

Brussels, 27 May 2013

Product Safety and Market Surveillance, strengthening confidence and competitiveness in the European marketplace

Orgalime Comments on the Commission Proposal for a
“Product Safety and Market Surveillance Package”¹

1. EXECUTIVE SUMMARY

Orgalime welcomes the objectives of the Product Safety and Market Surveillance Package as it strives to simplify and bring coherence to the legal framework for an improved enforcement of internal market rules. However, we invite the European Council and Parliament to adapt those features of the Package which, in our view, may undermine the objectives of simplification, coherence and proportionality, to the detriment of both European manufacturers’ competitiveness and the safety of consumers.

Product safety and enforcement of internal market legislation would be further simplified if:

- The ‘risk’ assessment to be carried out by the market surveillance authorities includes as a first step the compliance check with applicable Union harmonisation legislation;
- The scope of the Consumer Product Safety Regulation’s (CPSR) is clearly limited to non-harmonised consumer products;
- The unnecessary and costly indication of origin on consumer products is removed.

Product safety and enforcement of internal market legislation would be more coherent if:

- Obligations of economic operators were better aligned with Decision 768/2008, taking into account all possibilities of reducing administrative burden;
- European reference laboratories were accredited their role clarified so that they do not compete with conformity assessment bodies;
- The room for discretionary decisions by market surveillance authorities was minimised;
- The implementing powers conferred on the Commission had a limited scope and time-span
- The voluntary nature of standards was preserved;

Product safety and enforcement of internal market legislation would be more proportional if:

- Sanctions and penalties were related to the severity of the infringement and the level of illegitimate revenue derived from it, instead of the size of the undertaking;
- Economic operators were granted a cost-efficient right to redress;
- The precautionary principle is not used at enforcement level;
- Mandatory third-party certification is not introduced under the package.

¹ http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/market-surveillance/index_en.htm

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.

2. ORGALIME WELCOMES THE OBJECTIVES OF THE PACKAGE

Towards more consistent and efficient enforcement of European product legislation

Orgalime welcomes the objectives of the European Commission's proposal for a Product Safety and Market Surveillance package. We believe that the proposed Regulations, i) for market surveillance of products ([COM\(2013\)76 MSPR](#)), and to some extent, ii) for consumer product safety ([COM\(2013\)78 - CPSR](#)) provide for a good legal basis to:

- **Simplify and bring coherence to the rules applying to the marketing of products and to the enforcement of these rules**, whether for safety, environmental or other public interest issues and whether for products subject to Union harmonisation legislation or not.
- **Establish a system of “mutual assistance” between national Market Surveillance Authorities (MSAs)** (Art. 23, MSPR), co-operation with third countries (Art. 24, MSPR), and the **establishment of a European Market Surveillance Forum (EMSF)** (Art. 25, MSPR) supported by an EC Executive Secretariat (Art. 26, MSPR) and provided **with some financing powers** (Art. 29, MSPR).

→ **Orgalime invites the European Council and Parliament to endorse the Commission's ambition to harmonise the enforcement of harmonised product legislation.** We believe that this is central to achieving greater consistency and efficiency of enforcement, which would strengthen confidence in the functioning of the Internal Market, while at the same time providing greater legal certainty and predictability to companies, which is fundamental for Europe's economic recovery.

Manufacturers' investment into product compliance deserves protection

The overall legislative framework applying to the marketing of products on the European internal market has considerably grown in details and complexity over the past decade. This comes at a high cost for legitimate manufacturers who invest more and more resources, not only in testing and risk assessment, but also in burdensome procedures to demonstrate compliance of their products with all applicable requirements.

Manufacturers' investments in compliance need to be protected. Otherwise any incentive for higher compliance rates will vanish. This is especially true in the face of an increasing number of cases of unfair competition from rogue trading.

Adequate funding should be provided in support of this package

Adequate funding is key to unleashing this legislative package's potential to meet its objectives of improving product safety and compliance levels and supporting the competitiveness of the European engineering industry.

→ **Orgalime calls on the European legislator to provide for adequate funding in support of the accompanying “*multi-annual plan for market surveillance of products*”** ([COM\(2013\)76](#)). This could be achieved in particular via the financing scheme of the Structural Funds and by earmarking infringement fines (cf. CPSR Article 10) to fund at least part of market surveillance authorities' activities.

3. ORGALIME GENERAL RECOMMENDATIONS FOR IMPROVEMENT

Simplification for higher compliance levels and more efficient enforcement

The more complex and demanding the legal framework, the higher the risk to see more dangerous and otherwise non-compliant products on the market. Why? Because uninformed or unlawful market operators tend to save on risk assessment and compliance management.

→ **Orgalime calls on the EU legislator to make further progress towards a simple and coherent legal framework.** We recommend clarifying further the interface of both proposed Regulations with Union harmonisation legislation as aligned with Decision 768/2008. In particular:

- **In the MSPR**, the sequential steps of the risk assessment to be carried out by MSA should **include as a first step the compliance check** with applicable essential or material requirements of Union harmonisation legislation.
- **In the CPSR**, greater clarity is needed with regard to the scopes of application between the different pieces of Union legislation applying to consumer products and to remove unnecessary overlaps. We believe that this could be achieved by **focusing the entire scope of the CPSR on non-harmonised consumer products**, i.e. consumer products that are not already subject to the health and safety provisions of sector-specific Union harmonisation legislation.

Need for coherence and proportionality

Orgalime welcomes provisions at various places of the package calling for proportionality in the way authorities carry out their enforcement activities (e.g. in MSPR articles 6§3; 10§2; 16§3; 30§1; 31 and in CPSR Art. 8§3 and 8§4).

→ **However, Orgalime believes that greater coherence and proportionality are still needed in relation to:**

- **obligations of economic operators**, which should be fully consistent with those set in Decision 768/2008, bearing in mind the need to reduce the administrative burden on manufacturers, in particular SMEs, given the generally lower level of risk involved in non-harmonised consumer products;
- **sanctions and penalties**: these should not be related to the size of an undertaking, but be proportionate to the severity of infringement and the amount of undue revenue derived from it.

For a cost-efficient right of redress

Orgalime welcomes the right of redress in national courts mentioned in MSPR articles 10§7 and 16§5. However, experience shows that companies, especially SMEs, do not have the means to appeal to courts of law, due to the very costly and time consuming procedures.

→ **Orgalime suggests that market operators should be provided with a right of redress with an administrative body**, independent of the authority whose decision is challenged. The possibility of a third-party arbitration, preferably at European level (e.g. at EMSF level) would be equally welcome.

European reference laboratories should be accredited

Orgalime does not welcome the idea of introducing European reference laboratories (MSPR article 28§1) as long as their role in relation to the conformity assessment bodies intervening in the pre-market phase, and the assessment of their technical competence remain unclear.

→ **Orgalime requests clarification that such reference laboratories do not compete with conformity assessment bodies and that they must be accredited** according to Regulation (EU) 765/2008.

4. WRONG SOLUTIONS TO “FACILITATE” MARKET SURVEILLANCE

Conversely, we call on the European Parliament and the Council to refrain from wrong solutions, which could have a detrimental impact on the competitiveness of European manufacturers. This would be particularly the case with the following six regulatory approaches:

Wrong solution 1: Opening up room for discretionary decisions by market surveillance authorities

Orgalime is wary of a number of provisions leaving MSAs with too much room for interpretation during their risk assessments. It is not the task of national and local authorities to substitute the EU legislator in setting the acceptable level of protection for categories of users; their task is to check whether the product has been lawfully made available on the market or not.

→ Therefore, **Orgalime calls on the Parliament and Council to reduce as much as possible room for discretionary decisions by market surveillance authorities** in the following provisions:

- The concept of ‘*product presenting a risk*’ (MSPR, Article 3.13) should include the compliance check with Union harmonisation legislation as a first step;
- Instances of formal non-compliance should **not**, as such, give sufficient reason to believe that the product may “present a risk” (MSPR, Article 9§2)².
- The possibility to challenge the legislation itself should not be granted to enforcement authorities (MSPR, article 13§3) should they consider that ‘new evidence’ implies that a product ‘presents a risk’, despite compliance of the product in question with harmonised legal requirements.

Wrong solution 2: Precautionary principle at enforcement level

If the precautionary principle were to be re-introduced in the CPSR, or worse, in the MSPR, it would open up the ground for arbitrary bans and marketing restrictions from local inspectors.

As clearly stated in Article 114 § 3 of the Treaty on the Functioning of the European Union, **the precautionary principle is for use by the legislator only in the face of scientific uncertainty**³. Local authorities have neither the means, nor the legitimacy to devise – instead of the legislator – the acceptable level of protection for safety or other public policy objectives.

→ Orgalime calls on the Parliament and Council to **refrain from introducing the precautionary principle** in either the CPSR or MSPR.

Wrong solution 3: Regulatory or de-facto mandatory third-party certification

Contrary to common belief, introducing mandatory third party testing and certification would not make products safer or ‘greener’. Rather, it would only cause unnecessary costs and burden for reputable manufacturers. Even worse, it would give yet more competitive advantages to those

² Nevertheless, customs authorities, who trace counterfeit products during their administrative checks, should consider them as suspicious for presenting non-compliance or a risk. Counterfeit products are often accompanied by counterfeit CE marking and have neither undergone conformity assessment, nor been declared by the original manufacturer to be in conformity with the applicable EU legislation. Therefore, we aspire Regulation 5129/2013 and the PSMSP to promote the cooperation between market surveillance and custom’s authorities and enhance the physical controls of counterfeit products either at customs or after these are placed in the internal market.

³ See also the Commission communication on the precautionary principle [COM/2000/0001 final](#)

manufacturers who do not care about following the law. There are at least 3 pieces of evidence in support of this:

- Third party certificates and marks are forged and counterfeited as easily as the CE marking, especially where they represent a marketing asset, as the GS mark in Germany. Many examples of dangerous products bearing marks of reputable third-party test houses are on display in the RAPEX notification system⁴. Certifiers themselves warn against the forgery of their own marks and publish “black lists” of misuse⁵.
- Even if the certificate is correct, third party testing of product samples cannot as such ensure the conformity of the production and that the final product placed on the market is actually safe⁶ or otherwise compliant.
- Experience shows that effective market surveillance is equally necessary in those regimes in other world regions (e.g. China) that provide for mandatory third- party certification. This is also why a significant share of MSA does not believe in the extra guarantee from third party testing⁷.

→ **Orgalime therefore calls on the European Parliament and the Council to refrain from introducing any role for third-party certification** in either of the proposed Regulations. It should remain the free choice of market operators (or public authorities) to resort to this private service, free from regulatory interference, *(as stated in a study on the market surveillance of electrical equipment in Finland⁸)*.

Wrong solution 4: Unlimited implementing powers for the EC

The proposals provide for the delegation to the European Commission of implementing powers in relation to a number of measures that are of critical importance to manufacturers (MSPR Article 6§1; MSPR Article 9§5 and CPSR Article 13§2 and 13§3; MSPR Articles 12§1 and 18§4). These powers should not compromise the legal certainty that manufacturers enjoy, especially under harmonised legislation.

→ **Orgalime invites the European Parliament and the Council to:**

- **Limit the scope of possible implementing acts**, especially those that set marketing restrictions for entire categories of products or risks. Restrictive measures of a permanent nature should preferably undergo the appropriate legislative procedure and be adopted by the European Parliament and Council.
- **Limit in time such measures to 2 years** as a general rule for all products (e.g. in MSPR Article 12§1), not only for those covered by the REACH Regulation (MSPR Article 12§2).
- **Oblige the Commission to systematically consult “Organisations representing the interests of industry, small and medium-sized enterprises, etc...”** (MSPR Article 25§6) in the preparation of implementing acts, for example **through a consultative Board of stakeholders attached to the European Market Surveillance Forum** (MSPR Article 25).

⁴ Examples of RAPEX notifications showing numerous photo examples of dangerous products bearing a third-party mark: e.g. in 2013, reports n°2, n°7, ref. [A12/0042/13](#); reports n°4, n°5, ref. [A12/0133/13](#); report n°6, 23, ref. [A12/0190/13](#); n°36, ref. [A12/0203/13](#); n°40, ref. [A12/0207/13](#); reports n°10, n°12, ref. [A12/0387/13](#)...

⁵ For instance : [TÜV Rheinland](#) ; [TÜV SÜD America](#) ; [VDE](#) ; [CSTB](#) ; [UL](#)...

⁶ In 2005, a third-party certified electric iron killed 3 in Greece: the surface coating submitted to type testing was changed on the marketed product, from a neutral into a metallic one that was in contact with live parts. RAPEX notification n°2-203/05 model “CIR PERLA 2038C” from China. [More](#).

⁷ 21% of the respondents to the inquiry for the “evaluation of the feasibility of a consumer safety mark”. Framework Contract on Evaluations ENTR / 04 / 093, Lot 1 DG Enterprise and Industry, Final Report, 1 October 2008. [More](#) on p 41.

⁸ “Third party certification should not be mandatory but be used on a voluntary basis as appropriate. Unsafe products, brought to the market by criminally negligent manufacturers who also falsely use SDoC as certificates, undermine the credibility of both types of conformity declaration”. TUKES Publication 9/2002. Market Surveillance of Electrical Equipment in Finland. Analysis and Development. Jyri Rajamäki. The Safety Technology Authority, Helsinki 2002. [More](#).

Wrong solution 5: Turning standards into de facto mandatory requirements

Orgalime is concerned that the European Commission could use its implementing powers to turn voluntary European standards into *de facto* mandatory requirements.

Unlike what is stated in the CPSR (Article 16§1), a European standard does **not** primarily “*aim at ensuring that products that conform to such standard comply with the general safety requirement*”. The manufacturer must respect the law. It must, however, remain the manufacturers’ free choice whether or not to use a European standard. Any new specific safety requirements decided by an implementing act should be addressed to all manufacturers concerned, as is currently the case under Union harmonised legislation.

→ Orgalime calls on the European Parliament and the Council to further align the CPSR with the New Legislative Framework and to explicitly require:

- the Commission to determine in the text of an implementing act any relevant consumer safety requirements. The resulting Commission Decision should be addressed to all manufacturers concerned, not only to European standards organisations.
- the publication in the OJEU of such an act adopted by Commission Decision.

Wrong solution 6: Indication of origin: unnecessary, burdensome and costly

Orgalime is against the requirement to indicate the origin of consumer products (CPSR Article 7), although some of its members see some benefits in this. This proposal was neither covered by the impact assessment, nor is it contained in the New Legislative Framework, and would in most members’ view:

- neither improve consumer safety nor product traceability, which are already ensured by other means in harmonised legislation and in the CPSR (e.g. CPSR Article 8 point 7);
- create confusion for consumers of products that integrate components and systems sourced from a complex worldwide supply chain, for which the representation in the form of a single indication of origin would have little meaning, be difficult and costly from an administrative perspective;
- add yet another task for understaffed and under-resourced enforcement authorities.

→ Orgalime suggests deleting article 7 of the CPSR on the “indication of the origin”.

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N.B.: Our detailed comments and suggestions for amendments to the MSPR and CPSR proposals are provided in separate position papers.

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