ORGALIME

# Position Paper

## Brussels, 5 April 2018

# For simpler compliance with and smarter enforcement of EU harmonisation legislation

### Comments on the Commission proposal for a Regulation laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products COM(2017) 795 [1]

## Executive summary


The industry represented by Orgalime supplies a broad spectrum of industrial and consumer goods in the mechanical engineering, electrical and electronic engineering and metalworking sectors. These goods are almost all covered by Union harmonisation legislation, the requirements of which are ever more complex and costly to comply with. Simultaneously, our companies increasingly suffer from unfair competition, due to lack of resources on the ground in Member States to ensure effective compliance checks. Therefore, we welcome the Commission proposal, which is a step in the right direction. We especially welcome:

- the strengthening of border controls and administrative checks by Member State authorities for products entering the Union market.
- the improvement of powers for market surveillance authorities in the area of new business models in online distribution services.
- the proposed concept that a person established within the Union market should be responsible for providing compliance information.
- the possibility to undertake private initiatives to support market surveillance authorities in getting the support and technical expertise they need to be more efficient and effective
- efforts to simplify how companies can obtain information on applicable product rules from the national Product Contact Points in all EU Member States.
- the obligation of Member States to provide sufficient budgetary and other resources to market surveillance authorities for the proper performance of their duties.

However, we see room for improvement by:

- removing the “double sanction” for legitimate manufacturers: not only must they comply with additional costly administrative obligations on top of existing ones in Union law (e.g. publication of the declaration of conformity, company audits), they will also continue to suffer unfair competition from rogue traders who will continue ignoring these obligations, especially those established outside the EU and so outside the reach of Member State authorities.
- ensuring that cooperation and dialogue between the authorities and economic operators will prevail over unspecified automated or superficial administrative controls.
- improving the way authorities will apply the proportionality principle, for instance in the application of their extended powers or in the use of evidence and investigation findings.
- enabling the possibility for economic operators to trigger the SOLVIT problem-solving procedure in case of disagreement with an administrative decision of a local authority, which would affect them adversely under Union harmonisation legislation.


[1] https://ec.europa.eu/docsroom/documents/26824

*Orgalime, the European Engineering Industries Association, speaks for 42 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.*


www.orgalime.org

**ORGALIME** aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

## General comments on the proposal

The industries represented by Orgalime are almost all covered by Union harmonisation legislation in the mechanical engineering, electrical and electronic engineering and metalworking sectors.

The overwhelming majority the 130,000 companies represented throughout our membership comprises small and medium-sized manufacturers. Their experience has shown that the Union legislation applying to their products is becoming ever more complex and costly to comply with. Simultaneously, these companies increasingly suffer from unfair competition, due to lack of resources on the ground in Member States to ensure effective compliance checks.

Therefore, Orgalime welcomes the Commission proposal, which is a positive step forward both in terms of protecting the health and safety of consumers and other users and preserving the ability of the European manufacturing industry to grow and to create jobs.

Orgalime particularly appreciates the emphasis in the proposal on intensified collaboration and communication between market surveillance authorities, as well as between authorities and economic operators. These elements have the potential to make a real difference on the ground and make the most of available resources in times of limited budgets.

We believe, however, that the Commission could have responded to a greater extent to the European Parliament request for a "*lowering of administrative burdens and compliance costs on businesses, especially SMEs, and repealing unnecessary legislation*" as stated in the EP IMCO "own initiative" resolution of 26 May 2016 on the Single Market Strategy (2015/2354(INI) [2].

Despite the aim of streamlining the rules on market surveillance for products under Union harmonisation legislation into a single Regulation on compliance and enforcement, the proposal unfortunately adds complexity to the rules for placing engineering products on the Union market. It would apply in addition to Regulation (EC) 765/2008 on accreditation and market surveillance,[3] Directive 2001/95/EC on general product safety (GPSD)[4] and product-specific harmonisation legislation. We are concerned that this will make it more difficult for authorities to perform their support and enforcement tasks in all Member States, and for economic operators to understand and comply with their obligations – something that would be particularly challenging and burdensome for micro and small manufacturers.

In our view, it is paramount to preserve the dialogue between national authorities and willing economic operators to enable the latter to voluntarily carry out corrective measures. Therefore, we are against any mandatory forms of unspecified automated web-based compliance systems that would no longer enable such a dialogue, while providing a disincentive for authorities to carry out physical checks as they will be busy performing superficial administrative controls.

We therefore look forward to seeing improvements in this proposal that would enable market surveillance authorities to do more with less: within their national constraints as regards staff and financial resources, Member States have a duty to embrace a collaborative approach with businesses and other stakeholders so as to improve in efficiency and demonstrate both effectiveness and proportionality in the way they carry out their duties. The legitimacy of the complex intricacies of Union product-specific harmonisation legislation is at stake, and the extent to which it can protect the interests of consumers, end-users, compliant economic operators, and EU citizens as a whole.

Orgalime calls on members of the Parliament and the national delegations in the Council to pragmatically consider this ambitious Commission proposal, with the aim of bringing intelligence and efficiency into market surveillance of products under Union harmonisation legislation.

---

[2] More: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2016-0237+0+DOC+XML+V0//EN&language=EN

[3] Accreditation and Market Surveillance http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R0765

[4] GPSD http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0095



**ORGALIME** aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

# Specific comments on the articles of the proposal

## Article 1 – Subject matter

As mentioned in the Whereas n°1, it is important to require Member States to create the conditions under which fair competition in the Union market for goods can thrive. In order to place one single technical product on the Union market under harmonisation legislation, manufacturers must comply with a wide array of requirements to meet a variety of regulatory objectives (typically a dozen or so Directives or Regulations). In addition, Union law often requires the manufacturer to follow increasingly costly conformity assessment procedures to demonstrate that they have met all applicable requirements. Such investment into the demonstration of compliance, which is symbolised by the affixing of the CE marking on the product, should be protected through efficient and effective market surveillance by the public authority. Moreover, a commitment to establising a level playing field in the market will contribute to the preservation of the growth and jobs of all the legitimate economic activity generated in Europe.

Therefore we believe that this Regulation should provide also the conditions for a level-playing field among economic operators in the Union market.

## Article 2 – Scope

**The proposal adds complexity to the EU legislative framework for placing engineering products on the Union market,** as it would apply in addition to Regulation (EC) 765/2008 on accreditation and market surveillance[5], Directive 2001/95/EC on general product safety (GPSD)[6] and product-specific harmonisation legislation. We are concerned that this will make it more difficult for authorities to perform their support and enforcement tasks in all Member States, and for economic operators to understand and comply with their obligations – something that would be **particularly challenging and burdensome for micro and small manufacturers**.

In its current form, the ***Lex Specialis* clause** of Article 2 paragraph 2 appears limited to the provisions on "market surveillance and enforcement", while the proposal mixes up the market surveillance and border control provisions under Chapter IV to VIII with new pre-marketing obligations for economic operators under Chapter II. Therefore, the Lex Specialis clause should apply wherever needed in Union harmonisation legislation that would not be aligned yet with the model provisions of Union harmonisation legislation, as devised in Regulation (EC) 765/2008 on accreditation and market surveillance, and more specifically in Decision 768/2008/EC on a common framework for the marketing of products[7]. For the sake of better regulation and simplification of the applicable Union legislation for the marketing of products, there should not be any additional requirement in this Regulation for manufacturers whose rights or obligations are already covered by product-specific legislation further to the model of the New Legislative Framework.

## Article 3 – Definitions

Orgalime welcomes the new definitions that complement those in this proposal that are already provided for in the Regulation (EC) 765/2008 and Decision 768/2008 (EC), especially those necessary for the operation of an improved co-operation between market surveillance and customs in their control of imported goods.

---

[5] Accreditation and Market Surveillance: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R0765

[6] General Product Safety Directive: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0095

[7] Common framework for the marketing of products: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:EN:PDF



**ORGALIME** aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

However, the proposal introduces a new definition of the term 'economic operator', which differs from the definition of the same term used in Decision 768/2008/EC, Regulation 765/2008/EC and in product-specific Union harmonisation legislation.

**Article 3 (12) – Definition of 'economic operator':** The use of the same term with a different meaning creates confusion, depending on whether it is used to cover either:

- actors bearing certain obligations with regard to the making available of products on the market as specified in Union product-specific legislation
- or actors that can be the addressees of market surveillance and enforcement measures.

Therefore, for the sake of consistency and coherence of this proposal with the legislative framework for the marketing of products in the EU, such modifications should be implemented through a recast of Decision 768/2008/EC.

## Chapter II – Compliance information

Compliance information is both intrinsically linked to a given product model or category and is either intended for market surveillance authorities or professional purchasers, both of whom have the proficiency to read and understand it. Our experience is that it is sufficient for authorities to reach out to the person responsible for compliance information, whose name and address are already requested to be affixed on the product or packaging and/or mentioned on the declaration of conformity that accompanies the product.

While there is nothing wrong with making such information publicly available, its publication on a website should remain a free choice for economic operators: setting up such a dedicated website and maintaining it entails a significant cost (including upfront translation costs), especially for small businesses. Web publishing, especially if required on only the manufacturer's website, should not be turned into a counter-productive obligation and liability for economic operators, nor into a new administrative compliance check to be added to the already overly long list of market surveillance authorities.

Ultimately, what matters is that the product that has been placed on the market is effectively safe and otherwise compliant with Union legislation, even if the name of the person responsible for compliance or the declaration of conformity corresponding to the product are not published on a website. Preventive action against the bulk-marketing of potentially non-compliant products (whether imported or not) can always be put in place thanks to the public-private partnership agreements foreseen under Article 7 of the proposal or under a memorandum of understanding under Article 8.

## Article 4 – Person responsible for compliance information

We support, in principle, the idea in the proposal to oblige manufacturers established outside the EU either to have an importer or to designate another person established within the EU as the person responsible for compliance information. In our view, it is paramount to preserve the dialogue between national authorities and willing economic operators to enable them to voluntarily carry out corrective measures.

However, we have some suggestions to make this compatible with the existing product-specific Union harmonisation legislation.

**Paragraph 1(b), paragraphs 4 and 5**: It is unclear what is meant by "identity". Product-specific Union harmonisation legislation requires manufacturers and importers to indicate "their name, registered trade name or registered trade mark" on the product. The use of the term "identity" carries the idea that the "person responsible for compliance information" should be a natural person, at odds with the definitions of 'manufacturer', 'importer' and 'distributor' in the proposal.

The expression "**identity**" in Article 4 should be replaced by "**the name or registered trade name**", which is consistent with the provisions of Decision 768/2008/EC.

**Paragraph 1(a) and 3**: Although the tasks of the "person responsible" are identical to those of an "authorised representative" in Union harmonisation legislation, a new term is introduced. This leads to confusion with existing Union harmonisation legislation.

The expression "**person responsible for compliance information**" is to be replaced by "**authorised representative**", which is already defined in Article 1 and consistent with the provisions of Decision 768/2008/EC

**Paragraph 3(a):** In this paragraph, the "person responsible for compliance information" is responsible for "keeping the declaration and technical documentation at the disposal of market surveillance authorities". Such a task is identical to the (minimum) obligations placed on an authorised representative within the meaning of Article R3 of Decision 768/2008/EC. However, to prevent discrepancies in the interpretation of such an obligation and to avoid unnecessary administrative burden and additional costs for manufacturers, it should be clarified that it does not imply the need for these documents to be permanently and physically present within the territory of the Union. It should be sufficient for the person to ensure that these documents can be provided to the authorities within the period of time determined by them, in line with the provisions of product-specific Union harmonisation legislation.

**Paragraph 4:** For the reason mentioned earlier, the obligation to publish the name or registered trade name of the person responsible for compliance information on a dedicated website and to keep this updated entails a significant cost, especially for small businesses. Moreover, it is unnecessary, as this name is already affixed on the product or its packaging, as required by Union harmonisation legislation. The expression "in the absence of a website" should be deleted to offer as a valid alternative the existing means in Union harmonisation legislation of publicising the name or registered trade name of the 'manufacturer', 'importer' or 'authorised representative', who is by the letter of existing Union legislation responsible for compliance information

## Article 5 – Declaration of conformity

The declaration of conformity (DoC) is a technical document which supports the claim of presumption of conformity of a product being made available on the Union market under harmonisation legislation. While some manufacturers voluntarily make the DoC available on a website, they do this essentially as a supporting information resource for their professional customers or market surveillance authorities. Turning such a voluntary business-to-business or business-to-authority service into a mandatory obligation entails a number of drawbacks which have been minimised in the impact assessment. It would:

- **Unnecessarily add** pre-marketing **complexity, a bureaucratic burden and costs** for manufacturers (especially SMEs), when authorities already have the possibility to retrieve such compliance information from the responsible person indicated in Article 4.
- Add yet another check point for **market surveillance authorities**, thereby counter-productively leading them to:
    - **favour administrative checks** of the DoC only **over physical checks** of the conformity of the product itself with applicable legislation
    - **take restrictive measures** for the placing of the product on the market **without** entering into a **dialogue** with the person responsible for compliance information, further to a reasoned request, as prescribed by Union product-specific legislation as aligned with Decision 768/2008.
- **Generate confusion as to the meaning** and relevance of the DoC to the non-specialist general public.

The publication of the EU declaration of conformity on a website should be turned into an option for manufacturers and a voluntary alternative to the existing means in specific Union harmonisation legislation (e.g. on machinery, products operating in explosive atmospheres or radio equipment), by replacing "shall" with "may" and by deleting the expression "in the absence of a website".

The text of Article 5 should request amending Decision 768/2008 (EC) of 9 July 2008, Article R2 (2) on the 'obligations of manufacturers'.

## Article 6 – Information to economic operators

Product Contact Points are a useful first point of contact for companies, especially smaller firms and micro enterprises that have a low level of awareness about applicable internal market legislation, including whether harmonised or non-harmonised legislation applies to their product.

Therefore, Orgalime welcomes very much the suggestion to set up Product Contact Points for harmonisation legislation, as is the case pursuant to Article 9 of Regulation 764/2008/EC, with the tasks foreseen by Article 10 of the same Regulation. Such a facilitation has already been introduced under the Construction Products Regulation and our members consider it provides valuable support for cross-verifying the information on technical rules that they need to meet for placing their products on the Single Market.

While such information needs to be updated and co-ordinated centrally, a single multilingual portal is not the best way to ensure greater awareness on the part of small businesses.

Therefore, we believe that such information should be made available first and foremost at local level, in a tailored manner for each sector, possibly building on the experience of national sector trade associations and other stakeholders.

## Article 7 – Compliance partnership arrangements

Orgalime acknowledges the need for such compliance partnership arrangements that could stimulate the cooperation between market surveillance authorities and economic operators, especially importers, distributors and fulfilment centres.

We believe that such arrangements could prove to be mutually beneficial to authorities and economic operators, provided that they are made in full transparency under the supervision of the European Commission and other Member State authorities, as provided for under Article 7 paragraph 2. Companies that would not have concluded a paid-for-partnership with the authority should not be put at a disadvantage as regards market surveillance inspections and corresponding measures. When a market surveillance authority gives guidance, it should be clear that this activity is separate from the authority's practical market surveillance activity, minimising the risk of conflict of interest.

## Article 8 – Memoranda of understanding with stakeholders

Orgalime very much welcomes the proposal under Article 8 that would enable industry to share intelligence and tests with the public authorities: efficient physical checks are based on three key enabling elements: competence, finances and legitimacy. As reported in the REFIT analysis, "market surveillance is considered to be the weakest part of the implementation system, partly due to the inherently difficult nature of the task and in part due to varying levels of resources and technical expertise available in different countries"[8].

Industry could provide financial resources and technical expertise, on a voluntary basis. However, the last key element – legitimacy – needs to be organised and agreed upon among national market surveillance authorities at the European level.

Therefore, we call on the European Commission to facilitate a high-level agreement between the Member States, whereby they would accept a common set of criteria for the acceptance of test results carried out by independent laboratories, at the request of either other Member State authorities or accredited stakeholder organisations. Such memoranda of understanding would enable the establishment of a framework of acceptable conditions for a public-private partnership between market surveillance authorities and voluntary self-financed market surveillance support initiatives, such as the recent initiatives in the machinery sectors (http://**machinery-surveillance.eu**, supported by CECIMO, CECE, CEMA, CECIP, EUROMAP, FEM and Orgalime), or the electrical installation sectors (http://**mssi-electrical.org**, supported by CAPIEL and CECAPI).

[8] SWD(2014)23, section 4.8 and 7.1



**ORGALIME** aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

Of course, such memoranda of understanding should be made and operated under clear, unbiased and peer-scrutinised conditions to be agreed upon by Member States in the Union Product Compliance Network referred to in Article 31. We welcome the requirement in Article 8 paragraph 1 requesting authorities to make the concluded memorandum available to the general public and listed in the system referred to in Article 34.

**Article 8 paragraph 3:** We believe that the provisions in paragraph 3 regarding the non-infringement of the requirements of professional secrecy are too demanding and could actually prevent businesses and organisations from entering into the foreseen memoranda of understanding. Also, such information exchange could relate to, or touch upon, know-how or intellectual property owned by third parties who are not parties to such a memorandum.

## Article 12 – Activities of market surveillance authorities, paragraph 3 (b)

In carrying out their activities, market surveillance authorities should apply proportionality in assessing the risks arising from products placed on their markets, including as a first step in checking the compliance of the product with applicable Union harmonisation legislation. Therefore, it is disproportionate to require market surveillance authorities to take the same restrictive measures regardless of whether they are in the presence of a product:

- that presents a non-conformity with the essential requirements of the applicable Union harmonisation legislation
- or a formal non-conformity with administrative requirements (e.g., size of the CE marking, place of product labelling and other formal non-conformities referred to in the relevant Articles in product-specific Union harmonisation legislation, e.g. Article 22 Low Voltage Directive 2014/35/EU).

It has become apparent that there is a growing number of products presenting purely formal non-conformities due to the steadily increasing number of detailed administrative requirements in product-specific Union harmonisation legislation.

However, such formal non-conformities by no means imply that the products concerned would also be unsafe or non-compliant with other essential safety requirements. In the recent past, we have increasingly encountered cases where market surveillance authorities concentrate on such purely formal aspects (without even checking whether there was also a material/technical non-compliance) and take the same restrictive measures against the product as in the case of non-compliance with the essential requirements of Union harmonisation legislation.

Point (b) of Article 12 paragraph 3 should be replaced by the text of Article R34 on “Formal non-compliance” of Decision 768/2008/EC.

## Chapter IV – Organisation and general principles of market surveillance (Articles 10 to 13)

Orgalime very much welcomes this chapter.

## Chapter V – Market surveillance powers and measures

In our view, it is paramount to preserve the dialogue between national authorities and willing economic operators to enable them to voluntarily carry out corrective measures. In practice, the behaviour of market surveillance is, for historical, political and cultural reasons, organised in very different ways from one Member State to another, leading to a very scattered picture as to the effectiveness and efficiency of market surveillance practices.

The examination of RAPEX figures shows in an exemplary manner the diverging approach to enforcement from one Member State to the next. For instance, "*Graph IV • Notifications in 2015 by type of measures taken by notifying country*" (page 25 of the RAPEX Report 2015 Results) shows a striking divide between 2 groups of Member States. In the first group of 14 Member States, authorities seem to have few traceability issues and are able to have a dialogue with economic operators, which lead them to take voluntary corrective measures. On the contrary a larger group of 16 Member States, are mostly taking compulsory measures. Either the countries in this second group get all the products from unknown origin (10% only) or, rather, they regrettably do not privilege the dialogue with the economic operators involved.

## Article 14 – Powers and duties of market surveillance authorities

It is important to give market surveillance authorities the necessary resources to make use of their powers to carry out more effective and deterrent action and we generally welcome the provisions proposed under this chapter. However, it is equally important to make sure that they will make both an effective and proportionate use of these powers, which should not be increased beyond what would be necessary to prevent, stop or remove hazardous and otherwise materially non-compliant products from the market.

The proportionality principle is particularly important in instances of formal non-conformity entailing restrictive measures or bans as set out under Article 12. Therefore, we believe that it is not appropriate for national enforcement administrations to have powers that are usually granted to courts of law, such as:

**Paragraph 3 (b):** grants market surveillance authorities "[the power] to perform system audits of economic operators' organisations, including audits of any procedures that they have in place to ensure compliance with this Regulation and with applicable Union harmonisation legislation".

We believe that this power is excessive and interferes with manufacturers' freedom to organise their internal conformity assessment procedures as they see fit and proportionate to their business activity. There are no such requirements in Union product-specific legislation, which is based on the overarching principle that market surveillance starts at the moment in time when a product is placed for the first time on the Union market.

Besides, market surveillance authorities already have the possibility to carry out pre-marketing surveillance activities by monitoring how notified bodies are fulfilling their conformity assessment duties and ensuring that these bodies provide adequate guidance to their client manufacturers to interpret the essential health and safety requirements in the same way at national level.

**Paragraph 3 (e) (2):** grants market surveillance authorities "[the power] to seal any premises or seize any information, data or documents of an economic operator during the inspection (…)". The seal of premises should be requested by a court order. Additionally, it should only be prompted by a demonstrated case of non-compliance with the proper legal justification, and not just for the sake of the investigation.

**Paragraph 3 (e) (3):** grants market surveillance authorities "[the power] to request any representative or member of staff of the economic operator to give explanations of facts, information or documents relating to the subject-matter of the inspection and to record their answers". Such a power is usually granted to the national judicial power in case of a proceeding for a criminal investigation. It is excessive in the context of a reasoned request of a market surveillance authority which should be addressed to the person designated by the manufacturer as responsible for answering the questions of the authority.

Therefore, paragraphs 3 (b), 3 (e)(2) and 3 (e)(3) in Article 14 should be deleted.


**ORGALIME** aisbl | BluePoint Brussels | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 206 68 83 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

## Article 19A – Problem-solving procedure

We welcome the provisions that set a common basis for enforcement authorities to take measures in a consistent manner across the EU territory and at its external borders. However, it is our members' experience that the local enforcement authority may have a diverging opinion on the interpretation of a specific provision of Union harmonisation legislation, whether on essential requirements (for health and safety, environment protection, etc.) or on administrative obligations related to the applicable conformity assessment procedures (establishment of the declaration of conformity, reference to a harmonised standard, size of the CE marking letters, translation requirements, etc.).

Despite various tools including the general 'Blue Guide' and other Union-legislation-specific application guides, the dialogue between the enforcement authority and the economic operator under inspection sometimes ends up in a stalemate, with serious economic consequences for the manufacturer and/or other economic operators in the supply chain. The severity of these consequences is increased by the exercise of the extended powers of market surveillance under Article 14 and, in case of disagreement between the parties, as a result of a penalty imposed by the authority that would consider the disagreement as "a failure or refusal to cooperate during market surveillance controls and activities" as provided for in Article 61 paragraph 5.

Therefore, we believe that manufacturers under Union harmonisation legislation should be able to benefit from the same problem-solving procedure put forward in Article 8 the COM(2017)796 proposal on mutual recognition: an economic operator affected by an administrative decision of a local enforcement authority with which he disagrees, should be allowed to lodge a complaint to the Internal Market Problem Solving Network (SOLVIT). Introducing the same problem-solving facility would be absolutely necessary to approximate a divergence of views between the economic operator and the enforcement authority, especially in the case of the direct applicability of a market surveillance authority's decision in other EU Member State as per Article 25 paragraph 3 (see below).

## Article 20 – Union testing facilities

Orgalime is not in favour of the creation of a new category of laboratories. Rather, the European Commission should, in our view, consider setting up a network of existing 'testing facilities' attached or linked to market surveillance authorities. This could be facilitated under the Union product compliance network provided for under Article 31.

In any case, we believe that these Union testing facilities should be required:

- to undergo the same accreditation programme as conformity assessment bodies
- not to compete with other accredited conformity assessment bodies in providing services to the private sector, as Orgalime stated in its position paper of 27/05/2013

Otherwise, the value of the conformity assessment attestations issued during the pre-market phase would be put at risk.

## Article 21 – Financing and recovery of costs by market surveillance authorities

Orgalime welcomes the reiterated requirement in Article 21 paragraph 1 that "Member States shall ensure that market surveillance authorities within their territory are provided with the necessary financial resources for the proper performance of their tasks." It is alarming to read in the accompanying REFIT papers that those Member States that answered the Commission survey have decreased their overall budget by 8% in the four past years.

There is a recurrent link between non-compliance and the lowest retail price of products in their range, especially from unknown brands; it usually reflects insufficient investment into safe and compliant design and testing for that product. Therefore, Orgalime agrees with the possibility conferred in Article 21 to empower market surveillance authorities to claim fees from operators whose products have been demonstrated as non-compliant. This may be a way to make controls by market surveillance authorities more frequent, as these will less depend on budget restrictions.

Conversely, such a system should not be turned into a cash machine to the detriment of market operators.

A new paragraph 3 in Article 21 may clarify the conditions under which such administrative fees in relation to instances of non-compliance could be levied. Such fees:

- could not be claimed if the authority has not sent 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 authority at an equivalent or cheaper rate than conformity assessment services available on the market.

## Article 25 – Use of evidence and investigation findings

Orgalime welcomes very much the paragraphs 1 and 2 of Article 25 which will facilitate the dialogue between market surveillance authorities and economic operators under inspection, as well as their enforcement decisions and actions against unfair economic operators on the basis of "any intelligence as evidence for the purpose of their investigations".

**Article 25 – paragraph 2 –** However, use of the evidence by market surveillance authorities in other Member States needs to be subject to the express condition that any arguments put forward by the manufacturer are equally forwarded to the other Member States, together with the evidence.

**Article 25 – paragraph 3 –** We are equally concerned by the automatic acceptance character of a local authority's decision in one Member States in all other Member States, as provided for in Article 25 paragraph 3, as this may jeopardise the legitimate interests of the economic operator concerned. It is not in the interest of innovation and the free circulation of goods to automatically extend the most restrictive interpretation of an EU harmonisation requirement to all other Member States. We believe that if a national Member State authority takes a decision on a product which is marketed all over Europe, then authorities in other Member States ought to use this decision with the arguments put forward by the manufacturer to make their own evaluation in their own territory, as is currently the case further to a RAPEX notification.

In any case, the conditions under which this provision may operate should be devised by the Union Product Compliance Network under Article 33 paragraph 1 (list of coordinated enforcement tasks).

**Article 25 – paragraph 4 –** Accordingly, these arguments by the manufacturer or economic operator need to be also published in the information and communication system, as referred to in paragraph 4, together with the decisions of the market surveillance authority.

## Chapter VIII – Coordinated enforcement and international cooperation

## Article 31 – Union Product Compliance Network

Orgalime very much welcomes the establishment of a Union Product Compliance Network ('the Network') under Article 31. This is a step forward to ensure equal treatment of all businesses throughout the internal market for industrial products. Such a European network to co-ordinate efforts of national enforcement authorities will, in our view, facilitate the efficiency of market surveillance authorities, by promoting their mutual cooperation.

Moreover, we believe that it may also incentivise Member States to step up their national legislation to make it equally dissuasive to rogue traders in each Member State.

Further to our comment under Article 25, the formal conditions under which the principle of free circulation of goods may be challenged further to the decision of one Member State market surveillance authority should be added to the Commission task list under Article 33 paragraph 1 (see rationale above under our comment on Article 25 paragraph 3).

## Article 32 – Composition of the Union Product Compliance Network

Orgalime especially welcomes the possibility under paragraph 3 to involve industry and other stakeholders in administrative coordination groups: we believe it will be useful to enhance the dialogue at European level between stakeholders and authorities on how to improve the efficiency of market surveillance activities, including both reactive and proactive risk-based market surveillance initiatives on an adequate scale, depending on the product categories and their intended use by professionals (self-employed, workers under the employer's supervision) or consumers.

## Article 19 & 34 and Whereas 41 – Exchange of information

In this context, we welcome the Commission's proposal to upgrade ICSMS and make it accessible to the Commission, market surveillance authorities and European stakeholders (Whereas 41).

The ICSMS database should also provide a basis of intelligence about defective industrial equipment and the economic operators involved. This information can be used for better risk-based targeting of the limited inspection resources in Member States and for international proactive projects, for example those coordinated by the Machinery ADCO.

## Article 61 – Penalties

Orgalime welcomes Article 61 of the proposal which requests that Member States step up their legislation on penalties applicable to infringements of the provisions of this Regulation and make them effective, proportionate and dissuasive. The criteria provided for that purpose in paragraphs 2, 3 and 4 are especially welcome.

*Adviser in charge*: Philippe Portalier (Firstname.Lastname [at] Orgalime.org)