ORGALIME

Position Paper

Brussels, 16 April 2013

No need to reform the internal market for industrial products

Orgalime answer to consultation on the initiative "Reforming the internal market for industrial products" from Commission Work Programme 2013 [1]

1. INTRODUCTION

Orgalime welcomes the European Commission's open consultation of stakeholders on remaining barriers to the free movement of industrial products.

We support Commission's statement in its "Industrial Policy Communication Update": a fully functioning internal market is a "*key tool to achieve a highly competitive social market economy*".

In this context, engineering companies represented by Orgalime in Europe have six key messages to communicate to policy makers.

1. **Professional non-harmonised sectors do not require harmonised health and safety regulation at European-level**. These products are not consumer-oriented and do not circulate in massive volumes within the EU. Non-harmonised sectors mostly concern large-scale installations or complex machinery. These are manufactured specifically for the client.

   Therefore, EU-level regulation for these sectors risks creating confusion. On the contrary, improving the implementation of mutual recognition among Member States could be beneficial.

2. **In harmonised sectors, full harmonisation is needed for all national rules and requirements** for placing products on the market.

   Often, Member States' legislation diverges from harmonised EU legislation, obliging manufacturers to comply with further approval processes and undergo numerous administrative procedures or even modify their products. Some sectors (for example electric generation and installation products) wish to see a greater degree of harmonisation of the putting into service, use and operation/installation of their products.

3. **Market surveillance needs to be stepped up.** The new Product Safety and Market Surveillance Package has the potential to promote efficient and effective market surveillance. Most importantly, it provides for proportionate and co-ordinated enforcement measures against infringement to all EU product legislation.

[1] http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=IMIP&lang=en

Orgalime, the European Engineering Industries Association, speaks for 38 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2012 accounted for some €1,840 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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4. **Products and applications related to Key Enabling Technologies (KETs) do not require specific legislation; some adjustments in existing legislation could support the uptake of KETs.**

   While KETs represent six important sectors, innovative products constantly enter the market. Where legislation exists or is adopted, this should provide the flexibility needed to facilitate innovation.

   In contrast, legislation which facilitates the commercialisation only of certain technologies risks being counterproductive to the flexibility and coherence of the overall legal framework.

5. **Products and applications related to 3-D printing do not need to be regulated at EU level**.

   However, we see some issues relating to their dual use (civil/military) and their potential for fraudulent use to counterfeit other goods. These issues need to be tackled under the existing regulatory framework, thereby avoiding establishing additional regulatory requirements for additive manufacturing.

6. **Harmonised legislation at EU level should be consistent**.

   Manufacturers often face contradictory requirements for placing products on the market. In this framework, each legal act's scope should be clearly defined, so that manufacturers can easily identify which piece of legislation to apply.

Our answer to the questionnaire is attached in Annex.

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ANNEX

2. PROFILE OF THE RESPONDENT

Name of the Organisation: Orgalime

Please indicate in what capacity you are replying to the questionnaire:

☒ business representative organisation

If you are a business representative organisation, please indicate the size of the enterprises you represent:

☐ Self-employed
☐ Micro enterprise (1-9 employees)
☒ Small enterprise (10-49 employees)
☒ Medium enterprise (50-249 employees)
☒ 250-499 employees
☒ More than 500 employees
☐ Other / Unknown

Where are you based?

Belgium

Please select the NACE sector corresponding to the main activity of your enterprise or the enterprises you represent

C. Manufacturing

- ☒ **25 Manufacture of fabricated metal products, except machinery and equipment**
- ☒ **26 Manufacture of computer, electronic and optical products**
- ☒ **27 Manufacture of electrical equipment**
- ☒ **28 Manufacture of machinery and equipment n.e.c.**
- ☒ **33 Repair and installation of machinery and equipment**

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3. IDENTIFYING AND ELIMINATING THE REMAINING BARRIERS TO THE INTERNAL MARKET FOR INDUSTRIAL PRODUCTS

What, if any, are the regulatory barriers to the effective functioning of the internal market for industrial products?

Member States impose national conditions for placing products on the market, or putting them into service. These often constitute regulatory barriers against the internal market's smooth functioning.

Member States oblige manufacturers to comply with diverging approval processes and undergo various administrative procedures or even require manufacturers to modify their products. For example, widely differing technical standards and requirements exist for connecting electrical generating equipment to public electricity mains.

Even in the harmonised sector, Member States tend to "gold-plate" Internal Market directives with additional requirements. For instance, they tend to maintain well-established but not legally necessary certification procedures, after harmonised directives are adopted.

Additionally, manufacturers are discouraged from placing products on multiple markets due to the complexity of applying diverging VAT rules.

Finally, in certain cases EU harmonised legislation is not consistent and may even imply contradictory requirements for manufacturers, as illustrated with the following examples:

1. The Ecodesign Directive (2009/125/EC) establishes a framework for the setting of ecodesign requirements of all environmental aspects of energy-related products throughout their life cycle. However, the Directive on waste electrical and electronic equipment (WEEE, 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (2011/65/EU, RoHS) develop in isolation from the Ecodesign Directive.
2. The environmental footprint methodologies risks undermining and conflicting with the existing Ecodesign Directive and its agreed implementation methodology, namely the MEErP (Methodology for the Ecodesign of Energy-related Products)
3. The same uses of substances in the same products and processes risks being regulated twice, under the RoHS Directive and the REACH Regulation. We therefore hope that the Commission should ensure companies do not have to seek in parallel RoHS exemptions and REACH authorisations for the same substance used in the same appliance.

Such national requirements have an impact on the free movement of goods.

Likewise a lack of harmonisation in certain rules, such as those governing off-road machinery also have an impact on the free movement of goods.

How could any such regulatory barriers be overcome?

In harmonised sectors, Orgalime welcomes past and on-going efforts to harmonise national rules and requirements for placing on the market, putting into service, use and operation of products/installations.

Furthermore, Orgalime supports the progressive change of directives establishing rules for placing products on the market into directly applicable Regulations: it removes the ground for Member States to add marketing conditions and bureaucratic requirements. Therefore it could lead to an improved cohesion of the Internal Market.

In any case, the Commission should regularly scrutinise unjustifiable, additional national requirements and, insofar this is possible, take legal action against them. Otherwise, national legislation will always undermine the positive impact of EU harmonised legislation.

The Commission should make the best possible use of Directive 98/34's notification procedure. We agree with the Commission's statement that this procedure could help improve national legislation and introduce a "competitiveness check"[2].

Additionally, Orgalime recommends more training of market surveillance authorities' staff and experts to consolidate mutual confidence in non-domestic products.

What, if any, are the non-regulatory barriers to the effective functioning of the internal market for industrial products?

Orgalime recommends tackling two non-regulatory barriers in the harmonised area:

1. Firstly, market surveillance should improve. As the volume of EU legislation increases, legitimate economic operators are increasingly required to invest in traceability and compliance procedures (from 2% to 25% of manufacturing costs, depending on the product category).

   This investment remains largely unprotected from the unfair competition of non-compliant products.

   Therefore, Orgalime places high hopes in the Commission's proposal for a Regulation on the Market Surveillance of Products. It has the potential to improve the level playing field for placing industrial products on the Internal Market.

2. Secondly, Member States' authorities should co-operate and thereby increase their knowledge on the relationship between essential requirements and standards. Currently, they often consider European and national standards as quasi-legislation. Therefore, they require manufacturers to comply either with often-diverging national standards or with quality standards, such ISO 9001. This situation undermines the benefits of flexible compliance procedures providing presumption of conformity to essential requirements under New-Legislative-Framework-type legislation.

To our knowledge, non-harmonised electrical, mechanical or metal products do not suffer from non-regulatory barriers to trade.

Do you rely on mutual recognition for supplying products to another Member State of the European Union?

☒**Yes**

Do you think that Regulation (EC) 764/2008 on mutual recognition is a good instrument for ensuring the free movement of industrial products not covered by harmonisation legislation? If not, what is its main weakness?

The reversal of the burden of proof of Regulation 764/2008 and Directive 98/34's notification procedure are powerful tools for placing products on the internal market. As mentioned earlier, certification and other conditions for the marketing of products would undermine the smooth application of mutual recognition.

Therefore, efforts should focus on the removal of additional national requirements for placing products on the market. The scrutiny of technical rules on products should be followed up, where possible, by legal action against remaining technical barriers to trade.

[2] Industrial Update COM (2012) 582, page 16

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We consider that industrial products in the non-harmonised area should not be subject to European harmonised legislation. National legislation is sufficient for placing such products on the market, as these are mostly products manufactured to specification.

Are there products not covered by EU industrial products legislation that would benefit from being harmonised in view of facilitating their free movement in the internal market?

☒ **No**

Is there a need for a special procedure allowing for a faster dispute resolution of cross-border litigation related to the free movement of products within the EU?

☒ **Do not know**

B) Services related to a product

The value-chain of certain industrial products often includes the provision of a service. Have you come across any impediment to deliver and to receive services with respect to industrial products?

☒ **Yes**

If yes, please specify for which products or categories of products

Conditions for putting products into service vary among Member States. For instance, diverse conditions exist for setting up a factory, for example conditions for acquiring permits and for equipment installation.

If yes, what type of service barriers do you refer to?

☒ **Engineering and design**
☒ **On-site installation**
☒ **Maintenance, support and after-sales services**
☒ **Repairs**

Are there other issues related to the interpretation of products and services that you would like to raise in view of ensuring a smoother functioning of the internal market for industrial products?

C) –High-growth / New technology products

Do you see specific regulatory barriers impeding the development, commercialisation or market uptake of KET-related applications and products[3] within the EU?

☒ **Yes, future regulatory barriers are expected**

If yes, please specify which are these barriers

Innovation, which is at the core of key enabling technologies, needs stimulation to provide cost-effective answers to new policy requirements on the traceability of products, energy efficiency and resource efficiency.
However, we see the reference to the precautionary principle in the GPSD and some pieces of environmental legislation as a hurdle for the market uptake of innovation in this area. Diverging risk assessments among market surveillance authorities could also constitute a major barrier to trade.

If yes, please specify for which of the KETs you see face these barriers?

We consider micro-and nano-electronics can face barriers. In particular in the field of:

- Mobile telecommunications
- The future of nano chargers could be blocked by a misconceived application of the precautionary principle

Are there barriers to the free movement of KETs-based products within the EU?

☒ **No**

Are there aspects of 3-D printing that need to be regulated at EU level?

☒ **No**

Are there actual or potential barriers to the free movement of 3-D printed products within the EU?

☒ **No**

Are there actual or potential barriers to the free movement of sustainable and environment-friendly products within the EU?

☒ **Yes**

If yes, please specify which are these barriers

Inconsistent market surveillance and varying national legislation hamper the free movement of compliant industrial products with respect to environmental legislation. We hope that the Commission proposal for a “Market Surveillance of Products” Regulation will ensure adequate enforcement of environmental legislation.

[3] A KET-based product is defined as a product induced by Key Enabling Technologies and/or produced by advanced manufacturing technologies. Examples are high-efficiency photonic LEDs; advanced batteries combining advanced materials and nanotechnologies for electro-mobility; biochips combining advanced materials, nanoelectronics and photonics to detect diseases; nanocomponents issued from nanoelectronics or mobile phones etc

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Nevertheless, we are still worried that some Member States impose diverging environmental rules creating barriers to the free movement of products complying with EU regulation. For example, some Member States impose a stricter interpretation of article 7 and article 33 of the REACH Regulation, stemming from the 0.1% w/w threshold referred to in these provisions.

The concepts "*sustainable goods*" and "*environment-friendly*", as well as "*green goods*" are vague. This gives Member States more room for imposing national criteria to the environmental labelling of goods and we therefore do not support moves to use or to define such criteria.

We support the strong implementation of the energy label, but we consider that the EU Eco Label should keep its voluntary character. Besides, the use of a methodology on the environmental footprint in EU legislation risks to be misleading: this would be particularly the case for information to consumers on the environmental performance of complex products, such as electrical and electronic equipment, and thereby would create market distortion (More on Orgalime's contribution to the consultation on delivering more sustainable production and consumption, 5 April 2012).

2) Simplification and alignment of existing rules

The marketing of a product in the harmonised area is typically regulated by more than one piece of Union harmonisation legislation. Overlaps, inconsistencies and even conflicts between different legislative texts should be eliminated as far as possible. These may for instance concern traceability and marking rules.

This section of the questionnaire therefore looks into the common features of the different legislative texts, for instance relating to traceability or conformity marking, so as to ensure that the rules are coherent and do not create unnecessary burdens for economic operators and market surveillance authorities.

Which type of legal instrument is more suited to the aims of technical harmonisation?

☒ **Regulations**

Are there overlaps or conflicts between different pieces of legislation that have an impact on EU industrial products?

☒ **Yes**

If yes, please specify which provisions of EU legislation are concerned, how they overlap and in what way they conflict

There are 3 categories of regulatory overlaps hampering the free movement of industrial goods:

1. There are overlaps in scope of EU legislation. Scope overlaps affect very negatively manufacturers as they do not know which conformity assessment procedure to apply and, where relevant, which notified body to address. For example:
    a. the scope of the REACH Regulation and RoHS Directive overlap since they regulate the same substance used in the same equipment and the same process (see relevant Orgalime position).
    b. the Commission's proposal for the Radio Equipment Directive does not clarify that Radio Equipment Directive should not apply where, for radio equipment, the

essential requirements referred to in Article 3 are wholly or partly covered more specifically by other EU directives. Therefore, we believe the text should recall the principle of "lex specialis", with a similar formulation as in the Machinery Directive (2006/42, Art. 3). (see relevant Orgalime position)

2. There is confusion among administrative requirements and conformity assessment methods that apply to each product. It is crucial to align European legislation for product's marketing needs with the New Legislative Framework and update the Guide to the implementation of directives based on the New Approach and the Global Approach (known as Blue Guide) accordingly.
3. National legislation should cease adding requirements for placing products on the market. The case of potable water is an example where there are frequent complaints from manufacturers.
4. Mistrust among Member States jeopardises the application of mutual recognition. The notification procedure of Directive 98/34 should be accompanied with a benchmarking of national legislation for non-harmonised sectors and legal action should be taken against trade barriers.

Are there categories of products that should be increasingly subject to mutual recognition and less to EU harmonised rules?

☒ **No**

Is there scope to broaden the essential requirements of some pieces of harmonisation legislation to cover a wider range of products from related industry sectors?

☒ **No**

Is there scope to merge the essential requirements of different pieces of harmonisation legislation?

☒ **Yes**

If yes, please specify which pieces of harmonisation legislation are concerned

In general the scope of harmonised legislation is specific to a given category of products or technologies and does not require further horizontal clarification across directives.

Nevertheless, there are cases, such as the Gas Appliances Directive, which should cover gas accessories for the installation of domestic sinks, which are currently covered by the Construction Products Regulation. This would improve the sinks' security.

Are there provisions in the internal market legislation for industrial products which could be identical and apply across a range of sectors in view of reducing divergence and potential conflicts between different legislative texts?

☒ **Yes**

If yes, which ones? Multiple-response question

☒ **Rules on free movement**
☒ **Rules on the obligations for manufacturers**
☒ **Rules on the obligations for importers**
☒ **Rules on the obligations for distributors**

☒ **Rules on the authorised representative**
☒ **Cases in which the obligations of manufacturers apply to importers and distributors**
☒ **Rules on the identification of economic operators**
☒ **Rules on conformity assessment procedures**
☒ **Rules on the presumption of conformity with standards**
☒ **Rules on the EU declaration of conformity**
☒ **Rules on CE marking**
☒ **Rules on notification, notifying authorities and notifying bodies**
☒ **Rules on penalties**
☒ **Rules on the validity of certificates of conformity**

In the case of capital goods which are developed and supplied to be used by professionals for the development of other products: do these products require a special treatment in harmonisation legislation?

☒ **Yes, they do not need to comply with the usual labelling and requirements for the accompanying documents shaped mainly to protect consumers, but they need to comply with the substantive requirements**

A) CE marking

Should CE marking be accompanied by other information, for example, labelling such as:

☐ A direct reference to the applicable legislation
☐ A marking(s) referring to the applicable legislation
☐ The notified body number
☐ The conformity assessment procedure

☒ **No**

<u>Are there elements concerning CE marking which can be</u> improved in view of ensuring a smoother functioning of the internal market for industrial products?

Market surveillance should limit the volume of non-compliant CE-marked products. Therefore, Orgalime supports the Commission's proposals in the Alignment Package and the Regulation for the Market Surveillance of Products: proportionate legal action should be taken against administrative non-compliance. A misuse of the CE marking, whether intentional or unintentional, may undermine the marking's validity in the consumers and economic operators' eyes.

<u>Accreditation, Conformity Assessment, Declaration of Conformity</u>

Should accreditation be made compulsory for the purposes of demonstrating the technical capacity of conformity assessment bodies?

☒ **Yes**

Should third party conformity assessment be required for all industrial products?

☒ **No**

Do you prefer the Single Declaration of Conformity being a simple compilation of individual Declarations of conformity?

☒ **Yes**

Do you prefer that each piece of product legislation provides for a customised Declaration of Conformity?

☒ **No, there should be one single template for the Declaration of Conformity**

Final general question

Are there any other suggestions you wish to make to ensure a smoother functioning of the internal market for industrial products?

Efficient and effective market surveillance remains the main challenge for a smoother functioning of the internal market. We hope that the proposed Product Safety and Market Surveillance Package will remove remaining barriers and ensure a level playing field for manufacturers of industrial products.

Limit gold plating which just undoes the benefits of harmonising legislation.

Mandatory third-party certification should only be used in strictly limited categories of products, such as for dangerous machines under the Machinery Directive. In most cases, manufacturers should be entitled to conduct internal product controls by themselves. Where they feel the need, it should remain their free choice to get support in conducting their conformity assessment from a third party body. As product certificates and markings are easily forged, third party conformity assessment cannot be a substitute to market surveillance for all industrial products. It would only add cost to legitimate manufacturers.

Whenever deemed necessary, **manufacturers should be allowed to use accredited in-house bodies**, where available. Such bodies are both cost-effective and importantly contribute to the improvement of the production processes, as the know-how acquired from the conformity assessment process stays in the company.

It is important to **ensure regulatory stability and predictability for manufacturers**. Once the on-going alignment of harmonisation directives with the New Legislative Framework is completed, these directives should be applied for numerous years without revision. This way, manufacturers could focus on the development of innovative products, without having to worry about changing conditions in the regulatory framework. For example, we were negatively surprised by the Industrial Emission's Directive, which shortly after its finalisation and implementation, is already moving towards re-discussing the scope of the directive to cover (very) small installations with a total rated thermal input below 50 megawatts. This does not contribute to legal certainty for our industries. Such changes practically mean that an important part of companies' innovation efforts and resources are occupied with regulatory compliance.

The revision of the Guide to the implementation of directives based on the New Approach and the Global Approach (known as Blue Guide) should clarify all disputable issues, e.g. e-commerce conditions and the possibility of having a single Declaration of Conformity in the form of a dossier.

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