ORGALIME

Position Paper

Brussels, 27 May 2013

Market Surveillance of Products

Orgalime Comments on the Commission Proposal for a Regulation on Market Surveillance of Products – COM(2013)75 [1]

1. EXECUTIVE SUMMARY

The Commission's Proposal for a Regulation on Market Surveillance of Products (MSPR) paves the way to improved market surveillance, among other through more detailed obligations, Union action against products presenting a serious risk and a system of mutual assistance. To unleash this potential, we call on the European legislator to improve the Commission's proposal so as to ensure a level-playing field among market operators and legal certainty. In particular, there is a need to:

- Clarify that market surveillance authorities evaluate potential risks and non-conformities posed by products placed on the market. This is different to the manufacturers' risk and conformity assessment which is carried out before these are placed on the market (article 1).
- Add a definition for "non-compliant product" or modify the definition of "product presenting a risk" to include the compliance check with applicable Union harmonisation legislation as a pre-requisite to market surveillance authorities' (MSAs) "risk" evaluation (article 3.13).
- Align economic operators' obligations and the concept of non-compliance with the New Legislative Framework (articles 8 and 9).
- Encourage market surveillance authorities' participation in standardisation (article 6).
- Frame the Commission's implementing powers, both by limiting the scope and the time span of implementing acts (article 9.5 and 12.1). The Commission should be requested to decide promptly on whether a market surveillance measure is justified or not (article 11.4).
- Remove market surveillance authorities' right to challenge the law itself (article 13.3).
- Grant economic operators a more efficient right of redress than with national courts, in case of dispute with the decisions of market surveillance and customs authorities (article 10.7).
- Ensure that RAPEX notifies only products presenting a serious risk and includes the economic operator's arguments in response to the claimed infringement (articles 19.1 and 20.2).
- Establish a standing Advisory Board composed of relevant European stakeholders to provide input and feedback to the European Market Surveillance Forum (article 25).
- Subject the envisaged EU reference laboratories to European accreditation (article 28.2).
- Ensure that sanctions are proportional to the seriousness of the infringement and the size of illegitimate revenue, instead of to the size of the undertaking (article 31.2).

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0075:FIN:EN:PDF

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2. ORGALIME WELCOMES THE ESTABLISHMENT OF A SINGLE EU MARKET SURVEILLANCE FRAMEWORK ALLOWING GREATER EFFICIENCY OF ENFORCEMENT

Orgalime welcomes the European Commission's proposal for a Regulation on the market surveillance of products (MSPR). It reflects a number of our recent expectations[2] and our "*call for an effective pan-European market surveillance system*", as jointly stated in 2009[3] with ANEC[4].

In particular, the Commission clearly acknowledges, in its Communication COM(2013)74 that "*There is scope for lowering compliance costs for economic operators, reducing the administrative burden on national authorities and eliminating unfair competition from unscrupulous traders*."

Orgalime particularly welcomes:

- **General obligations of Market Surveillance Authorities** (MSA) which are more detailed than in Regulation EC 765/2008. We believe that it is correct and adequate to require the competent authorities to:
    - follow-up the corrective actions that they have required from market operators.
    - take account of test results and risk assessments issued by the economic operator (Art.9§1, MSPR).
    - "*deal with the risk*" (even if not a serious risk), also when "*the identity of the relevant economic operator cannot be ascertained*" (article 10§1), including by requesting the destruction of the products at the expenses of (other) "*relevant economic operators*" (Art.10§2), including importers (Art. 16§3 as is the case in food/feed legislation).
- **Union action against products presenting a serious risk** is made possible through an implementing act (Art.12§1) by the Commission so as to oblige Member States to take effective action. **However, we believe that such emergency measures should be limited in time for a maximum period of 2 years.**
- **Other positive aspects:** besides the confirmed role of the RAPEX (Art. 19 and 20) and ICSMS procedures/databases (Art. 21), Orgalime welcomes the proposed **system of "mutual assistance"** between MSAs (Art. 23), co-operation with third countries (Art. 24), and the **establishment of a European Market Surveillance Forum** (EMSF) (Art. 25) assisted by an Executive Secretariat (Art. 26) **with some funding** (Art. 29).

3. ORGALIME SUGGESTIONS FOR IMPROVEMENT OF THE 'MSPR' PROPOSAL

CHAPTER I
General provisions

Article 1- Subject matter

As mentioned in Recital 1, this regulation is "*to guarantee the free movement of products within the Union*", based on Article 114 of Treaty relating to the approximation of Member States legislation relating to the functioning of the internal market. It should be made clear that market surveillance deals with products once they have been placed on the market, as opposed to the pre-market

[2] Orgalime position paper: "*Efficient and effective Market Surveillance: a priority to preserve the benefits of the Internal Market and the competitiveness of legitimate manufacturers*", 30/10/2012. More

[3] Orgalime position paper "*Call for an effective pan-European market surveillance system*", 22 April 2009. More

[4] ANEC is the European consumer voice in standardisation. More

phase which must remain the domain of conformity assessment, carried out under the responsibility of the manufacturer. Moreover, we believe that verifying that products meet requirements (..)" is only a part of what market surveillance is supposed to do and what this Regulation regulates. The consequences of such verification, in particular the need for corrective actions against unsafe or otherwise non-compliant products, should be included in the "Subject matter". Also, market surveillance should ensure a level-playing field on the internal market among market operators.

➔ Therefore Orgalime believes that Article 1 should clearly state that the Regulation lays down a framework for verifying that products **placed on the market** meet the relevant requirements, **including a level-playing field for market operators** through effective and proportionate measures against non-compliant products.

Article 3 - Definitions

(13) 'product presenting a risk'

As mentioned in Recital 14, "*the entire market surveillance process [should be] transparent and easy to follow for both market surveillance authorities and economic operators*".

The definition of product presenting a risk in Article 3 (13) is not easy to apply and would trigger much legal uncertainty for market operators. Moreover, the term "risk" is commonly used to refer to a safety-related context; however, this Regulation is supposed to cover not only safety but all other issues of public interest protection, such as environmental protection, energy efficiency, EMC.

Therefore, the 'risk' assessment should focus on evaluating compliance with the relevant legislative requirements of applicable legislation and their enforcement. Room for interpretation by local market surveillance authorities should be minimised. The first step of the assessment to be carried out by the enforcement authorities should be to determine whether the product is covered by applicable Union harmonisation legislation and to verify if the essential or other material requirements contained in that legislation are complied with.

➔ Orgalime suggests:

- Either adding a **new definition for "non-compliant product"** (covering non-compliance with Union harmonisation legislation) under Article 3 (n° 12 **bis, new**), which would be similar to the concept of Article 16§2 of Regulation (EC) 765/2008 and Article R31§1 of Decision 768/2008/EC. This would imply adapting the relevant provisions accordingly and complementing or replacing the reference to "risk" by "non-compliance / non-compliant product";
- Or amending the definition of "product presenting a risk" under Article 3 (n°13) by adding a **sub-paragraph which would include, as a pre-requisite, the evaluation of the product for non-compliance with the essential or other material requirements of Union harmonisation legislation**.

Article 4 - Market surveillance obligation

Orgalime welcomes the general obligation that Market Surveillance authorities should take effective measures. However, we believe that these should be also efficient and proportionate.

'*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.

➔ Orgalime suggests clarifying that “Market surveillance shall be organised and carried out (…) with a view to ensuring that (…) effective, **efficient and proportionate** measures are taken”.

Article 6 - General obligations of market surveillance authorities

As recalled in Regulation 1025/2012, national market surveillance authorities shall 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***”. Thereby, they could more easily fulfil their duty under sub-paragraph (c) to “*keep up to date with developments in scientific and technical knowledge concerning the safety of products*” and hence, adequately represent societal interests in standardisation work.

CHAPTER II – Union market surveillance framework

Article 8 – "general obligations of economic operators"

Orgalime is of the opinion that provisions of Article 8 should be aligned with the wording of the relevant Articles in the New Legislative Framework (Decision 768/2008/EC, Articles R2§9, R4§9, R5§5) and, in particular:

- The obligation to provide ‘any’ documentation or information to the authorities is disproportionate and not consistent with Union harmonisation legislation. The role of each economic operator within the supply chain should be respected.
- This obligation should be conditional to receiving a reasoned request from the competent authorities;
- The volume/extent of the documentation/information to be provided needs to be specified: such documentation or information should be related to the carrying out of market surveillance of the product, including in particular checks on the demonstration of the product’s conformity with the relevant requirements where they exist, or evidence that the manufacturer has carried out a risk assessment.
- Paragraph (2) of Article 8 seems to repeat paragraph (1), which already requires the provision of documentation and information. We suggest that, instead, the cooperation obligation contained in the New Legislative Framework Decision should be transferred to that paragraph.

Economic operators have different obligations according to their respective roles in the supply chain. Market surveillance authorities should not ask, for example, a distributor to provide the technical information, as he will not be able to provide this.

CHAPTER III – Control of products within the Union

Article 9, paragraph 2 – Products presenting a risk

Instances of **formal non-compliance** (such as an incorrect sizing of the CE-marking) should not, as such, give sufficient reason to believe that the product may present a "risk" [5]. Such an approach

[5] *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.*

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.

It also sends the wrong signal to MSAs which might concentrate their efforts on detecting formal non-compliance issues, rather than focusing on material safety/non-compliance problems.

➔ Therefore, we urge the European Parliament and the Council to take over the concept of "formal non-compliance" as foreseen in the New Legislative Framework and **replace Article 9 paragraph 2 by Article R34 of Decision 768/2008/EC.**

Article 9, paragraph 5 – Products presenting a risk

In Orgalime's opinion, the Commission should not establish, through implementing acts, specific obligations on the information manufacturers should share about their corrective actions.

Modalities for sharing information on corrective actions are already prescribed in sufficient detail in applicable Union harmonisation legislation (for example the Machine Directive), or the CPSR. This implementing power of the Commission may unnecessarily upset the common practice specific to each product sector.

➔ Therefore, Article 9, paragraph 5 should be deleted.

Article 10 paragraph 7 – Legal remedies against measures taken by market surveillance authorities

Businesses must have access to an efficient and effective redress in cases of restrictive measures taken by national market surveillance authorities.

Therefore, we believe that companies should have a redress possibility from a different third party body than national courts. Where appeals are limited to national courts, the associated costs and time spent proves to be a deterrent for companies seeking redress[6]. Some disputable authorities' measures represent a significant barrier to the free movement of goods within the Internal Market.

Arbitration by a standing sub-group of the European Market Surveillance Forum could act as a useful facilitator. The same reasoning should apply to Article 16 paragraph 5 "*Refusal to release*".

Article 11 paragraph 4 – Union assessment for products controlled within the Union and subject to harmonisation legislation

Orgalime fully agrees with the proposal of the Commission's powers to decide if the notification of a market surveillance measure is justified. This would avoid keeping the national measure on hold for too long, to the detriment of the economic operator concerned.

However, we urge the Council and the Parliament to oblige the European Commission to take the relevant implementing act within a given time frame. This can be achieved by replacing in Article 11 § 4, the term '*may'* by '*shall'*. The Commission should be obliged to take a decision on whether a notified national measure is justified or not, within a maximum of 3 months.

Article 12 paragraph 1 – Union action against products presenting a serious risk

We believe it is appropriate that the Commission should be empowered to take action at EU level against products presenting a serious risk. This would not only minimise duplications, but would also promote the most effective solution throughout the internal market.

Nevertheless, Orgalime recommends that the European legislator should thoroughly scrutinise the powers to be conferred on the European Commission to regulate the marketing of products through implementing acts. In particular, we strongly recommend that **implementing acts restricting the placing of "*a product, or a specific category or group of products*" on the market should not exceed 2 years. Its renewal should be subject to an impact assessment.**

[6] The "EU justice scoreboard" for 2013 shows the inefficiencies of several national justice systems to resolve administrative cases, cf. COM (2013)160 final, page 6 and 7.

Where deemed necessary, further consultation with Members States' representatives and relevant stakeholders in the relevant Union legislation consultation committees, the Commission should undergo all necessary steps for initiating a change in the legislation.

Article 13 paragraph 3 – Risk assessment

Orgalime welcomes the description of the market surveillance operation. However, we have the following comments:

- The national enforcement authorities should not be given the right to challenge the law itself. This would be a major potential source of legal uncertainty for market operators and would just further undermine the internal market. Local enforcement authorities should only have the right to challenge the presumption of conformity to the law (as referred to in points (b) and (c) of paragraph 2). Therefore, the second sentence of Article 13 § 3 should not refer to point (a) of 13 § 2
- Such a provision taken from the GPSD is neither present in Union harmonised legislation, nor in Regulation (EC) 765/2008 on market surveillance, which serves as a basis for the new Regulation.
- The current provision is in contradiction with the definition of "*product presenting a risk*", especially in combination with Article 6 § 2, which includes the concept of a compliance breach and obliges market surveillance authorities to act. Either the product is compliant or it is not. Therefore, should the presumption of conformity be challenged under point (b) or (c), it should be in case of a serious risk, as defined in Article 13 (14).
- As the situation is exceptional, it should require a reversal of the burden of proof so that authorities should be obliged to duly justify their decision and the action taken. Subsequently, they should notify it through the RAPEX procedure.

Article 16 - Refusal to release

See our comment under Article 10, paragraph 7 "*Measures taken by market surveillance authorities*".

CHAPTER V – Exchange of information

Article 19 paragraph 1 – Union Rapid Information Exchange System - RAPEX

Orgalime believes that **only products presenting a *'serious risk'*** as defined in Article 3 (14) should be notified to the Commission through RAPEX. This is consistent with Article 22 § 2 of the current Regulation EU 765/2008 on market surveillance of products.

Indeed, it is important to distinguish between the various levels of risks and to process them more adequately. RAPEX should continue to be reserved for cases involving a serious risk, requiring immediate action. All other cases should be dealt with through the ICSMS tool.

Article 20 paragraph 2 – Notification through RAPEX of products presenting a risk

Orgalime suggests adding to the information to be provided for market surveillance measures under paragraph 2, 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 ground to question the provisional measure taken.

Article 20 paragraph 4 – Notification through RAPEX of products presenting a risk

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.

CHAPTER VI – Cooperation

Article 25 - European Market Surveillance Forum

Orgalime welcomes the proposal for such a European cross policy co-ordination platform of national market surveillance authorities. **In addition, we suggest setting up a standing Advisory Board composed of relevant EU stakeholders** (including manufacturers and importers) to provide input to the European Market Surveillance Forum, following the same structure as the European Accreditation Advisory Board.

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

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

Article 25 paragraph 6 – European Market Surveillance Forum

We believe it is important that relevant stakeholder organisations be involved at least as observers in standing subgroups. As a result the EMSF could benefit from all available information relevant for market surveillance.

➔ Article 25, paragraph 6 should be brought in line with the wording of recital 27 of the Commission proposal.

Article 28 paragraph 2 – European Union reference laboratories

Orgalime calls on the European Parliament and the Council to subject the envisaged EU reference laboratories to **European accreditation pursuant to Regulation (EC) 765/2008**. This is necessary to place them on an equal footing with other accredited conformity assessment bodies. Otherwise, this provision would undermine mutual confidence among Member States and accredited laboratories.

Furthermore, the role of these envisaged reference laboratories should be specified so as to ensure that they do not compete with other accredited laboratories in providing services to the private sector.

CHAPTER VIII – Final provisions

Article 31 paragraph 2 – Penalties

In principle, Orgalime supports the use of penalties to be deterrent to deliberately cheating market operators. Fair and well-meaning businesses are more likely to succeed in a level playing field where competitors who cut corners and flout the rules are penalised.

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.

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