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Simpler and more effective Market Surveillance of Products is urgently needed

Executive Summary

In its Communication on a Renewed Industrial Policy Strategy for Europe (13/09/2017), the European Commission announced “rules (...) to revise the rulebook on market surveillance”.

For this upcoming Commission proposal on the enforcement of Union harmonisation legislation applying to products, Orgalime, which represents European engineering industries as a whole, calls on the European Commission to table a proposal that will effectively improve and facilitate economic operators’ demonstration that their products are compliant with the law. It must also aim to reinforce the means to deter rogue and non-compliant economic operators.

Orgalime has repeatedly called for setting up an enforcement framework that is supported by Member States, which facilitates compliance through education and guidance, and imposing minimal burdens on legitimate economic operators while tightening the control on those elusive few who try to cheat the system.

This paper draws on previous Orgalime positions in the area of market surveillance. It addresses various issues including the scope of the legislation or the definitions to be included. It includes a tentative proposal for a Union market surveillance framework that would allow market surveillance authorities to act swiftly, efficiently and effectively to deter rogue economic operators. Within this framework, it is important to consider the organisation of the control of products within the Union as well as the control of products entering the Union, the exchange of information and coordination and cooperation. Finally, it is important to consider how the available financing can be best used and how penalties should be imposed.

We trust this position will add a constructive and supportive voice to the discussions.

Orgalime, the European Engineering Industries Association, speaks for 41 trade federations representing the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs nearly 11 million people in the EU and in 2016 accounted for some €2,000 billion of output. The industry represents over a quarter of the output of manufactured products and over a third of the manufactured exports of the European Union.

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Orgalime welcomes the European [Commission's communication on a Renewed Industrial Policy Strategy for Europe \(13/09/2017\)](#), which announces “rules (...) to revise the rulebook on market surveillance to better assist the more than 500 national market surveillance authorities in coordination and performance of their tasks.” (on page 6 paragraph 2).

At the eve of a new Commission proposal on the enforcement of Union harmonisation legislation on products, due to be launched before the end of the year, Orgalime industries call on the European Commission to table an ambitious text that would improve and facilitate economic operators' duties in demonstrating that their products are compliant and that will reinforce the means to deter rogue and non-compliant economic operators.

1. Industry calls on Member States to support an ambitious enforcement framework

To date, less than one per cent of the products of our industry imported through ports and otherwise placed on the Union single market are physically checked for compliance with EU harmonisation legislation; almost none are for compliance with energy or environment requirements.

However, the complexity of EU legislation that applies to those products is growing at a rapid pace; even more so the conformity assessment procedures and related costs that manufacturers are expected to bear to demonstrate compliance of their products to the law. Unfortunately, this investment of legitimate manufacturers is not protected.

Therefore, Orgalime calls on the European Commission to table an ambitious proposal to ensure that legitimate manufacturers that invest into product compliance can continue to operate in a level-playing field, especially at a time of growth of imported products sold through digital platforms.

2. Make it easier for everyone, but rogue economic operators

The future legislative proposal should ensure that EU law on compliance, enforcement and market surveillance is kept simple and that unnecessary burdens are removed. As suggested in the inception impact assessment of May 2016 and the subsequent questions to the public in targeted consultations, we expect the new European Commission's proposal to facilitate the way economic operators should demonstrate their compliance with EU harmonised requirements.

To make the everyday lives for legitimate operators easier and, as a true relief on bureaucracy, the electronic transmission in digital format of the Declaration of Conformity, the technical file and other required compliance evidence – when required by market surveillance authorities in the performance of their checks –, should be accepted by all MSAs throughout the EU. However, digital compliance can in no way replace physical checks and on-the-spot controls of products placed on the market or at the borders of the EU.

An improved market surveillance framework must foremost address the legal “outsiders”, that deliberately cheat on the rules and do not care about providing evidence of their conformity with the law. This is why an online register that would store the technical files of lawfully operating producers would not detect the dangerous behaviour of non-compliant operators. Instead, such a digital compliance system would only add bureaucratic burdens to legitimate operators - especially small businesses - that are already struggling hard to be fully compliant while remaining competitive.

3. Make compliance procedures simpler

We believe that the decisive factor in making market surveillance effective is that all actors involved assume responsibility for their particular field of duty. Such a virtuous circle of responsibilities starts with the EU regulator itself, by adopting appropriate and easily applicable laws and by keeping compliance costs low, and proportionate: this is essential from the perspective of both economic operators and Member States which face resource constraints.

Market surveillance authorities should co-operate and mutualise efforts, starting with reinforced physical checks already upon arrival in ports and on the market by all Member States in accordance with the “culture of compliance” promoted by the Commission and with the objective to deter rogue operators.

The more complex the world and its challenges, the simpler the rules: this maxim will produce a “win-win” that will facilitate the tasks of both economic operators to comply and national authorities to enforce, with a better EC-led co-ordination at European level and a smart partnership with stakeholders. The inclusion of soft market surveillance in terms of education and guidance will further increase capacity across stakeholders and eliminate unintentional non-compliance.

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See detailed Annex attached

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Annex

Orgalime's recommendations ahead of the European Commission proposal on Enforcement of Union harmonisation legislation on products

This position groups the Orgalime industries' main concerns and expectations ahead of the European Commission's announced regulatory proposal that would improve the enforcement of Union harmonisation legislation on products and facilitate economic operators' duties in demonstrating that their products are compliant with it.

This position builds on the policy options envisaged in the [Inception Impact Assessment on "Enforcement and Compliance"](#) (13/05/2016), the questions raised during the public consultation (August-October 2016) and, for the ease of reading, borrows its structure from the previous [Commission proposal of a Market Surveillance of Products Regulation](#) (MSPR COM/2013/075 final - 2013/0048 (COD)) which has been stalled in the Council of the EU since 2014.

All the following Orgalime suggestions are made with due consideration for the [Blue Guide on the implementation of EU product rules](#)" (last updated 26/07/2016).

1) Scope

a) Union harmonisation legislation and the General Product Safety Directive (GPSD)

Orgalime has great expectations that this new Commission proposal will finally acknowledge **maintaining a level-playing field among market operators as a core policy objective** of the envisaged enforcement legislation, next to safeguarding a high level of the health and safety of persons, workers, consumers, the environment, public security, and other public interests. This would be necessary to meet this Commission's ambition to secure growth and jobs in Europe.

Should the scope of the proposed Regulation apply to both product-specific harmonisation legislation and the GPSD which is user-specific (consumers), it should be clarified that compliance with Union legislation for products takes precedence over the GPSD when the product is intended to be used by consumers. Consequently, no additional evidence or compliance procedure should apply on top of Union procedures for market surveillance in the Member States.

b) Online platforms and fulfilment centres

It is important to more efficiently address the control of products made available via e-commerce, through the facilitation of online platforms and the services provided by fulfilment centres. To achieve this the European Commission has given hints of its intention to consider **fulfilment centres** and **online platforms as distributors** in the supply chain (whether these are established within the EU or not).

Orgalime calls on the European Commission to **set out** in its proposal **clear criteria for considering fulfilment service providers as distributors**, when these "*provide services (...) which go beyond those of parcel service providers*" and to oblige them to "*fulfil the corresponding legal responsibilities*". A mere shipping or parcel delivery service provider should not be considered a distributor.

c) Liability under Union harmonisation legislation

Orgalime believes that the new proposal should clarify the distinction between:

- the persons liable for placing products on the Union market who are the manufacturer, his authorised representative, or the importer (see definitions of economic operators in Decision 768/2008/EC) and
- the persons responsible for providing the contact details of the liable person, that are service providers to these liable persons and other economic operators

There is almost always a contact person based in the EU that could facilitate market surveillance work to trace back the person liable for placing products on the Union market. Furthermore, manufacturers are already obliged under some Union legislation such as Directive 2006/42/EC (Annex II, No. 1 A, No. 2: to provide the name and address of the person authorised to compile the technical file, who should be established in the European Union).

2) Definitions

Re-iterating the need for a definition of “non-compliance” as well as the definitions of “product presenting a risk” and “product presenting a serious risk”:

While the GPSD and the European Commission proposal of a Market Surveillance of Products Regulation (MSPR) proposal have definitions for a product presenting a “risk” or a “serious risk”, Orgalime calls on the European Commission to introduce a definition for “non-compliance”, which is missing in the MSPR, that characterises products placed on the market that **fail to comply with the essential or other material requirements of Union harmonisation legislation**.

The definition of a product presenting a risk defined in the MSPR was not satisfactory, because there was no distinction between *formal/administrative non-conformity* and *technical/material non-conformity*. Therefore, we urge the European Commission to adopt in its new proposal the **concept of “formal non-compliance”** as foreseen in the New Legislative Framework (NLF) in **Article R34 of Decision 768/2008/EC** for the following reasons:

- Instances of **formal non-compliance** (such as the incorrect size of the CE-marking) should not, as such, give sufficient reason to believe that the product may present a “risk”¹. Such an approach may lead to disproportionate measures. More importantly, it would dilute the general concept of risk conveying a material hazard in relation to the public interest at stake.
- This issue becomes ever more important as we observe a growing number of purely formal requirements in EU legislation which increasingly invite Market Surveillance Authorities (MSAs) to concentrate their efforts on detecting formal non-compliance issues, rather than focusing on material safety/non-compliance problems.

The manner to deal with formal non-compliance was clearly stated in the Commission working document N. 2015-IMP-MSG-15 “[EU general risk assessment methodology](#)” of 16/10/2015, last paragraph of clause 4 (Page 16).

¹ 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.

3) Union market surveillance framework

a) General obligations of market surveillance authorities (MSAs)

Orgalime believes that it is of the utmost importance that MSAs can act swiftly, efficiently and effectively to deter rogue economic operators from placing dangerous products and otherwise non-compliant products and serviced solutions on the Union market.

In this context, Orgalime suggests clarifying in the expected European Commission's proposal that **MSAs should:**

- **Be organised with a view to ensuring that effective, efficient and proportionate measures are taken to mitigate both the risks to end users and unfair competition to legitimate market operators.**
 - *'Efficient measures'* of market surveillance are of paramount importance to ensure the effective functioning of Internal Market legislation. For example, Member States should step up their efforts by reinforcing their legislation so as to be dissuasive for deliberately unlawful market operators,
 - Conversely, *'proportionate measures'* refers to the educative role of enforcement for operators willing to improve their business process, further to adequate dialogue with market surveillance authorities, as provided for in Article 6 § 2 of the MSPR.
 - The MSA has to be able to take measures against every legal person acting in the distribution chain, including those that are not explicitly mentioned as an economic operator under NLF-type legislation.
- **Be encouraged to participate in national standardisation activities** aimed at the development or revision of standards requested by the Commission in accordance with Article 10 of Regulation (EU) N° 1025/2012.
- **Not be given the right to challenge the relevance of the law itself**, as was unfortunately the case in the MSPR proposal (cf. Article 13 – paragraph 3 and Article 15 – paragraph 3). This would potentially be a major source of legal uncertainty for market operators and would further undermine the internal market.

b) Assistance and cooperation with economic operators: partnerships and points of contact

The Inception impact assessment paper rightly stresses the need for more assistance for economic operators, especially SMEs and for co-operation with market surveillance authorities. This dimension was missing from the MSPR.

- **Information points of contact as in Regulation 764/2008/EC**
Orgalime suggests that the **Points of Contacts** established under Regulation 764/2008/EC (Mutual Recognition) could also provide assistance to economic operators for application issues under Union harmonisation legislation. This would require some co-ordination and assistance from the European Commission to ensure that such a service could be delivered with the adequate level of skills concerning the applicable body of Union harmonisation legislation, possibly in coordination with the Euro Info Centre Network.
- **Partnerships**
Orgalime calls on the Commission to enable the possibility for Market Surveillance Authorities (MSAs) to set up **partnerships with economic operators** in order to collect advisory expertise in relation to the application of a harmonisation Directive or Regulation. **Such partnerships should be "officially" made possible between businesses, trade**

associations and MSAs, to assist authorities in identifying cases of non-compliance or to promote compliance behaviours in a given industry sector and/or geographical outreach.

Such partnerships could be useful both at a national level (within the country of the MSA and the economic operator) and at the EU level (between an economic operator and several MSAs in the countries where the economic operator is active).

This could be translated rapidly into practice, building on already existing private initiatives at national level (such as [ASEC](#), active for the past 10 years in France) in cooperation with a dedicated MSA contact (such as in Germany with the '*Richtlinienvertreter*') and at European level (such as [MSSI Electrical](#) since 2016).

Such an agreement should be established **under clear criteria of independence and impartiality**, which could be devised at the European level, possibly under the comitology procedure, whereby all possible conflicts could be ruled out such as:

- conflicts of interests (as for instance those of conformity assessment bodies);
- conflicts with anti-competitive behaviour under competition law.

The creation of such partnerships is in line with current evidence that supports how public regulators in a contemporary Western European democracy should seek to affect the market behaviour of traders (C. Hodges, 2016).

4) Control of products within the Union

a) Risk assessment

The first step of the MSA's risk assessment should be to determine whether the product is covered by applicable Union harmonisation legislation and to ensure that the essential requirements contained in such legislation are properly taken into account in the risk assessment by the enforcement authorities.

b) Products that present a risk

To minimize legal uncertainty for economic operators, the risk assessment should focus on enforcing applicable legislation and minimising room for interpretation by local market surveillance authorities. To avoid any distortions between Member States, a harmonisation of the risk analysis for a given product should be made under the responsibility of a European Organisation involving all experts.

As devised in its [EU general risk assessment methodology](#) (Action 5 of the Multi-Annual Action Plan for the surveillance of products in the [EU \(COM\(2013\)76\)](#), "*The risk assessment of a harmonised product is inherently linked to the evaluation of its compliance with legal requirements*". The MSA has to take into account the state of the art for the degree of the fulfilment of the essential requirements of the Harmonisation Legislation.

Contrary to what was inferred by Article 9 §2 of the MSPR, instances of formal non-compliance (such as the wrong size of the CE marking) should not, as such, give sufficient reason to believe that the product may present a "risk". See above our suggestion to provide a definition of "non-compliance" and to handle formal non-conformities without reference to the concept of "risk" as foreseen in Article R34 of Decision 768/2008/EC.

c) Union assessment for products controlled within the Union and subject to harmonisation legislation

- We expect the new Commission proposal to stipulate that:
 - When carrying out their tasks, MSAs should duly take into account the manufacturer's risk assessment report and third party test certificates, if any;
 - Immediately inform the liable economic operator of any enforcement action against its products,
 - Allow the economic operator to take appropriate measures to collaborate swiftly with the authority to protect its reputation and consequently protect the end-customer, as far as possible.

- **Digital means should be allowed to show compliance, on a voluntary basis**

At a time when everything is going digital, the European Commission proposal would be well advised to allow all MSAs to accept the possibility of substituting the postal address on products or packaging by a web address: it would allow for quicker access to relevant information, including a unique physical address in several countries, which can be updated when needed. Such a choice to use web compliance or not should remain entirely with the manufacturer.

Furthermore, the manufacturer should be able to provide the declaration of conformity with applicable Union harmonisation legislation in electronic format, such as in a portable document format (PDF, via email) or in HTML format in a Web-based document repository solution hosted by the manufacturer. Of course, these options should be made possible as an alternative to the existing paper format.

Any economic operator whose product is deemed non-compliant by market surveillance authorities should be granted the opportunity to demonstrate the compliance of the product with the law and to answer the MSA within a reasonable time.

- **Provide rapid remedies against a disproportionate mandatory withdrawal or ban on the sales of his products on the market.**

In the face of a disproportionate or unjustified enforcement decision, economic operators should have a **possibility of repeal from a third party that is not systematically the national courts**. Businesses must have access to an efficient and effective redress in cases of restrictive measures taken by national market surveillance authorities. Where appeals are limited to national courts, the associated costs and time spent proves to be deterrent for companies seeking remedy.

Some disputable restriction measures by market authorities represent a significant barrier to the free movement of goods within the Internal Market. Arbitration or other alternative dispute resolution by a standing sub-group of the European Market Surveillance Forum could act as a useful facilitator.

d) Union action against products presenting a 'serious risk'

Either the product is compliant or it is not. Therefore, the 'risk' assessment to be carried out by the MSAs should include as a first step the compliance check with applicable Union harmonisation legislation; instances of **formal non-compliance** (such as an incorrect sizing of the CE-marking) should not, as such, be considered as sufficient a reason to believe that the product may present a "risk" while we expect that MSAs be allowed to challenge the presumption of conformity only in case of a "*serious risk to (...) the environment or any other public interest*" (as referred to in Article

27 paragraph 3a of Regulation (EC) 765/2008), according to an EU harmonised risk assessment methodology applicable to both MSAs and Customs authorities.

As the situation is exceptional, it should require a reversal of the burden of proof so that the authorities would be obliged to duly justify their decision and the action taken. Subsequently, the risk should be notified through the RAPEX procedure.

e) Measures taken by market surveillance authorities (MSAs)

- To request any information from economic operators to demonstrate compliance **further to a reasoned request**

As explained in the Blue Guide (26/07/2016, OJEU C272, p.31), the market surveillance authority should explain to the manufacturer “*the context in which the information is requested (e.g. inspection on specific characteristics of the products, random checks, etc.)*” so that the manufacturer can “*provide the part of the technical documentation related to the claimed non-conformity and appropriate for demonstrating whether the issue has been dealt with by the manufacturer*”.

This is why **Orgalime is opposed to a blind digital compliance system** which would oblige manufacturers to upload unspecified information to the system, without a possibility for dialogue between the economic operator and the authority. Such dialogue is in fact, the best way to bring willing economic operators to the path to improved compliance.

- **Possibility of inspecting the premises of fulfilment centres**

As suggested in our [position paper of 13/02/2017 on online trade](#), we believe that **MSAs should have the right to access the premises and warehouses of fulfilment centres**, obtain samples of products and their respective declarations of conformity, or get information from fulfilment centres to trace back the importer or the manufacturer established outside the EU/EEA. They should be able to impose mandatory measures such as sales prohibitions in case the controlled products are not compliant with EU legislation.

However, fulfilment centres should be required to provide information that exceeds their specific role in the supply chain. Just as with the case of installers, dealers, suppliers, etc., they can and should only be required to provide information to a reasonable extent, given their specific role or commercial activities.

f) Products presenting a non-conformity with EU harmonisation legislation:

We understand that the Commission is considering **entitling consumers or professionals to seek remedies directly** from the manufacturer **in case of non-conformity** by virtue of [Directive 1999/44/EC of 25 May 1999](#) “*on certain aspects of the sale of consumer goods and associated guarantees*”.

When the manufacturer signs a declaration of conformity for a given product and affixes the CE marking on it, it could be conceived as a kind of contract between the manufacturer and society at large, but hardly with a given customer in particular.

It would be therefore surprising to see an entitlement for private remedies in a policy proposal aiming at sanctioning breaches to public order law. Such remedies are provided under the different grounds of civil laws, starting from the demonstration that the victim’s claim is for a real damage or a loss she/he would have suffered in relation to the non-conformity.

Therefore, were such a provision to be incorporated into the future Commission proposal, it would blur the lines between criminal and civil law and require at least an administrative decision of the MSA to open an entitlement for civil compensation in case of a non-conformity of a product with public order law.

Besides, we have serious doubts about the effectiveness of such a provision for deterring rogue economic operators, especially those established outside of the territorial sovereignty of EU Member States.

Finally, it may not be ethical to open a private right for financial compensation to entitle the end-user continuing to mitigate an “illegal” risk, which stems from the non-conformity of the product.

g) “Gold-plating”: National/local technical barriers to trade

The current regulations (EC) 765/2008 and 1025/2012 EU provide for the European Commission to act against Member States that would impose national standards as a technical barrier to trade. Orgalime suggests for the proposed Regulation to include a similar clause.

5) Control of products entering the Union

Orgalime calls on the Commission to require **customs authorities to carry out controls** at the point of entry into the European Union and to co-operate systematically with MSAs.

a) Checks and suspension of release – contact person

To facilitate controls, **Orgalime would support the idea that any economic operator established outside of the EU** would be required to have a **point of contact in the EU** responsible for providing MSAs with contact details and elements of the demonstration of conformity with EU law.

Such a person could be the fulfilment centre or online platform that necessarily has the contact details of the original manufacturer or supplier responsible for the placing of products on the EU single market.

Controls of the misuse or abuse of the affixing of the CE marking and other mandatory Union markings on products should be tougher.

b) Release – for a special status for Authorised economic operators

As requested by Orgalime in its [position of 10/05/2012](#), on the role of **Authorised Economic Operators (AEO)** under the Union Customs Code – currently accredited to facilitate imports into the EU – the AEOs should be given more responsibilities to verify that imported products are indeed intended for the European market and should be made responsible for facilitating the provision of compliance information to the authorities, including the declaration of conformity, on a reasoned request.

6) Exchange of information

a) Union Rapid Information Exchange System – RAPEX

In contrast to the MSPR, we urge the European Commission to reserve the Rapid Alert system for non-food products ([RAPEX](#)) for cases involving a serious risk that require immediate action. All other cases should be dealt with through the Information and Communication System on Market Surveillance ([ICSMS](#)).

Now that the European Commission owns ICSMS, the future Commission proposal should **increase the role of ICSMS** to collect and structure the information on verified cases both of compliance and non-compliance with Union harmonisation legislation.

Economic operators may use the ICSMS, on a voluntary basis, should they wish to inform authorities and the general public of compliance issues that they have encountered after the making available of their products on the market of several Member States. This would include the voluntary measures that they may have taken to correct or mitigate the risks stemming from such a situation.

b) Notification through RAPEX of products presenting a risk

Orgalime suggests adding to the information to be provided for market surveillance measures, the arguments put forward by the manufacturer or the relevant economic operator. This is consistent with Article R31 § 5 of Decision 768/2008/EC and necessary to protect the interests of the economic operator.

It would also allow other Members States to be in a position to judge whether there could be grounds to question the provisional measure taken.

c) Information and communication system for market surveillance

Orgalime suggests that the communication on market surveillance measures by the Commission should be made "without delay". This would avoid keeping the national measure on hold for too long, to the detriment of the economic operator concerned.

We hereby reiterate our firm rejection of a digital compliance system which would be unacceptable for industry, since in our view it would be disproportionate in terms of costs and burden on manufacturers, entail risks of losing confidential business data, know-how and intellectual property rights (IPR) and raise uncertainties concerning liability and negative consequences on businesses in the case of a technical or similar failure of the database.

In addition, if future compliance control were performed by reviewing data in a European database, the data in the database itself must be verified to ensure that it is correct and complete. Otherwise, it would provide a competitive advantage for irresponsible market operators. By entering incorrect data in the database, or not registering a product at all in the database, actors could avoid further product compliance checks. This would damage overall consumer trust in the CE marking.

Finally, the Commission proposal should require MSAs to safeguard Intellectual Property Rights, confidential business data and know-how transmitted by electronic means.

7) Coordination and cooperation

a) European cross policy co-ordination platform of national market surveillance authorities (MSAs)

Orgalime welcomed the MSPR proposal for a “European Market Surveillance Forum” and expects the European Commission to devise a similar provision in its new proposal. It is important that the Commission engages with Member States to help in providing their enforcement authorities with the necessary financing, staff and expertise to perform their tasks.

In addition, we suggest setting up a standing Advisory Board composed of relevant EU stakeholders (including manufacturers and importers) to provide input to a possible European coordination platform of MSAs. This should take a similar form to the European Accreditation Advisory Board.

Such a consultative body would enable a coherent and regular dialogue between European stakeholders, the Commission and MSAs, with a view to providing:

- input about risk assessment methods and priority settings for both market surveillance and import controls, detecting problems and needs, collecting expertise and views on areas of concern (implementation at national level), as well as providing concrete suggestions for the elaboration of a general methodology of compliance and risk assessment;
- feedback on guidance documents for MSAs and economic operators;
- guidance to harmonise risk assessment for a given product family.

b) Commission support and executive secretariat

Orgalime suggests that the Commission in its upcoming proposal:

- provides guidance (Blue Guide), perhaps via implementing acts, on the interpretation of provisions for the enforcement of Union legislation;
- determines criteria for a proportionate risk assessment by product family or sectors;
- sets in place ad hoc pre-import control systems in cooperation with third countries without establishing a more favourable system for imports than for domestically manufactured products;
- sets independency, neutrality and legitimacy criteria for establishing cooperation agreements between MSAs and economic stakeholder associations that would be ready to provide support in intelligence or in kind (test reports);
- sets criteria to help Member States to update their fines and sanction legislation in a more coherent Europe-wide manner.
- commits to evaluating the impact of the regulation no later than 5 years after its coming into force.

c) European Union reference laboratories

A proposal to designate reference laboratories across the EU for market surveillance purposes was tabled in Article 28 of the MSPR, but to our knowledge, received weak support from several Member States.

Orgalime is not in favour of the creation of a new laboratory category. Rather, the European Commission should, in our view, consider setting up a network of test laboratories attached or linked to MSAs.

Should the European Commission deem it necessary, such a network of laboratories would ensure an EU-wide harmonisation of the testing methodology, a harmonised risk analysis and the ability to perform large test campaigns, on the request of several MSAs on the same range of products, provided that:

- the test results could be shared across all EU Member States authorities
- the reference laboratories would undergo the same accreditation programme as conformity assessment bodies;
- it is ensured that these laboratories would not compete with other accredited laboratories in providing services to the private sector, as Orgalime stated it in its [position paper of 27/05/2013](#);

8) Financing

a) Dedicated operational Union budget

In Orgalime's opinion, a **dedicated Union budget** should be allocated to stronger co-ordination among Member States, including the sharing of test results, training, joint actions, meetings, etc... This would be especially useful to give incentives to both member States and privately organised market surveillance support initiatives to exchange intelligence about market surveillance priorities and other relevant information about sector-or-geo-specific situations of non-compliance that could lead to users being put at risk and unfair competition to legitimate economic operators.

b) Administrative compliance verification fees

In the public consultation, the possibility to empower **MSAs to claim fees from operators** whose products would have been found not compliant was evoked. If it is a fair and transparent claim to be compensated for the compliance assessment costs incurred by the authority, this may be a way to increase the deterrence of controls by MSAs, as these will be less dependant on budget restrictions. Conversely, such a system should not be turned into a cash machine to the detriment of market operators.

Were this be envisaged in the future proposal of the Commission, Orgalime calls on the Commission to clarify that such administrative fees:

- should apply exclusively to costs incurred for physical checks on products, not to cases of formal non-compliance;
- cannot be claimed prior to a reasoned request to the economic operator, so as to avoid initiating a costly compliance verification procedure when evidence of conformity could be easily provided by the manufacturer;

- should not exceed the actual cost incurred by the MSA at an equivalent or cheaper rate than conformity assessment services available on the market;
- should be recoverable by the manufacturer or the importer from the authority in case the manufacturer can produce evidence that the product is technically compliant;
- should take into account the good or bad record of compliance of the market operator so as to incentivise first time offenders to learn from their mistakes (no fee or a reduced fee for the first instance of non-compliance);
- are not used as a substitute to a fine or a sanction in case of repetitive negligence or fraud;

9) Final provisions – Penalties

Orgalime supports the use of penalties as a deterrent to market operators who cheat. Compliant businesses are more likely to succeed in a level playing field where competitors who cut corners and flout the rules are penalised.

Therefore, we call on the European institutions to encourage Member States in stepping up their national legislation on penalties so as to be more effective and deterrent against rogue traders that voluntarily circumvent applicable EU harmonisation legislation.

However, penalties must be both dissuasive and proportionate. The size of the undertaking in this context is irrelevant. **Rather, sanctions should be proportional to the seriousness of the infringement and the amount of illegitimate revenue** generated by the placing of non-compliant products on the market (cf. [Orgalime position paper of 27/05/2013](#)).

In the upcoming proposal, we believe that the Commission would be well advised **to suggest a number of criteria** for national sanctions, that could characterise the seriousness of the infringement, the financial health of the undertaking and the offsetting of illegitimate revenue generated by the placing of non-compliant products on the market.

10) Conclusion

The Commission Proposals for Regulations on Market Surveillance for Products (MSPR) and Consumer Product Safety (CPSR), which we generally supported, have drifted away from their original objectives, at both the level of the European Parliament and Council. Therefore, as the result of this legislative process did not add anything useful to the existing Regulation (EC) 765/2008, we called for the withdrawal of this package in our [position of 1/12/2014](#).

Now with the announced new Commission proposal on enforcement of Union harmonisation legislation, Orgalime places good hopes that smarter market surveillance will be taken as seriously as devising Internal Market rules for the appropriate protection of consumers, workers, the environment, and growth and jobs in Europe, especially in our enabling industry sectors.

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