ORGALIME POSITION PAPER ON

Draft Certif. 2005-16 Rev.2: Elements for a horizontal legislative approach to technical harmonisation

Brussels, 21/04/2006

General comments

Orgalime believes that the discussion paper Draft Certif. 2005-16 Rev.2 is very constructive at addressing the problems arising from the lack of harmonisation of the legal framework of New Approach directives and will be pleased provide our support for maintaining the core elements of this approach during the further proceedings with the European Parliament and the Council.

Better and simpler regulation is a real issue, if our European regulatory system, both EU and national, is to stop undermining Europe's international competitiveness and our continued potential as a manufacturing base in the face of ever stronger global competition. Improving European competitiveness requires a strategy that involves both a horizontal and pragmatic approach to ensure the proper functioning of the internal market and the reduction of administrative and regulatory burdens.

For our industry, we believe that where legislation is needed, it should translate policy objectives in terms of essential requirements and keep administrative requirements at a minimum. For Orgalime, it is key to the process to establish a clear separation between policy objectives and their technical implementation, which should be left up to stakeholders to define during the standardisation process.

Orgalime also believes that enforcement of legislation is crucial to ensuring a level playing field. Market surveillance at Member State level must be strengthened in order to maintain a balance between pre-market and post-market controls. At European level, the Commission can act as a facilitator to enhance cooperation between Member States and promote best practices.

To achieve these objectives the regulator should seek alternatives to regulation wherever possible, harmonise European legislation and enhance global regulatory cooperation. By defining framework legislation, which translates the policy objectives into essential requirements, which change only minimally over time, one can expect to achieve a great degree of regulatory stability. By leaving it to experts to determine how essential requirements can be achieved at the level of products through standards, the Community has provided a flexibility of the regulatory framework. Standards, and in particular product standards can be regularly updated to take into account changes in the state of the art.

In order to preserve a simple and flexible regulatory approach, Orgalime urges the European Commission to make greater use of Module "A" (internal control of production and self – declaration of conformity) as the preferred procedure for conformity assessment in revising the framework of New Approach directives.

We believe that it would substantially contribute to better regulation to apply these general principles beyond the scope of New Approach directives to all product-related legislation, regardless of the policy area (safety, environment protection, energy efficiency, etc…).

The horizontal framework should be as binding as possible and at the same time compatible with the needs of the different sectors. Orgalime suggests solving possible contradictions by a "built-in flexibility" that would not compromise the binding nature of the framework.

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Comments on sections

The legislative strategy (cf. C1)

Orgalime suggests that there should be an introductory part of the paper, recalling the main principles of the New Approach and the Global Approach, as described in the Blue Guide.

Referring to point 1), it is important to stress that the common horizontal Act should not in itself "set the overall framework for safety etc." Such requirements are to be set in the sectoral directives. Thus, the purpose of the horizontal framework should be to define the common elements for enhancing the functioning and enforcement of New Approach directives and other product legislation.

The scope of the horizontal paper should be all sectors covered by New Approach directives, as well as other appropriate product legislation. Thus, there should be no distinction between consumer and capital goods.

Obligations for economic operators (cf. C2)

Orgalime welcomes the clarifications on obligations for economic operators. It should be made further clear that all economic operators, including importers into the EU, must ensure that only products intended and manufactured for use in the EU are placed on the market in full compliance with all regulatory requirements, such as requirements on health and safety, environment protection, and energy efficiency.

Therefore, we support that obligations for economic operators correspond to their respective roles in the supply chain and are determined in accordance with the proportionality principle, because disproportionate obligations down the supply chain may put larger burdens on reputable manufacturers to endlessly supply the same information to all points down the supply chain.

The definition of obligations for each economic operator must, however, be seen as one element in a system where traceability, market surveillance and external border controls are equally important elements in order to effectively prevent non-compliant products being placed or remaining on the internal market. With a view to strengthening market surveillance, it should also be made clear that market surveillance authorities must withdraw a product from the market as a sanction against economic operators that have failed to demonstrate that they have complied with their respective obligations (see Market surveillance below).

Traceability requirements (cf. C3)

Obligation to identify the manufacturer and the importer on the product: Orgalime believes that this identification requirement could be expressed in more general terms: therefore Orgalime proposes to mention the “legal entity responsible in the EU” as an alternative to “company”. Consequently, the last sentence would read: “The minimum information should contain the name and the address of the legal entity responsible in the EU”.

Obligation to identify every individual product: Orgalime calls for a clarification of the words “every individual” in a way that it does not mean a unique number for every single product unit as this might cause difficulties to manufacturers of mass products.

Obligation to have an authorised representative in the EU: Orgalime does not favour this as a general obligation, which would constitute a barrier to trade. It is sufficient that one responsible legal entity in the EU is mentioned on the product: the EU manufacturer, its authorised representative or the importer of the product into the EU.

Registration system: Orgalime is clearly against any EU-wide registration system. It is our experience that registers do not help in the enforcement of legislation, but rather place an administrative burden on those companies that comply with the legislation, while free riders are not caught.

Conformity Assessment Procedures (Cf. C4)

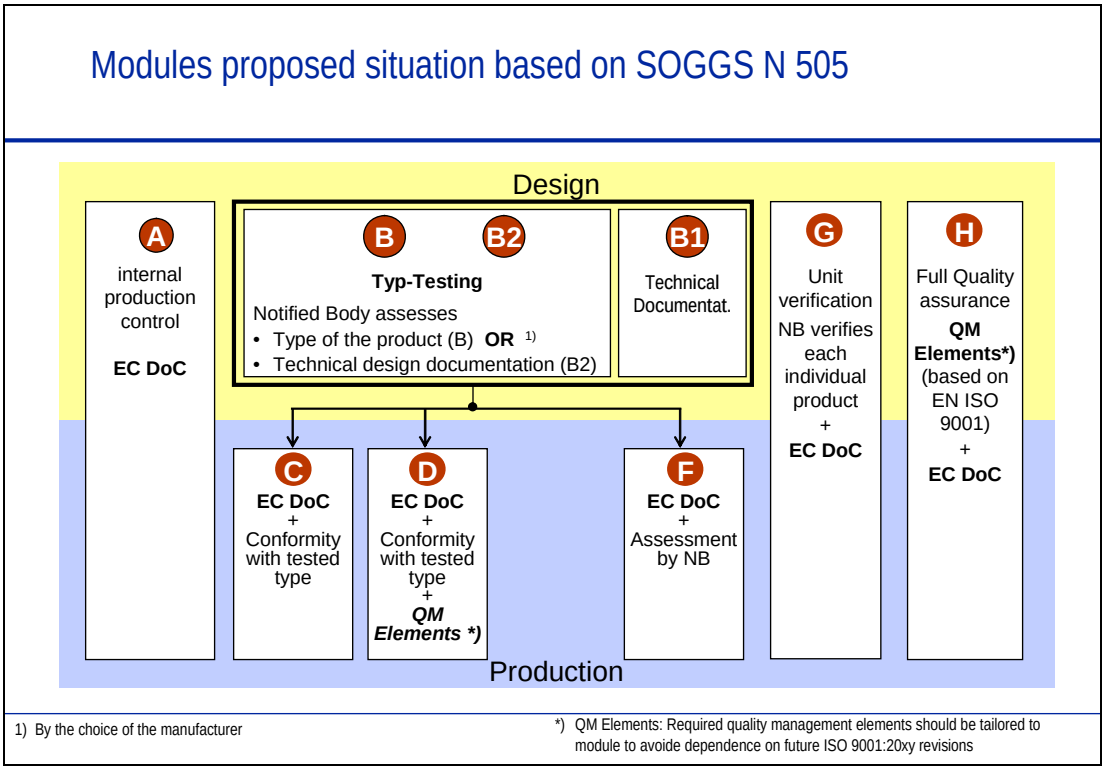
Orgalime believes that the conformity assessment modules set up in Council Decision 93/465/EC are generally efficient for their intended purpose and do not give rise to significant problems. In particular, we urge regulators to continue making use of Module 'A' (self declaration of conformity) as a preferred option in any new or revised product legislation. Module 'A' does not need any additional measure in order to gain credibility other than efficient market surveillance.

However, in order to adapt the conformity assessment (CA) modules to the current practice and to take account of the revision of international standard ISO 9001:2000, Orgalime would appreciate the amendment of module B as suggested by the Commission in its first issue of "CERTIF 2005-1". In particular, the proposed module B2 is needed, especially for highly innovative and non-serial products.

Consequently, besides Module 'A' as the preferred option, Orgalime proposes to simplify the system of quality assurance modules down to 2 quality assessment modules only:

- Module 'H' that would provide for a "full" quality assessment system and
- Module 'D' that would allow a "tailored" quality assessment,

as graphically represented in the chart below:



The suggested introduction of a new module on inspection for post-production surveillance is considered as superfluous. Because it does not contribute to the conformity assessment of a product in respect to its first placing on the market, it cannot be used by itself but only in conjunction with other CA modules. Therefore, such a module is not in line with the principles of the New Approach. Furthermore, the manufacturer has to survey his products in the market anyway and market surveillance authorities do not need to refer to a special inspection module when carrying out their work.

A detailed Orgalime position paper on conformity assessment procedures (14/04/2005) is available on Orgalime's web site [http://www.orgalime.org/positions/positions.asp?id=213].

Conformity assessment bodies/notified bodies (Cf. C5)

Concerning the rules for notification of conformity assessment bodies, Orgalime suggests that it should be possible for in house laboratories to be notified if they comply with the rules for a body to be notified. In some areas, the laboratories, which are competent to carry out some tests, are laboratories belonging to manufacturers or to second-party companies. If such laboratories/bodies are per se excluded from notification, some countries might not have competent notified bodies, and this would create difficulties for manufacturers.

Accreditation (Cf. C6)

Orgalime is against competition between accreditation bodies, either within the national territory of a Member State or between accreditors belonging to different Member States, as it might put the high level of quality at risk. Furthermore, in our view, an accreditation body must self-evidently not compete with the bodies that it accredits. At European level, accreditation bodies should, however, be able to operate across borders in certain situations, provided that there are mechanisms to guarantee that the quality of accreditation is comparable and maintained over time. We therefore support regular peer-to-peer evaluations at European level within the European co-operation for Accreditation (**EA**). The peer-to-peer evaluation system must be transparent and effective. It requires Member States to follow up on evaluation results by means of policy actions at national level. Cross-border cooperation between accreditation bodies is also important and must not be excluded. In any case, accreditation must remain an activity under the control of public authorities.

We support the statement on empowering the Commission to set up a programme for carrying out testing of inter-comparisons and for having at its disposal a pool of external expertise as proposed in paragraph 4 c) on market surveillance.

Concerning EA's role, Orgalime agrees it will be necessary for the national accrediting bodies to work with the Commission, EFTA and the Member States to create a framework for accreditation in Europe in which all the stakeholders can have confidence. However, we would not wish to see notified bodies having a role in the choice of conformity assessment procedures used in legislation. Similarly their role in standardisation should go no further than the standards needed for the smooth and efficient running of that framework.

Market surveillance (Cf. C8)

Orgalime welcomes the approach to strengthen market surveillance throughout the internal market. There is need for more action to be taken by the Commission, in order to facilitate and improve co-operation between Member States and to ensure the use of best practices. The elements proposed in the horizontal paper could serve as a good basis to make this happen.

Paragraph 8.1 k): we believe that, if the technical documentation is not made available to the competent authorities of a Member State, the market surveillance authority should have an obligation to ensure that the product is withdrawn from the market, as this situation provides a strong presumption that the product doesn't conform with the essential requirements (see also Orgalime's detailed position paper on market surveillance (09/10/2005) available at: http://www.orgalime.org/positions/positions.asp?id=220).

External border controls (Cf. C8.3.2)

Orgalime agrees that increased cooperation with customs authorities is both welcome and needed. The current Customs Security Programme and the various anti-counterfeiting initiatives under "Operation FAKE" should be further developed in order to include controls on the product's conformity with EU legislation.

Orgalime suggests the following measures in order to make such cooperation efficient in practice:

1) **First measure**: an EC declaration of conformity – or a direct internet link to it – should be attached to the shipping documents for all imported products that fall under the scope of New Approach legislation.

This would not be an extra burden for manufacturers, and it would facilitate customs controls. An indication in the list of customs codes may be a means for alerting customs officials, whether such a declaration of conformity would be required or not. If, on the other hand, the EC declaration is supposed to be elaborated by the legal entity within the EU that takes over the obligation to bring the product in conformity with EU legislation, the name and address of such entity should be indicated in the shipping papers. Alternatively, the importer into the EU, who, in any case, has to inform the customs of its expected shipments, should indicate that he takes over the obligation to ensure that the product conforms to European legislation.

2) **Second measure**: along the lines of "Operation FAKE", instruct customs authorities to react on the basis of an application for action triggered by market surveillance authorities concerning products reported to be unsafe.

3) **Third measure**: profit from the concept of "Authorised Economic Operators" (AEO) that customs are introducing in order to facilitate trade. A number of criteria have been set up to appoint such AEOs. Orgalime suggests that records on product safety are included in the criteria, in order to ensure that AEOs are aware of their obligations to ensure that products placed on the market are indeed designed and manufactured for use in the EU.

Definitions (Cf. Annex 1)

Orgalime supports the definition provided for an importer, which is in line with our position paper on market surveillance (09/10/2005).

The date when a product is placed on the market is very important for economic operators, as this is when their obligations with regard to EU legislation begin. Therefore, Orgalime believes that there is no need to change the current "definition" of *placing on the market* as defined in the Blue Guide to the application of New Approach legislation. In this context, Orgalime is concerned about the proposal in Certif 2006-16 rev 2 regarding the definition of "placing on the market" and the description of "making available". In particular the subparagraph on "making available" appears to be very confusing to manufacturers.

Orgalime would, however, welcome a guide that would detail the various situations when a product could be placed on the market.

CE-marking (Cf C7)

Orgalime believes that the New Approach has been instrumental in the success of the EU internal market with its key benefits: free movement of products, safe everywhere in Europe. We wish to keep the CE marking as a symbol of declaration of conformity to the New Approach legislation thereby concluding a whole process of risk assessment and internal production controls. All market operators should be aware of their individual obligations with regard to the CE marking on a product being marketed in the EU. We welcome the efforts of the European Union and Member States to set up the appropriate legislative and administrative framework. For these measures to have real effectiveness in the market, awareness on the meaning and significance of the CE marking must be improved and shared by all market operators including importers and retailers, in particular by launching information campaigns at both national and European level.

Market surveillance must be improved in order to fight free riders that do not respect the significance of the CE marking when placing non-compliant products on the EU market. This would be the best way to reinforce the confidence in the whole New Approach system and to decrease the number of non-compliant products to an acceptable level for society, thereby strengthening users' confidence in the internal market, while at the same time enhancing the competitiveness of EU manufacturers[1].

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[1] The full Orgalime position paper on CE-marking is available on Orgalime's web site [http://www.orgalime.org/positions/positions.asp?id=229].[1]