ORGALIME POSITION PAPER

Towards Comprehensive and Efficient Market Surveillance

Brussels, 09/10/2005

EXECUTIVE SUMMARY

To avoid that the European market becomes a preferred market place for free riders, we need efficient market surveillance. In order to ensure that, Orgalime suggests that all market operators should be responsible for their respective role in placing a product for the first time on the European market. 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.

We therefore call on all Member States to take their full responsibilities for ensuring efficient and harmonised market surveillance. Market surveillance should be quick, homogeneous and effective so as to protect users from unsafe products, while preserving the rights and enforcing the obligations not only of manufacturers but of all market operators.

For this to happen, it is necessary that the responsibility for breach of EU regulatory requirements and its enforcement should be redefined and focused on those who place a product on the market instead of only those who design and produce a product.

Orgalime believes that the European Commission should initiate such changes within the review of the legal framework of New Approach directives. The subsidiarity principle should not deter the Commission from encouraging intelligent market surveillance by Member States authorities. The role of the Commission could be to help facilitating co-operation between Member States and a dialogue with trade and consumer organisations.

General considerations

First of all it is important to note that efficient market surveillance starts by having clear and unambiguous legal texts. Implementation of regulation means not only transposition into national law, but also uniform interpretation and enforcement in practice, i.e. by market surveillance authorities.

The New Approach has brought many significant benefits for the development of the Internal Market while ensuring a high level of product safety. Orgalime therefore strongly supports the main principles of the New Approach and the Global Approach. 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. Therefore, Orgalime welcomes the Commission's proposal to examine with the members of the Senior Officials Group for Standardisation policy and conformity assessment (SOGS) some areas where improvements to the New Approach may be required, especially in the area of market surveillance.

Orgalime welcomes in particular the note for the attention of the SOGS “CERTIF 2005-7 project: A Community framework for market surveillance” which outlines the duties of Member States in this respect and the role that the Commission could play. Nevertheless, we would like to add some considerations and recommendations hereafter.

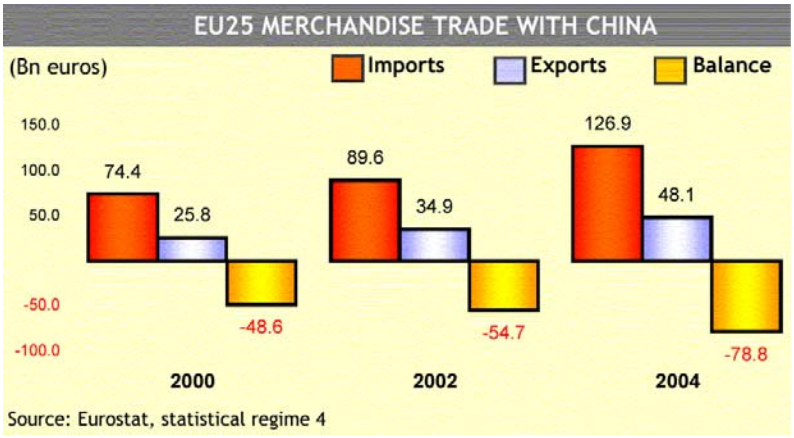
The NA helped to remove internal barriers to trade...

At the time when the first NA directives were drafted, the overwhelming majority of manufactured products were made in one of the Community Member States, under a relatively simple distribution chain, which, for engineering products, was to large extent

under the control of the original manufacturer. Consequently, legal requirements of NA directives have been designed in a product-oriented and single market-centred approach, in order to meet society's expectations for safety and free movement of goods.

… while ensuring a high level of safety and equity before EU law for all.
Over the past 20 years, the New Approach directives have contributed extensively to establishing a high level of safety for both professional users and consumers in Europe. For example, for electrical and electronic equipment, the number of fatal electrical accidents per million inhabitants is decreasing every year 20 years ago, the person who should take liability for a product placed on the market was obviously the manufacturer, who, moreover, was generally established within the Community market.

Barriers to EU trade have been removed. Those to foreign trade too.
Nowadays, it is not exaggerated to state that the situation has been almost completely inverted with the globalisation of both markets and manufacturing processes: from a legal point of view, it does not matter anymore where and by whom the product and its subcomponents are manufactured; what matters, however, is that the product placed on the EU market should be safe as defined in European regulation. In the past few years, the number of products that are imported from third countries has considerably grown1. For example, according to the Commission's own files, from China alone, EU-15 imports of ICT and electronic products (NACE 30, 32 and 33) grew by an average annual rate of more than 25 % over the past seven years2. In 2004, 22.28% of all machinery and mechanical appliances, electrical equipment and parts imported in the EU originated from China3 (see for instance the chart below).



Compliance to EU legislation has a cost that EU manufacturers should not pay alone.
Expert estimations say that fulfilling the safety and administrative provisions required by our regulations can add up to a fifth of total manufacturing costs. Market surveillance is therefore important not only for safety reasons, but also for ensuring a level playing field between EU

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[1] "Before 1992, there were many who believed that the Internal Market would become a "Fortress Europe" throwing up protectionist barriers and trading only with itself. Over the past ten years, extra-EU imports into the EU have grown steadily. This is a clear sign that the EU market is increasingly open and that the existence of a single system makes market access easier for firms from third countries." Source: http://europa.eu.int/comm/internal_market/10years/docs/workingdoc/workingdoc_en.pdf

[2] Cf. European Competitiveness Report 2004, Commission DG Entreprise B/2 staff working document "SEC (2004)1397. Source: http://europa.eu.int/comm/enterprise/enterprise_policy/competitiveness/doc/comprep_2004_en.pdf

[3] Statistics collected by the European Commission, DG Trade from EUROSTAT Comext - TDC XVI of the international Harmonised System. Source: http://trade-info.cec.eu.int/doclib/docs/2005/july/tradoc_113366.pdf.

manufacturers and those who operate from abroad. Especially in price-sensitive areas, some manufacturers might be tempted to "take the easy way" and to market non-compliant products. The increasing penetration of the European market by products that are not in compliance with the essential requirements of EU directives undermines the confidence that customers should enjoy as the safety of engineering products and their compliance with of our environmental, energy efficiency and other regulation.

The Way Forward: make legislation simple to apply and easy to enforce.
Efficient market surveillance starts by simple and easy-to-understand product legislation that would match modern trade practices in an enlarged, richer, globally-open single market.
The more complex legislation is, the more costly compliance to it becomes and the more burdensome the controls that are required. In the current framework of NA directives, stricter controls would hit mostly the EU-based manufacturer. Market surveillance should be effective for all products placed on the EU market regardless of where they are manufactured or how they are distributed.
Controls should be easy to perform on the product itself or by controlling accompanying documentation, because enforcement by officials of a member state stops at the borders of that state. E-commerce poses challenges that need to be addressed, especially through customer awareness raising and international co-operation.
Orgalime would like to stress in particular that consumer confidence could not be achieved on the long run through a generalised and mandatory third-party certification scheme, as a means of pre-market control. Experience shows, that in the face of a weak market surveillance, third-party certification marks are as easily copied or misused as the CE marking is. For the vast majority of the machinery and electrical industry, third-party controls would increase costs and induce profit losses due to a prolonged time-to-market period, without corresponding added value for users.
Consequently, in our view, the only way forward is to reinforce the confidence in the New Approach and its basic principles by improving the overall efficiency of market surveillance in the EU.

Towards an equitable review of the liability of market operators in product Directives.
We believe that should the manufacturer still be considered in the future as the only responsible person vis à vis the market surveillance authorities, then the full enforcement of EU regulation is doomed to failure. Consequently, Orgalime recommends reviewing the liability of market operators in product-directives in an equitable and pragmatic manner, according to their functional responsibility on the market.

When a product is found not to be in compliance with EU regulation:

1) **The manufacturer**, of course, **bears the primary responsibility for the design and manufacturing of the product for a final use in the EU**, according to the requirements of the EU market's regulation. He should comply, as required in all NA directives, with the essential safety requirements and provide the declaration of conformity on request.
2) **The natural or legal person who places a product on the EU market should, however, bear the responsibility** to make the necessary verification **that the product is indeed intended and manufactured for the EU market according to our regulations**. The reason for this is that if the product was never intended for import and distribution on the EU market, its manufacturer should not be held responsible for it being placed on the EU market and for the risks that such an event may cause, whether the manufacturer is based in Europe or not.

   ➔ The person who places the product for the first time on the EU market could be the manufacturer, his authorised representative in the EU, or the EU-importer – i.e. any natural or legal person established in the Community who places a product

from a third country on the Community market. The EU-importer might be the distributor, the retailer or a professional user.

➔ When the manufacturer is not established within the Community and in the absence of an authorised representative, the EU-importer must assume the responsibility, that the product is *intended and manufactured for the EU market* according to our regulations.

This approach is not revolutionary in nature as it appears already in the Product Liability Directive (1985, Art.3-1), and more recently in the Machinery Directive (1998, Article 8.7) and in the General Product Safety Directive (2001, Art.2e.ii), where the manufacturer's responsibility is shifted to the person who has placed the product on the market (e.g. the importer and even the distributor), if neither the manufacturer nor his authorised representative fulfil the legal obligations or could be traced back. In the EUP directive on eco-design (2005), the primary responsibility of the manufacturer is entirely shifted to the EU-importer of foreign products (see box above).

Example of responsibility shift:
EuP Directive on eco-design requirements for energy-using products 02005/32/EC

"Article 4: **Responsibilities of the importer**

Where the manufacturer is not established within the Community and in the absence of an authorised representative, the obligation

- to ensure that the EuP placed on the market or put into service complies with this directive and the applicable implementing measure,
- to keep the declaration of conformity and the technical documentation available,

shall lie with the importer."

We need a pragmatic approach to enforcement.

The liability for meeting the requirements of EU regulation varies in scope and depth between directives. Therefore, one should be clarify for all product directives what triggers liability of the market operators according to their function on the market and how this operator relates to the product. This would not affect the specificity of liabilities according to the scope of each of these product directives.

To ensure joint responsibility between the manufacturer and the person who places the product on the EU market, **the Commission and Member States should in our view consider the following recommendations**:

1) **maintain the current system of conformity assessment** to the EU legal requirements **for manufacturers**, as far as the design and manufacturing of the product are concerned (i.e. 'module A' as the preferable option in the framework of NA directives).

2) **ensure the traceability of the product to the person who has placed it on the EU-market**, such as the EU-importer for products manufactured abroad.

3) **enforce separately** the responsibility for **placing the product on the EU-market** from the responsibility of designing **and manufacturing the product**. The placing on the market could be made by either the manufacturer himself, his authorised representative, or the EU-importer.

This means that the business and retail services sector along with importers must also be held accountable in relation to their responsibility for ensuring that only those products that fulfil regulatory requirements are being marketed and sold. In particular **the person who places the product on the market should be fully liable in case they cannot**:

➔ **trace back the original manufacturer established in the EU** (e.g. through the invoice's legal provisions): this would particularly address the case of products whose origin could not be traced or of counterfeit and goods fraudulently placed on the market;

➔ **provide the declaration of conformity and technical documentation when the manufacturer is not established in the EU or has no authorised representative in the EU:** the person who places the product on the market shall demonstrate that the product fulfils EU regulations. This would particularly address the case of products imported by a trader in the EU.

In support to our general recommendations, we are pleased to provide more specific proposals in the attached annexes to this paper:

Annex I - 12 Orgalime recommendations for a more efficient market surveillance;

Annex II - Detailed Orgalime comments on EC discussion paper "CERTIF 2005-7" on "A community framework for Market Surveillance" of 4 July 2005.

This position paper is also well complemented by Orgalime position paper on "Clear and Common Definitions for EU product legislation in the context of the review of the New Approach".

Annex I

12 Orgalime recommendations for a more efficient market surveillance

1. **Focus on the targets** and concentrate on products and sales channels that have shown an above-average non-conformity rate in the past;
2. **Adjust the speed of your surveillance to the speed of sales**: it makes no sense to chase sold-out sales promotion products; *Distributors should take up their responsibility to sell only CE marked products (where the CE marking is mandatory)*;
3. **Make use of European industry platforms** and other stakeholder forums to learn more about market and users problems;
4. **Test products against the manufacturer's specifications** as indicated in the EC Declaration of Conformity, **especially when harmonised European standards are used**: it will facilitate and speed up your work;
5. **Participate in standardisation activities** in order to bring in your expertise and develop an understanding for the results of standardisation;
6. **Refrain from interpreting essential requirements when harmonised standards are available**: individual stipulation/evaluation of essential requirements can create legal uncertainty;
7. **Co-ordinate surveillance and harmonise enforcement practices with colleagues in other Member States** in order to enhance mutual confidence, avoid double checks and a waste of scarce resources and eventually achieve a consistent enforcement of the legal framework. Make use of best practices in order to move faster towards an effective and consistent market surveillance system throughout the EU/EEA;
8. **Co-ordinate surveillance with your national colleagues across ministries and regulation affecting the same products**. For both companies and authorities, it is not very efficient if one authority proceeds with a safety check one day, while, the next, another authority comes to conduct a voltage control, check electromagnetic compatibility or waste management procedures. This places unnecessary additional burdens on enterprises and in some ways constitutes a misuse of available resources on the authorities' side;
9. **Establish close and effective relations with customs authorities** in order to avoid forum shopping for the weakest countries within the EU, where the risks for rogue operators are low. Provide training and adequate resources to them so that they are able to check products, not only in relation to taxes and excise duties, but also with regard to compliance to EU laws, as required in Council Regulation (EEC) No 339/93 of 8 February 1993 on "checks for conformity with the rules on product safety in the case of products imported from third countries"[4];
10. **Act as much as possible at the start of the supply chain**. The earlier a non-compliant product is taken out of the market, the less damage it creates and the less effort is necessary for corrective action. Early action is not an invitation to introduce a pre-market access control;
11. **Co-operate with colleagues of non European countries**, in order to stimulate EU trade partner's authorities to take measures for the prevention of illegal exports to the EU of non compliant products;
12. **Raise awareness of product users and especially the general public about your action, working methods and achievements**, e.g. through a information campaign.

[4] Official Journal L 040 , 17/02/1993 P. 0001 - 0004

A key element of any such information campaign should be awareness raising on the meaning of the CE-marking and information on contact points, which companies and consumers can contact, should they discover non-compliant products.

Empower Market Surveillance Now!

Orgalime invites the European Commission and Member States to take on board the above-listed recommendations, which are mostly of pragmatic nature, in setting up their benchmark for assessing how efficient market surveillance tasks are performed.

In addition, **Orgalime calls on governments of the EU to allocate sufficient resources to their market surveillance authorities**: it is essential to good regulation to ensure effective and credible enforcement measures. Otherwise any efforts put into creating new legislation are wasted.

Therefore Member States should agree on a set of essential requirements for efficient European-wide market surveillance and commit themselves to apply it with adequate staffing and financial resources in order to match today's trade conditions.

Annex II

Detailed Orgalime comments on "EC discussion paper "CERTIF 2005-7" on "A Community framework for Market Surveillance" of 4 July 2005

The Draft Community Framework for Market Surveillance as presented by the EU Commission (Certif 2005-7) provides a good basis for discussion and for drawing up concrete measures within this area.

Market surveillance is a matter of public interest that Member States should seriously take in charge, in order to ensure a proper respect of European-wide regulation and a smooth operation of the internal market providing a level playing field for all those involved. With a view to ensuring that Member States will not water down their responsibility on the basis of the principle of subsidiarity, **Orgalime encourages all European institutions to agree on common, comprehensive provisions relating to market control and sanctions. We believe that** more responsibility could be delegated to the Commission in order to ensure more efficient a co-ordination across the 25 Member States.

Orgalime is strongly opposed to pre-market control through the implementation of compulsory third–party certification, as a means to compensate for the lack of comprehensive and efficient market surveillance. Certificates issued by third parties, as experience has shown, do not provide a greater degree of safety. Moreover such certificates can (and are) counterfeited, misused and copied. Orgalime sees no reason to impose additional burdens on European engineering industries that comply with EU regulation just because national authorities are not in a position to fulfil their tasks and obligations, thereby making it too easy for those producers willing to break the rules.

In Orgalime's view, market surveillance should concentrate on products where there are more likely to be cases of non compliance.

A ii: *"Establishment of a Community control mechanism …" and B "Community Control"*

> If such a "control mechanism" is deemed necessary, it should be set up in a careful way, in order to avoid the repercussion of any additional administration and bureaucratic burden for companies.

A iii: *"Member States should define the objectives, organisation and co-operation methods of their market surveillance authorities"*

> These essential requirements have to be elaborated in more detail. It is self-evident that the member states have to define their objectives, organisation and methods of cooperation. For each of these points Orgalime recommends to have also essential requirements. At least there should be guidelines on the requirements for market surveillance.

C ii: *Co-operation between the Member States should ensure: "Exchange of information (databases, test methods and results, exchange of expertise and best practice, meetings, etc.)"*

"The role of the Commission" seems to be limited essentially to acting as a reminder. We believe that the Commission should specify its role in greater detail and should take up the responsibility to facilitate the information exchange between Member States (e.g. by quick translations into a limited number of working languages).

Annex I – 4 – 2. bullet: *The Community framework for market surveillance is based on the following principles and objectives:* "*Respect of the principle of presumption of conformity for products bearing the CE marking or of other types of regulatory markings provided for by other Directives*;"

> The meaning of this paragraph is unclear. We believe it should be worded in a way, which expresses its probable meaning: the CE marking is an indication for conformity.

Therefore, the authorities should not intervene arbitrarily, but only in cases of sound suspicion or in the framework of a systematic surveillance action.

Annex I – 4 – 6. bullet: *"Obligation for the Member State to take appropriate provisional measures, which are proportionate to the (supposed) risk, in accordance with the implementing rules of the precautionary principle;"*

Orgalime questions the application of the precautionary principle by market surveillance authorities. The precautionary principle is applicable in the face of scientific uncertainty where a product exposes the user to a health or safety hazard. As stated in the conclusion of the Commission's Communication (2000/1), the decision to act or not to act is of an eminently political nature. Thus, it is usually the responsibility of governments, not of their administration, to take the decision to apply it or not. Therefore, it is questionable whether it should be up to market surveillance authorities to justify measures taken against products placed on the market in application of the precautionary principle. As an example, some Member States authorities might decide to ban mobile phones from the market based on the precautionary principle, simply because some people regard exposure to electromagnetic fields from these products as dangerous. This would open the door to uneven conditions and technical barriers to trade within the single market.

Annex I – 6a: "documentary checks"

We welcome this first attempt to define the technical documentation, which is relevant for the market surveillance authorities: "summary including, in particular, the essential technical data". This approach should be elaborated further; it would allow defining a reasonable amount of documentation that should be kept by the manufacturer.

About the role of documentation in reference to document N 492, 7, 3rd paragraph: "*The technical documentation should be available in the language of the country of destination of the product or in a language widely understood in that country*"

Although such requirement for translation of the technical documentation might seem to be a tool for improving the effectiveness of market surveillance, it would cause an enormous cost to manufacturers, especially for complex products. In this respect Orgalime would like to make reference to the first edition of the "Blue Book" of 1994, where the statements on the technical documentation in Part II/D are very helpful and should be taken into consideration. In particular, its chapter 4, second and last paragraph states: "*At Community level, market surveillance should be organised through co-ordinated inspections in a way that a manufacturer does not have to submit the technical documentation several times to different surveillance agencies".*[5]

Therefore we strongly suggest that any market surveillance measures shall be carried out after consultation and in close co-ordination with the market surveillance authority of the country of the identified legal person responsible for the placing on the market, be it the manufacturer, his authorised representative, the EU-importer, or the distributor.

Annex I – 6c: "laboratory tests"

[5] Free translation from the German language

This paragraph should specify that the technical specifications indicated in the EC declaration of conformity of a product should serve as a basis for laboratory tests: these are usually and preferably European harmonised standards, including measuring standards.

Annex I – 7.1 – Effective surveillance – 1. bullet: "*good co-ordination is in place by "the use of robust practices and, at the same time, sound management of resources*."

We support this important point. We recommend that market surveillance enforcement strategies should lead to more frequent, simultaneous and coordinated actions in Member States. Market surveillance should concentrate on products where there is more likelihood of accidents, based on the data provided on accidents statistics.

Annex I – 7.1 – Effective surveillance – last paragraph: "visibility of market surveillance action"

Orgalime supports this important element: market surveillance should improve its dissuasive character: all market operators should face the possibility of getting "caught" and users should be alerted in a neutral manner of the risks of buying or importing engineering products under their own responsibility.

Annex I – 7.2 effective monitoring – b) 2.1: "*exchange of information*"

The lack of inter-operability and comparison of collected data from the different information systems shows that it is urgent that Member States decide to implement and use a single information platform under the co-ordination of the Commission. Orgalime recommends using ICSMS, which is already used by a number of EU Member States.

Annex I – 8.1: external border controls

Orgalime strongly supports this recommendation to control products at the point of entry in the European market, in order to avoid that containers of non-compliant products flood the market. Once more, this does not mean that we support unnecessary systematic pre-market access checks. As mentioned in Annex I – 4 – 2nd bullet of the document, CE marking and presumption of conformity should stay the rule. Such border controls should be carried out more frequently at random or on purpose on the basis of cross-verified information sources.

Annex I – 11 – Link with the GPSD – 3rd paragraph:

Orgalime cannot share the concern expressed in the last sentence that "*the industrial and consumer products falling within the same directives could, in practice, be subject to different provisions for market surveillance*". Different procedures are inevitable due to the difference in nature of products and of the relationship with the customer. Measures which are appropriate for protecting consumers buying on the mass market would certainly be inadequate and over burdensome in business-to-business relationships. Professional products often require specific training, user competence, monitoring and maintenance, which are clearly specified in contracts or covered by social legislation and work inspections.

Annex I – 13.1 – Traceability – last paragraph: *"obligation to place at the disposal of the authorities of a Member State, the declaration of conformity (DoC) for each product"*

This paragraph has to be clarified. It can be construed that manufacturers have to register themselves and lodge the EC declaration of conformity in a database. Such a procedure would cause serious modifications to the current practice and would create unnecessary administrative burdens: it is worth stressing that manufacturers who already comply with the requirements would register, while those who do not would most probably not register. Consequently, free riders will likely not be caught, while lawful manufacturers will be inequitably subject to more administrative burdens.

Annex I – 13.2: Frauds and fight against counterfeits

Orgalime welcomes the suggestion to include the fight against counterfeits in the framework of efficient market surveillance. The engineering industry is keen to participate in the development of solutions against counterfeiting and to assist market surveillance authorities in the identification of frauds.

Annex I – 13.3: e-commerce

Orgalime welcomes work in the area of the surveillance of e-commerce: The worldwide trade via the Internet is not mapped yet by existing market surveillance procedures. New solutions are necessary.

Part II: Implementation of the Community market surveillance framework – Suggestions for concrete actions

The proposed actions are acceptable in principle. However, Orgalime believes that the time for the introduction of a unified system for the collection of information has come, instead of carrying out endless evaluations of all national ones. Orgalime suggests using a common information exchange system between Member States, which both preserves confidential information and ensures a Web-based interface with market operators, such as ICSMS, which is already in use in several EU Member States.

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