ORGALIME

Position Paper

Brussels, 28 November 2014

Orgalime's reply to the European Commission's provisional options for an e-compliance system

1. Executive summary

Orgalime welcomes the European Commission's extensive consultation on "*exploring how compliance with Union harmonisation legislation can be demonstrated / controlled electronically ("eCompliance" concept)*".

Orgalime considers that an e-compliance system could not replace physical checks and on-the-spot controls of products placed on the market, to ensure that market operators are putting on the market products in conformity with both the essential and administrative requirements.

Consequently, e-compliance should develop as a facilitation service for providing documentary evidence to increase the efficiency of market surveillance controls, so that more resources could become available for physical checks on products. Therefore, we support the idea of using electronic means to communicate more quickly with enforcement authorities.

In this framework, we suggest that the Commission should investigate how such electronic means could be made legally acceptable in all EU Member States within the existing framework of applicable internal market legislation (option 0), including the use of a website or an email address as an alternative to a postal address.

However, Orgalime is not in favour of policy options 1 to 4. We believe that these options significantly increase the administrative compliance costs of companies – especially SMEs – and do not ensure that authorities could effectively prevent misuse, fraud and avoidance to comply with legislation. More importantly, we consider that options 1 to 4 challenge the principle of "*reasoned request*" as given in chapter R2.9 of Decision No 768/2008/EC and on the Directives aligned with it.

We expect that the Commission will carry out a detailed impact assessment of their preferred policy options, with particular attention to their enforcement potential: we see no additional benefits for authorities to work with unreliable, misleading or even simply missing information.

Options 1 and 2 (EU-wide centralised database) in particular would entail serious drawbacks for legitimate market operators, such as a significant increase in administrative burdens and costs, confidentiality, security and translation issues in regards to transferred business-sensitive compliance data. This would run counter to the stated aim of the Commission to reduce administrative burdens on companies. Orgalime is also wary that it would jeopardise their right to redress against an authority's decision based on register checks only.

We hereby provide you with our detailed answers to the Commission's note "*provisional options for an e-compliance system and relevant questions to the interested parties*".

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2. For a flexible and paperless approach to e-compliance

Orgalime prefers "option 0", which involves no changes to the current practices of economic operators, while enabling them to move further away from a "paper-based" approach.

EU legislation already foresees the possibility to transfer documents in electronic format between economic operators and market surveillance authorities. For example, all Directives aligned with the New Legislative Framework (NLF) foresee that economic operators can provide authorities with all the information and documentation in paper or electronic form (such as Low Voltage Directive 2014/35/EU articles 6.9, 8.9 and 9.5).

Therefore, we call on Member States to efficiently and effectively transpose the relevant provisions of the Directives aligned with the NLF and to unleash the potential of a wider paperless communication and data exchange, which is still constrained by legal/administrative obstacles in many countries.

3. Orgalime rejects a centralised e-compliance system (Options 1 and 2)

Orgalime rejects any registration procedure regardless whether it is obligatory or not. This rejection also applies to the organisation of a database whether it is centralised or de-centralised for the reasons we state hereafter.

Confidentiality and data security issues

Many manufacturers are hesitant to share any documents through a widely accessed database system without prior notice or authorisation.

Moreover, they would be totally opposed to sharing their technical documentation with unidentified and unauthorised third parties, including market surveillance authorities, without a specific and reasoned request, as provided for in Decision 768/2008/EC and the legislation aligned with it.

Manufacturers concerns stem from the following:

- The dissemination of information and processing possibilities could lead to a **misuse of** product compliance documentation, which contains a **substantial volume of proprietary and business-sensitive data**.
- No manufacturer is ready to take the risk of a **significant loss of corporate know-how and proprietary information** from any malicious intervention into a centralised system.
- Manufacturers are interested to know which authorities are checking their products and to what kind of information they require access.
- This system would lead to huge **electronic security and insurance costs** for authorities to protect manufacturers' intellectual property against piracy and mishandling, while this is today under manufacturers' responsibility and control.

To limit these concerns to an extent, a centralised database –if established– should only allow authorities access to specific public documents after the submission of a secure and reasoned request from a known source.

Administrative burdens

SMEs reject by a vast majority any registration procedure, which would increase their compliance costs for placing products on the EU market. Some of them fear that they would not be able to cope with the expected registration procedure, due to lack of time and personnel capacity.

Moreover, manufacturers are against a system that would oblige them to duplicate all their internal information on an additional external portal.

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Existing systems prove to be very burdensome (experience from the US) and are often malfunctioning (see for example the negative assessment of the database on the Outdoor Noise Directive 2000/14 in the relevant study of CEPS).

Manufacturers raise even stronger concerns against a centralised database to which parts of the technical file would be uploaded or registered. Transforming the technical documentation consistently to become suitable for input into a database would continuously bind resources for the following reasons:

- The different parts of the technical file are seldom available in one **single electronic format**. Rather, the technical documentation is actually a compilation of many different types of documents that could be in the form of design drawings, circuit diagrams, printed circuit board layout details and mechanical drawings.
- The compilation of technical documentation could involve **several internal departments and external component suppliers** to cover all aspects of a product's life cycle.
- Often the various technical departments or suppliers involved use, for functional reasons, **software** that is not compatible with a single database software.
- The types of software used cannot be easily changed, because it is also part of the product's safety.
- Only a small part of the documentation required is readily available in **commonly used file formats**, such as MS-Office.
- Other file formats would have to be converted. This is not only an additional burden but, according to manufacturers' experience, it also carries a risk of error.

Further discrepancies with non-compliant economic operators

Even if a registration procedure were made obligatory, the system risks being rapidly filled with misleading or fake declarations of conformity or certificates. We strongly doubt that non-compliant manufacturers would upload trustworthy information into the system as long as the staff and financial resources for product checks and actual enforcement procedure remain minimal.

Therefore, an e-compliance system, far from saving time and resources of market surveillance authorities in documentary checks, would have the opposite effect of obliging them to check the registered information against the actual product's documentation.

Risk of disproportionate focus on administrative non-compliance

If introduced, we fear that such a registration procedure – whether mandatory or not – would lead market surveillance authorities to focus on administrative non-conformity rather than on assessing the technical compliance of products with the essential requirements of the law. Finally, manufacturers of unregistered products would benefit more from such an e-compliance system, as they would be even less bothered than they are today.

Reasoned request and direct communication is essential

Union harmonisation legislation rightfully foresees that product information should be communicated to authorities further to a reasoned request.

This allows for the establishment of a necessary dialogue between the authority and the challenged manufacturer, enabling the latter to precisely match the request for information to the necessary corrective measures.

This dialogue is useful to all market operators – especially SMEs – to improve their business process and compliance procedures and to prepare their defence. It should in no way be removed or undermined by a dematerialised e-compliance system.

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4. Orgalime rejects a decentralised e-compliance system (option 3)

Orgalime equally rejects a decentralised registration procedure, even if it is made voluntary, as it would add significant and continuous costs to manufacturers and in particular it would require SMEs to:

- adapt their compliance documentation to a single submission procedure using compatible strictly specified forms and formats for the information (beyond the DoC model);
- acquire an electronic data-management system (for many SMEs) or adapt their existing system (for medium/large companies) according to the above-mentioned needs.

Therefore, large companies would only be able to cope with a decentralised registration procedure, although they would have to make significant investments to adapt their existing systems to external interoperability requirements. Such a system would be often unaffordable to SMEs.

Furthermore, confidentiality concerns, regarding a centralised database as raised above, apply also to a de-centralised database, if it grants access to unidentified third parties.

Moreover, we do not see the merits of a decentralised registration system, as the electronic submission of data to authorities is already foreseen in the legislation aligned with decision 768/2008.

5. Orgalime rejects an obligatory e-labelling system (option 4)

Orgalime considers that e-labelling should be allowed as a voluntary system for substituting, not duplicating, current marking requirements. It should not be imposed as an obligation to all companies for the following reasons:

- E-labelling would only be beneficial for companies investing in it because it supports the overall in-house management of a supply chain.
- Most products without a communication function are not equipped by design with displays, tags or other electronic identifiers. Companies should not be obliged to re-design their products to add such elements.
- E-labelling bears the risk of duplicating the obligation to affix product-related information on the product, its packaging, or accompanying documentation. Any such obligation would result in disproportionate additional costs.

6. Costs estimates of various policy options

6.1. Provision of compliance information further to a reasoned request (Option 0)

Manufacturers from different Member States estimate that it can take between 1 to 3 employee days per product/technical file to retrieve and provide authorities with documentation after a reasoned request has been submitted. This estimate varies according to the company's size. A company with a range of thousand product variations may have up to 50 requests per year from market surveillance authorities. This already represents a considerable investment.

Moreover, one should be aware of the potential added translation costs according to the authorities' request.

Nevertheless, we consider that the current practice is more cost-effective than the establishment, operation and maintenance of a "blind" e-compliance system.

6.2. Systematic upload of product information into a dedicated database (Option 1 to 3)

The cost of a registration procedure into a database accessible to authorities, whether centralised or under the responsibility of the manufacturer, would depend largely on:

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- the company's product range
- the existing internal procedures of the responsible economic operator
- the obligatory frequency of updating the uploaded information
- the uploading of technical documentation

We are pleased to provide hereafter some company estimates:

Initial upload of product information into a database

The obligation for all manufacturers to upload all the required information for each product model would generate huge administrative burdens and corresponding costs in working hours compared to the current situation.

A) Case study of a large company in the electro-technical field with a range of 10.000+ products provided the following estimates:

- Currently this manufacturer holds the technical file documentation and compiles relevant information to respond to specific market surveillance investigations on request.
- Information may be stored across a number of manufacturing, design, and marketing departments spread in several places all over the world.
- Therefore, technical files are not held in a central location or single electronic repository.
- The initial registration of technical files for all EU directives for their full catalogue would take around 5 employee/days per reference in their catalogue.

The situation would be even worse for manufacturers with a large number of product variations.

- Currently, Declarations of Conformity and parts of the technical file can be common to several products of a given product family, as they share some characteristics that meet the essential requirements in the same manner.
- The following example from a French manufacturer of cables and electric installation equipment shows that they produce 20 times less declarations of conformity than product models actually placed on the market:

Family of products	Number of products in this family	Number of DoCs
Family of products 1	9629	120
Family of products 2	6060	114
Family of products 3	478	25
Family of products 4	327	153
Family of products 5	689	210
Family of products 6	509	164
Family of products 7	2152	135
Total	**19.844**	**921**

If a single entry should be created in a database, then this would equal to 19.844 entries instead of 921 Declarations of Conformity that the manufacturer is publishing today.

B) Case study of an SME under 50 employees which does not manage its technical information electronically: they would be obliged to scan/digitalise all relevant documents.

This requires extra hardware and software capacity (estimated €2.500), manpower to collect, maintain and update the required documents. Additionally, hardware for documentation will be required (storage of data). They would need to provide a special training for their employees to fulfil such e-compliance requirements. The costs are therefore considerable and in particular the allocation of scarce employee resources to unwarranted administration can only undermine the company's competitive position.

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Maintenance and update of compliance information into a single database

Maintaining the documentation in an e-compliance system, across all Directives and taking into account legislation changes and new products would probably lead to a significant loss of working hours and productivity.

A company with a range of 10.000+ products estimates that on average, it would probably take them 22 full time positions/year to maintain and update their entries into a different database than their own, instead of staffing more productive activities.

In addition, significant additional costs should be added to translate the uploaded documentation into all Member State languages, while currently translation costs are limited to the relevant parts of the technical file requested by the authority.

7. Suggestions for a pragmatic e-compliance system

We believe that particular attention should be devoted to achieving a change in mind-set among market surveillance authorities and companies to shift away from traditional "paper-based" practices to communication via electronic means.

We invite the Commission to carry out a study to identify the legal obstacles to the electronic transmission of information in the Member States, as was the case for the Regulation on Construction Products.

Such a study could consider the merits of using a website or email address as a voluntary alternative to a postal address. This would have tangible benefits such as:

- Speed: consumers and market surveillance authorities would be able to communicate more swiftly with the manufacturer.
- Accuracy: manufacturers could update over time their contact details in case they move premises (web address) or redirect the request for information to the responsible person or service in the company (email address).

To avoid misuse by rogue traders, such a website could be subject to very strict conditions:

- Functioning, with all the legally required information.
- Easy to use: Any user should be able to find within minimum clicks the following information in a language easily understood by end-users and market surveillance authorities:
    - Physical address of the contact point.
    - A phone number where technical, administrative or commercial information can be addressed.
    - A contact form which allows the customer or the authority to communicate with the economic operator via the site.

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