assimilate any importer as a manufacturer in line with '*Whereas n°18*' which provides that "*where an importer or a distributor either places a product on the market under his own name or trademark ... should be considered to be the manufacturer*".
- Consequently it leads to confusion as regard to the designation of the person liable for the product and the person who owns the trade mark.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

- Finally, it challenges the validity of any guarantees related to damages arising from transportation after the product has been manipulated in order to be re-packaged by an external party.

Therefore, Orgalime believes it sufficient that the information needed for traceability is put into the documentation or the packaging.

On Articles 10(2), 10(4) and 11 on the obligations of distributors

ORGALIME is committed to provide further assistance in the drafting of an application guide that will further clarify how the provisions of the abovementioned articles can function in practice.

On Article 12 – Identification of economic operators

Orgalime supports obligations for identifying economic operators throughout the supply chain according to the proportionality principle. Therefore, Article 12 should clearly refer to the period during which products are made available on the EU market only, in order to avoid any unnecessary costly and burdensome requirements on lawful manufacturers to endlessly supply the same information to all points up and down the supply chain, while rogue traders would in any case vanish from the market and evade such a provision.

In particular, Orgalime requests the deletion of the second paragraph of the proposed Article which appears superfluous as economic operators already need to keep this information available for taxation purposes. In addition, it could lead some Member States to require economic operators to undergo unnecessary and costly certified management systems that may be specifically set up in response to this unnecessary requirement.

On Chapter 3 on conformity of the product

On Article 13 – Presumption of conformity

Orgalime believes that European harmonised standards together with the New Approach are an excellent regulatory tool, which has efficiently supported the development of the European single market. By developing objective oriented legislation, which sets essential requirements to be fulfilled, but leaves it to experts to determine how these can be achieved at the level of products through standards, the Community has provided a flexible regulatory framework. We therefore very much welcome the endorsement of this positive experience in Article 13, which extends the principle of presumption of conformity to EU legislation for all products that would be manufactured in conformity with available harmonised standards.

Article 14 – Formal objection against harmonised standards

Under New Approach legislation, harmonised standards are used as a voluntary tool in support to EU legislation. They are drafted by the European standardisation organisations, CEN, CENELEC and ETSI, under the scrutiny of Member States representatives and of a consultant of the European Commission. They reflect the current state of the art. As such standards are the result of a democratic process and serve to relieve the legislator of the need to focus unnecessarily on drafting complex and detailed technical legislation which may soon be outdated due to rapid technological progress. This supports the objectives of better and simpler legislation. Through standardisation mandates, the European Commission often requests CEN, CENELEC and ETSI to make new standards in support to EU legislation or to revise existing standards, after discussion with Member Sates representatives under the Comitology procedure.

Since harmonised standards have successfully been used as a co-regulatory tool for more than 20 years, it appears both logical and consistent with better regulation principles to request under Article 14 an opinion from European standardisation organisations first, before challenging their standards.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

On Article 15 – EC declaration of conformity

Orgalime believes that it is not logical to request the EC declaration of conformity to be ''updated continuously, as set out under Article 15.A declaration of conformity is drawn up before the product is placed on the market and specifies the provision (directive or standards) applied to the specific product. Thus it cannot be updated 'continuously'. In the case of series production the declaration of conformity shall be updated for new series of products when the state of the art has changed, and has lead to modifications to the design of the product or the use of other standards.

As the declaration of conformity is increasingly used worldwide, i.e. also by countries outside of EU, manufacturers should be allowed to draft their declaration of conformity according to the model provided by international Standard ISO 17050-1, as long as the information required by EU legislation is included in the declaration. Orgalime would also favour a statement in Article 15 that the EC declaration of conformity shall be issued in one of the community languages at the manufacturer's choice, as it is currently the case in most New Approach directives.

On Article 16 - General principles of the CE marking

Orgalime supports the text of Article 16 on the general principles of the CE marking, which strive for an enforced and informed use of the CE marking by all market operators including importers into the EU. However, we miss a definition that could be introduced under Article 6 (see above). **Orgalime does not support abolishing the CE marking**, as suggested by some other stakeholders on the ground that "consumers are confused by the multitude of different markings and often do not use the informative value of the CE marking as a basis for their choice" (Cf. Impact assessment SEC(2007) 173). What is confusing to consumers is not the presence or absence of the CE marking itself, but the profusion of private or public marks promoted by certification bodies and various other compliance schemes.

In our view, it is crucial to make clear to all market operators as well as to users that the CE marking is and should remain the only visible symbol of declaration of conformity to EU legislation applying to a product thereby concluding a whole process of internal production controls and conformity assessment conducted under the legal responsibility of the manufacturer. We believe that it is the responsibility of Member Sates to carry out information campaigns that would target at importers, retailers, consumer and professional organisations, because they are the best channels to convey the message to professional users or consumers.

We see the corresponding provision of draft Regulation COM(2007) 37 on market surveillance and accreditation, as complementary in order to fight unlawful market operators that do not respect the significance of the CE marking when placing non-compliant products on the EU market.

On Article 26 – Application for notification

In relation with our position paper on accreditation in the context of draft Regulation COM(2007)37 on market surveillance and accreditation, Orgalime would like to stress that national accreditation bodies should have successfully undergone peer evaluation in order to be able to attesting that the conformity assessment body meets the requirements laid down in Articles …[22] and [24].

One of the fundamental objectives pursued by the review of New Approach is the strengthening of the regime for the notified bodies in order to ensure that all notified bodies perform their tasks to the same levels and to increase mutual confidence between the Member States (cf. Council Resolution on the review of the New Approach of 10 November 2003). The main instrument to achieve this has been to give accreditation a strong referential position with regard to other means of competence assessment applied by the national authorities. However, accreditation practices vary considerably among Member States, which is why it has been proposed that the European co-operation for Accreditation (EA) should play a key role for the harmonisation of these practices through the operation of its well-established peer evaluation system.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

Orgalime therefore believes that the intended referential position for accreditation can only be justified if the national accreditation body has demonstrated its competence through successful participation in the peer evaluation system as foreseen under the proposed Regulation, thus ensuring transparency and consistency of its operations in order to create the necessary level of trust in the notifications that are based on its accreditations.

On Chapter 5 – Safeguard procedures, Article 35 – Procedure to deal with products presenting a risk at national level

Orgalime believes that the suggested procedure under Article 35 fails to take into account the cases where the manufacturer/economic operator and the market surveillance authorities disagree about a case of non-compliance or on its nature. The manufacturer/economic operator who has strong evidences to believe that the product is compliant may refuse to take corrective actions such as those referred to in Article 35 paragraph 1. This is also why any measures taken by the authorities according to Article 35 paragraph 4 are *provisional*, awaiting the final results of the evaluation. The fact that the economic operator objects to taking corrective actions and the reasons for it should be brought to the attention of the Commission and the other Member States. They should know that there is a disagreement about a case of non-compliance because the absence of their objection will entail the qualification of the restricting measure as being justified according to Article 35 paragraph 7. Consequently, Orgalime believes that it is paramount to ensure the right of defence in such a case and to enable the manufacturer/economic operator to raise his viewpoint to the attention of the other Member States and the Commission.

On Annex I – Conformity assessment procedures

Orgalime is missing important "explanatory notes" which were envisaged by the European Commission at an earlier stage of preparation of this legislative package (cf. Working paper SOGS N560-2 of 06/09/2007). Such explanatory notes should be re-introduced in Annex I of the Decision. These notes provide important and useful statements on (a) the conditions for the affixing of the CE marking, (b) the scope of the declaration of conformity, (c) the use of the modules, (d) the equivalence between the definition of manufacturer in the present Decision and the notion of supplier used in relevant international standards and finally (e) the use of international quality management standards (such as ISO 9001:2000) and presumption of conformity to quality assurance requirements in the EU legislation. These notes provide important and useful statements that should be taken into consideration for any upcoming legislative changes of existing EU product legislation.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438