ORGALIME Position

on the Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS 2007/0029 (COD)

20 April 2007

Introduction

Orgalime welcomes this proposal of Regulation on accreditation and market surveillance and the closely related Decision on the common framework for the marketing of products: they are a further step towards to improving public trust in the internal market, which is key to both consumer confidence in the products they buy and to the confidence that companies should be entitled to have that they operating in a level playing field for manufacturing and placing their products on the EU market.

While mutual recognition is about building trust among Member States in each other's proficiency to control the market, full harmonisation is about achieving the trust of economic operators, their customers and public authorities on the basis of a common and efficient framework. Market surveillance is important not only for protecting health, safety or the environment, but also for ensuring a level playing field between manufacturers and other economic operators placing products on the EU single market.

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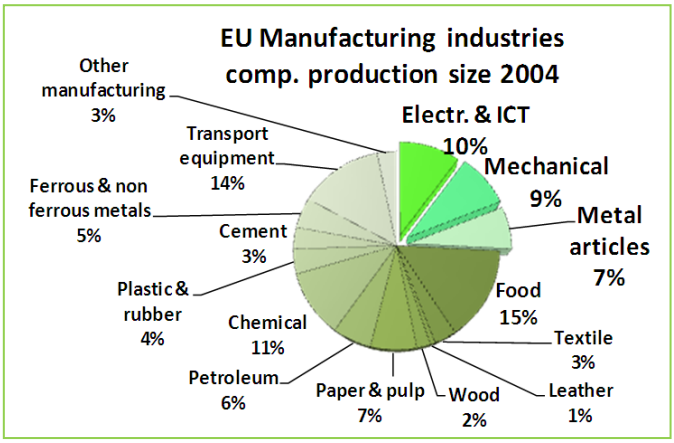
The engineering industry supplies one quarter of EU products and is the main sector concerned by this framework

Orgalime, the European Engineering Industries Association, speaks for 36 trade federations representing some 130,000 companies in the mechanical, electrical, electronic and metalworking industries of 24 European countries. The industry employs some **10.6 million people** in the EU and in 2006 accounted for an estimated **€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. It is an industry which, with an estimated growth of 6.6% in output in 2006, has been able to provide some 0.5% more jobs in 2006.

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, systems and innovations of our industry to flourish and to develop.

The engineering industries are also the main industry regulated under the New Approach: out of 28 New Approach directives or based on New Approach principles, 20 regulate engineering products (Cf Annex II, p.64 of the Impact Assessment SEC(2007)173/2 accompanying the proposal). The terms of the proposed Regulation and Decision are therefore of vital importance to the continued competitiveness of our industry both on the internal and on our export markets.

Towards improved marketing conditions of engineering products

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... the conformity assessment of which is evidenced by the CE marking. A significant part of our products that are intended for household use is also covered by the General Product Safety Directive. The New Approach has brought many significant benefits for the development of the Internal Market while ensuring a high level of product safety for both professional users (workers) and consumers. However the high level of safety achieved so far can only be sustained if market surveillance performs well in its task of preventing the placing on the market of non-compliant products.

We believe that the New Approach is an excellent regulatory tool, which has efficiently supported the development of the European single market. By developing objective oriented legislation, setting essential requirements to be fulfilled and leaving experts determine how best these can be achieved at the level of products through standards, the Community has provided a flexible regulatory framework. The approach has provided both an improvement of the health and safety of users (consumers and workers) and a boost to the competitiveness of the European

engineering industry. It has enabled our industry to establish a strong home base on the internal market providing for growth and jobs, while strengthening its capacity to operate on world markets. The New Approach is therefore, in our opinion, one of the cornerstones of achieving the Lisbon objectives.[1]

This draft Regulation is in line with the better regulation principles

The achievement of a greater degree of regulatory stability and simpler legislation would facilitate the task of the many SMEs in our industry which are finding it increasingly difficult to cope with the ever increasing and complex body of legislation.

We welcome especially:

- Common definitions and balanced obligations between economic operators
- Alignment of market surveillance between member states
- Improved information exchange among authorities and with economic operators
- Applicable to all policy areas (not only consumer health and safety, but also health and safety at the work place, environment protection, etc...)
- Improved cross EU-border controls

We believe that proper enforcement of legislation is crucial to ensure both an adequate level of protection for final users and a level playing field among economic operators.

Areas of possible improvement

Common definitions will contribute to consistent and facilitated compliance (Chapter I)

One should take into account that any product is more and more subject to a range of different directives which each have their own scope and obligations, for example: environmental conscious design, product safety, product liability, waste disposal, energy efficiency… Over the years, different definitions have been used to 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. We believe that they will provide more consistency in the regulatory framework and should facilitate the application and enforcement of such directives. However, in order to make sure that the conformity assessment system which is proposed in the Decision COM(2007)53 will be understood at international level, we feel it necessary to insert definitions for conformity assessment, conformity assessment body, designation and notification, as it was initially intended by the Commission in its open consultation on the review of the New Approach (Cf. Working paper SOGS 560-1).

On accreditation (Chapter II)

The purpose of accreditation is to provide an authoritative statement of the competence of a body that performs calibration as well as testing, certification, inspection and other conformity assessment activities. Accreditation is *the* fundamental instrument to provide confidence in the competence, impartiality and capabilities of bodies which carry out conformity assessment and in the conformity assessment results such as certificates and test reports issued by those bodies. In order to support the credibility of its products and therefore its competitiveness, industry needs an efficient and properly functioning European accreditation system that ensures the global acceptance of conformity assessment results and avoids any unnecessary duplication of assessments as far as possible.

[1] Orgalime position paper on "The Future of the New Approach" of 29/03/2002

Therefore Orgalime agrees that accreditation should be a system that operates under the authority and the responsibility of the public authorities. As such, accreditation should not be a matter for commercial competition, since if this were so, one would require yet another layer of control of the competence of these accreditation bodies. However in order to ensure a consistently high standard of accreditation, peer evaluation of accreditation bodies should be the norm.

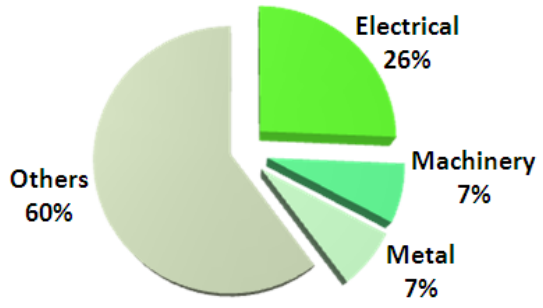
On market surveillance (Chapter III)

In its position paper of 09/10/2005, Orgalime called on for comprehensive and efficient market surveillance by Member States' authorities, in order to avoid that the European market becomes a preferred market place for free riders. We consequently welcome the provision of the regulation for ensuring an equivalent and consistent enforcement of Community harmonisation legislation, including cross-border cooperation between Member States authorities.

The scope of the Regulation should not exclude consumer products (Chapter III)

In this respect, Orgalime does not support the exclusion from the scope of market surveillance activities of products intended for consumers which are covered by the General Product Safety directive (Article 13.2). As there are countless products which may be suitable both for consumer and professional use, we fear that such an exclusion will lead to unclear procedures and responsibilities for the marketing of products. Since the important elements of GPSD have been brought into this instrument, a high level of protection is ensured. Besides, Orgalime does not foresee any conflict between the Regulation provisions and those of GPSD.

On controls of products entering the community market (Chapter III, Section III, Article 24):



Source: Europanorama (data 1995-2005)

"75%-80% of the safeguard clauses submitted to DG ENTR in 2005 were about products imported from third countries". "Approximatively 50% of products have a certification mark from an organisation that is also a notified body".
Source: Impact assessment study of COM(2007)37 and COM(2007)53, Annex III, Table 3.

Globalisation makes it difficult to determine how and by whom a product is manufactured and imports from third countries are growing faster than domestic production, while the effectiveness of controls at the borders of the EU and in the internal market are diminishing if only by the increased volume of transactions on an enlarged internal market. Therefore, we welcome Article 24 which requires customs authorities to perform in close co-operation with market surveillance authorities appropriate checks on a product before it is released for free circulation on the Community market. These controls should not be carried out outside the required cooperation between national market surveillance and the customs authorities, as it may lead to a costly duplication of control procedures.

You will find hereafter some specific comments and proposals for the formulation of some provisions which we believe would help to make the proposed Regulation easier to apply and clearer for the many users of this future community legislation. These are specified hereafter.

Preamble - Scope

First Recital

Regulation 2007/0029 (COD)	**Proposed Amendment**
(1) For the purpose of strengthening the overall framework ensuring that products respect a high level of protection of public interests, such as health and safety, it is necessary to establish certain rules and principles in relation to accreditation and market surveillance, which are important aspects of that framework.	*(1) For the purpose of strengthening the overall framework ensuring that products respect a high level of protection of public interests, such as health and safety* ***or the protection of the environment****, it is necessary to establish certain rules and principles in relation to accreditation and market surveillance, which are important aspects of that framework.*

Justification

In line with the Article 1 paragraph 1 on "subject matter and scope", Orgalime suggests to introduce a clear reference to the protection of the environment. Over the past few years EU environmental legislation has become increasingly complex; conformity assessment procedures in this area are becoming increasingly costly for EU manufacturers. Therefore it also important to make sure that all cases of non conformity to EU legislation, including especially in the environment field, should be adequately dealt with.

CHAPTER II - Accreditation

Article 1.1 – Subject matter and scope (all accreditation activities)

Regulation 2007/0029 (COD)	Proposed Amendment
1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, to be placed on the Community market. It also provides a framework for market surveillance and the control of products from third countries to ensure that substances, preparations and transformed products subject to Community legislation harmonising the conditions for the marketing of products, hereinafter "Community harmonisation legislation" respect a high level of protection of public interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security.	*1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies,* ***test and calibration laboratories,*** *performing assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, to be placed on the Community market,* ***irrespective of whether such accreditation is provided to support regulatory or non-regulatory conformity assessment.*** *It also provides a framework for market surveillance and the control of products from third countries to ensure that substances, preparations and transformed products subject to Community legislation harmonising the conditions for the marketing of products, hereinafter "Community harmonisation legislation" respect a high level of protection of public interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security.*

Justification

Recital 9 states that the binding rules will contribute to enhancing the principle of mutual recognition of certificates and test reports. Therefore the provisions on accreditation in the Regulation should apply to bodies carrying out conformity assessment and other activities that can be subject to accreditation in both the regulated and non-regulated areas. Orgalime stresses the importance of this issue and supports the statement.

Therefore, we suggest that the subject matter and scope (article 1.1) be broadened accordingly, in order to cover all activities undertaken by accredited bodies in both the regulated and non-regulated areas.

CHAPTER II - Accreditation

Article 2 – Definitions

Regulation 2007/0029 (COD)	Proposed Amendment
	(14) "Conformity assessment" means the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled."
	(15) "Conformity assessment body" means a body that performs conformity assessment services.

Justification

In order to make sure that the conformity assessment system, as set out by both the proposed Regulation COM(2007)37 and the Decision COM(2007)53, will be understood at international level, we feel it necessary to insert definitions for conformity assessment and conformity assessment body, as it was initially intended by the Commission in its open consultation on the review of the New Approach (Cf. Working paper SOGS N529 rev.2).

CHAPTER II - Accreditation

Article 3.1 – Scope (all accreditation activities)

Regulation 2007/0029 (COD)	Proposed Amendment
1. Where accreditation is used on a compulsory or voluntary basis to assess the competence of conformity assessment bodies to carry out conformity assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, this Chapter shall apply, irrespective of the legal status of the body performing the accreditation.	*1. Where accreditation is used* ***~~on a compulsory or voluntary basis~~*** *to assess the competence of conformity assessment bodies to carry out conformity assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, this Chapter shall apply, irrespective of the legal status of the body performing the accreditation,* ***and irrespective of whether such accreditation is provided to support regulatory or non-regulatory conformity assessment.***

Justification

This is similar to the change requested for in Article 1.1, which refers to Recital 9 in order to cover all activities undertaken by accredited conformity assessment bodies in both the regulated and non-regulated areas.
As the last level of authority control of the whole conformity assessment system, accreditation should provide equal assurance to both economic operators and public authorities that accredited conformity assessment bodies are competent to carry out their tasks, irrespective of whether such tasks are required by legislation or not. Any distinction, at the level of accreditation, between whether requirements are contained in legislation or set by customers in the context of a commercial relationship would lead to costly and unnecessary duplication of assessments and procedures, because customer requirements often already contain, anticipate or even go beyond the requirements laid down by legislation. In many other cases the implementation of EU legislation relies on procedures applied for the assessment of conformity with "voluntary" requirements.

In order to ensure that the proposed European accreditation system is understandable at international level and compatible with international practice, Orgalime believes that only such competence assessment should be covered as “accreditation” which is based on the use of the recognised standards. Such a restriction is also necessary in order to distinguish the scope of the Regulation from more general uses of “accreditation”.

CHAPTER II - Accreditation

Article 4 – General principles
Paragraph 8 (mandatory EA membership)

Regulation 2007/0029 (COD)	Proposed Amendment
8. The national accreditation body shall seek membership of European co-operation for Accreditation (EA).	*8. The national accreditation body shall* ***~~seek membership~~*** ***become member*** *of, the European co-operation for Accreditation (EA)* ***and should be a signatory to the relevant part(s) of the multilateral agreement (MLA) operated by EA****.*

Justification

In order to stress the importance of respecting the mutual recognition principle, Orgalime believes that it is necessary to establish a clear legal basis for a co-operative European accreditation system, of which all national accreditation bodies should be members. Confidence in the competence of bodies performing conformity assessment is essential, but equally so is confidence in the competence of those bodies that assess conformity assessment bodies. Mutual confidence in the certificates and other conformity assessment results issued anywhere in the internal market can only be strengthened through a properly functioning accreditation system which aims at ensuring equivalence, transparency, consistency and efficiency of the accreditation performed across Europe. In view of the role played by accreditation in support of Community legislation, it is also for the Member States to take responsibility for, and support, the proper functioning of the European accreditation system. Given the positive experience with the peer evaluation system operated by EA and the fact that this system *de facto* already today operates in support of the regulatory field, Orgalime supports the proposal that EA's role should be consolidated to formally entrust EA with the operation of the European accreditation network.

EA membership does not imply the obligation for national accreditation bodies to participate in peer evaluation, which is however the key instrument to achieve equivalence, transparency and consistency of accreditation practice. Orgalime therefore believes that the peer evaluation system should be organised at European level and operated according to the harmonised rules as applied within EA.

Beyond conveying assurance of compliance with the requirements for national accreditation bodies, peer evaluation has also a wider role to play for the strengthening of the respect of the principle of mutual recognition of test results. Orgalime therefore feels that it is necessary for the effect of the peer evaluation to be clarified and suggests that this should be included in the text.

CHAPTER II - Accreditation

Article 9 – Peer evaluation
Paragraph 4 (mandatory EA membership)

Regulation 2007/0029 (COD)	Proposed Amendment
4. The peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 7.	*4. The peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 7.* ***National accreditation bodies that have successfully undergone peer evaluation shall recognise the reliability of accreditations carried out by other national accreditation bodies and also of the conformity assessment results issued by conformity assessment bodies accredited by other national accreditation bodies.***

Justification

European Accreditation (EA) membership does not imply the obligation for national accreditation bodies to participate in peer evaluation, which is the key instrument to achieve equivalence, transparency and consistency of accreditation practice. Orgalime therefore believes that the peer evaluation system should be organised at European level and operated according to the harmonised rules as applied within EA.

Beyond conveying assurance of compliance with the requirements for national accreditation bodies, the peer evaluation system also has a wider role to play in strengthening the respect of the mutual recognition principle. Orgalime therefore believes that it is necessary to clarify the significance of peer evaluation.

CHAPTER III - community market surveillance framework and controls of products entering the community market

Section 1 – General provisions, Article 13 – Scope
Paragraph 2

Regulation 2007/0029 (COD)	Proposed Amendment
2. Articles 14 to 23 shall not apply to products as defined in Article 2(a) of Directive 2001/95/EC in so far as the health or safety of consumers is concerned.	***To be deleted***

Justification

This exemption should be deleted. Otherwise, the scope of the framework on market surveillance would be inconsistent since some authorities might apply the rules for consumer products as provided under Directive 2001/95/EC on General Product Safety (GPSD), while other authorities might use the rules of the present Regulation for the same kind of product. The borderline between products for consumer use and for professional use is blurred, and we fear that such an exclusion will lead to unclear procedures and responsibilities for the marketing of products. Since the important elements of GPSD have been brought into this draft Regulation, a high level of protection is ensured. Besides, Orgalime does not foresee any conflict between the provisions of the draft Regulation and those of the GPSD, which could both apply in a complementary manner.

Section 2 – Community market surveillance network , Article 16 on Obligations of the Member States as regards organisation, Paragraph 2

Regulation 2007/0029 (COD)	Proposed Amendment
2. Member States shall establish adequate procedures in order to follow-up complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues.	*2. Member States shall establish adequate procedures in order to follow-up complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues.* ***Member states shall establish adequate procedures in order to verify that corrective actions have been effectively carried out.***

Justification

It is Orgalime's experience that measures taken by authorities such as a ban on non-compliant products are rarely followed up by controls, whether the market operator concerned has effectively removed the products from the market or taken the necessary correctives measures in order to be in conformity with the law. This situation is threatening consumer confidence and the competitiveness of economic operators who respect community legislation. Therefore market surveillance should also ensure a concrete follow-up of corrective actions in the market place.

CHAPTER III - community market surveillance framework and controls of products entering the community market

Section 2 – Community market surveillance framework
Article 17 on market surveillance measures, Paragraph 1

Regulation 2007/0029 (COD)	Proposed Amendment
1. The market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, through documentary, and, where appropriate, physical and laboratory checks on the basis of representative samples. The authorities shall be entitled to require economic operators to make available such documentation and information as appear to them to be necessary for the purposes of Article 14. They shall also be entitled to enter the premises of the economic operators concerned where it appears to them to be necessary for the purposes of Article 14.	*1. The market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, through documentary, and, where appropriate, physical and laboratory checks on the basis of representative samples. The authorities shall be entitled to require economic operators to make available such documentation and information as appear to them to be necessary for the purposes of Article 14.* ***The authorities shall be entitled to seize samples of a product which they expect to be rapidly sold out.*** *They shall also be entitled to enter the premises of the economic operators concerned where it appears to them to be necessary for the purposes of Article 14.*

Justification

Market surveillance speed should be adapted to the speed of sales of batches of often inexpensive components or consumer products: these are often rapidly sold-out in a distributor's promotional sale. It is our experience that once products are placed on the market, delays between complaints and action by market surveillance authorities often lead to the situation where authorities are not in a position to carry out checks, as the products have been already sold . This is particularly the case for promotional or seasonal sales of consumer products, such as Christmas lighting. It happens also for small electrical components such as electrical controls, switchgears or small measuring instruments. Therefore, when customs authorities have a serious reason to believe that the imported product may not be in compliance with all EU requirements, they should be entitled to seize samples of the product in order to speed up the control by market surveillance authorities and ensure possible legal action against the importer or the manufacturer's authorised representative in case of characterised default of compliance with EU legislation.

Section 3 – Control of products entering the Community market, Article 24, Paragraph 1

Regulation 2007/0029 (COD)	Proposed Amendment
1. Member States shall ensure that their customs authorities perform or have performed appropriate checks on the characteristics of a product on an adequate scale before it is released for free circulation.	*1. Member States shall ensure that their customs authorities perform or have performed appropriate checks on the characteristics of a product on an adequate scale before it is released for free circulation.* ***Member States shall ensure that their customs authorities have the necessary powers and resources in order to properly perform their tasks***.

Justification

For the sake of consistency and efficiency of the overall framework for the marketing of goods, Orgalime suggests the introduction of a similar provision for customs controls as for market surveillance authorities under Article 16.3.