ORGALIME

Position Paper

Brussels, 30/10/2012

Efficient and effective Market Surveillance: a priority to preserve the benefits of the Internal Market and the competitiveness of legitimate manufacturers

Orgalime views on an anticipated "Product Safety and Market Surveillance Package", including the revision of the General Product Safety Directive (GPSD)

EXECUTIVE SUMMARY

We believe it is paramount for Member States to establish **proportionate and co-ordinated enforcement measures against infringement of all EU product legislation**, in order to ensure confidence in the Single Market, a level playing field for all market operators and growth and jobs in our industry. Therefore, **Orgalime welcomes the Commission plans for a Product Safety and Market Surveillance Package**, which we hope will reinforce the excellent New Legislative Framework in place since 2010.

The simpler the law, the more efficient its enforcement. We believe the package should:

- **clarify that not only health and safety but also other requirements matter** (such as environmental protection and energy efficiency) and should be enforced all over the EU;
- **reflect that product-specific legislation should take precedence** over user-focused/horizontal legislation in order to provide legal certainty to manufacturers;
- **set in place a single procedure** for authorities to check that products placed on the market, whether intended for consumers or professionals, **comply** with Union harmonisation legislation; **otherwise a proportionate risk assessment** based on evidence should be applied;
- **stress that non-compliance should be sufficient** for market surveillance authorities to apply proportionate risk management measures;
- **clarify the concept of risk** to minimise varying interpretation, taking into account the risk assessment of the manufacturer and the use for which the product is intended;
- **minimise administrative and traceability requirements** which would place cost burdens on legitimate manufacturers whilst providing no guarantee of catching rogue economic operators;
- **call on Member States to apply both proportionate and dissuasive sanctions** that will act as a deterrent to rogue traders and will protect the rights of other operators and their ability to do better.
- **refrain from setting new specific provisions to address e-commerce**, but suggest that products sold online are primarily checked at the point of shipping.

Orgalime, the European Engineering Industries Association, speaks for 37 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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Market surveillance coordinated at EU level: we therefore call on the Commission to:

- **set up a Horizontal Forum of national market surveillance authorities** which would involve sector specific administrative committees, so as to ensure the consistent implementation of a common approach to compliance and risk assessment;
- **set up an Advisory Board of relevant EU stakeholders** (especially manufacturers and importers) to ensure a regular dialogue with the market surveillance Forum and facilitate the setting of priorities and the sharing of expertise.

Facilitate the national implementation of market surveillance: the coordinated market surveillance at EU level can only become more efficient through:

- **further pooling and sharing of resources among Member States** (as, for example, through sharing of test results, infrastructures and information.
- **project funding at EU level** (for example. by making use of the structural funds) should be available to enable Member States to share their resources effectively and respond to special geographic or socio-economic challenges, as for example heavy traffic in maritime freight ports.

INTRODUCTION

Orgalime welcomes the European Commission's plans to set up a Single Market Surveillance Regulation, to implement a multiannual market surveillance plan and to revise the GPSD[1], with a view to achieving more efficient and operational market surveillance within the European Union and at its borders, and to reduce the number of unsafe or otherwise non-compliant products placed on the Internal Market. As an overall comment, Orgalime believes that the approach and basic requirements of Regulation 765/2008 on market surveillance need to be preserved in a new instrument, which could be even more precise, taking into consideration experience drawn since its entry into force.

We believe that the completion of the Internal Market and its success depends more on the actual, efficient and proportionate enforcement of existing EU legislation rather than on the adoption of new legislation. It is of crucial importance that Member States fulfil their duties with regards to law enforcement and that they step up their national enforcement legislation. This is particularly relevant in difficult economic times to enable the European manufacturing industry, and its large number of SMEs, to continue to provide growth and jobs in Europe.

As it will appear from this paper, Orgalime believes that market surveillance should react to *all* cases of non-conformity with the law. However, measures should be proportionate and include a fruitful dialogue with economic operators. Since product legislation is complex, information and dialogue should be part of market surveillance authorities' responsibilities so that SMEs, in particular, are kept informed and up-to-date.

[1] Reference to Commission Documents:

- Roadmap Review of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety (Version 5.1, October 2011)
- CERTIF 2011-02 - Draft ROADMAP – Enhancing the Market Surveillance enforcement for goods – A multi-annual plan (Version 0, 09 March 2011)

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Legislation without enforcement is challenging the functioning of the Internal Market

Orgalime is very concerned about unlawful manufacturers and importers who unfairly save on investing in product compliance, thereby putting the safety of users and other core EU interests at risk and generating costs and shortfalls on:

- **Member States**: who lose partially the confidence of citizens and economic operators in the market and consequently their overall credibility in their ability to make the Internal Market work.
- **Lawful and reputable manufacturers**: who see their investment in product compliance undermined: while EU legislation expands in all areas and increases the cost of traceability and compliance (from 2% to 25% of product costs, depending on the product category), the placing on the market of non-compliant goods discredits lawful business and exposes it to unfair competition.
- **Society**: because the placing on the Single Market of unlawful products jeopardises the very purpose of EU legislation, which is to strive for safe and sustainable products on the Single Market to the benefit of everyone.

Ensuring free and fair trade is as important as enforcing product safety

EU product harmonisation legislation is not limited to setting common levels of safety for consumers. Over the past decade, our industry has been subjected to a growing number of pieces of environmental legislation such as WEEE (electro-waste), RoHS (Restriction of Hazardous Substances), REACH (traceability of chemicals), or on the Eco-design of Energy-Related Products. It ought to be the duty of the Member States to preserve the investment of lawful economic operators in product conformity and to ensure a level-playing field in this respect.

Therefore, Orgalime believes that the purpose of the Regulation on market surveillance of non-food products should not be limited to ensuring that products are "safe", but that they comply with all applicable EU legislation, and to ensure both free and fair trade within the Internal Market for all economic operators, as we highlighted in our 2009 joint position paper with ANEC[2].

Harmonised EU legislation needs harmonised enforcement across the EU

Orgalime is convinced that the European Commission has an important role to play in setting up a cost-efficient framework and action plan for improved market surveillance of non-food products within the EU. We are pleased to provide hereafter a number of concrete recommendations.

I. THE SIMPLER THE LAW, THE MORE EFFICIENT ITS ENFORCEMENT

1) For product-specific (NLF) legislation to take precedence over user-focused/horizontal legislation

Product-specific legislation based on the NLF should take precedence (as *lex specialis*) over the GPSD and other horizontal legislation, e.g. environmental, for the following reasons:

- **To avoid confusion:** a large number of products could be used by consumers, or may use energy and can ultimately impact the environment; hence, horizontal policy-oriented legislation is bound to expand with growing risks of scope overlaps with product specific legislation, which makes the application and enforcement of the resulting body of EU legislation overly complex;

[2] "Call for an effective pan-European market surveillance system" (22/04/2009)

- **To improve consumer protection: Product-specific legislation is more precise** and, when properly applied, provides better protection against all risks foreseen for a given product category, with or without the support of standards. For instance, Standard EN/ISO 14121-1:2007 "Safety of machinery Risk assessment" provides detailed information on how to assess hazards for machinery products and how to mitigate them[3];
- **To enhance legal certainty:** In **product specific legislation,** risk assessment, demonstration of conformity and compliance checks are **less likely to be subject to varying interpretation** than in user-focused legislation, such as the GPSD, or other horizontal policy-oriented legislation.

Therefore, for the sake of legal certainty, **Orgalime calls on the European Commission to clearly exclude all products covered by specific Union legislation from the scope of the GPSD**. This would stop endless discussions regarding whether the GPSD applies or not on top of NLF legislation "*for aspects and risks or categories of risks not covered by those requirements*".

2) For putting in place a general compliance and risk assessment procedure

- **Compliance with the law is not an option, whether for large or for micro-businesses: internal market legislation, whether it addresses safety or other** policy purposes should not bear any exception as to the size of undertakings subject to it.
- **Market surveillance should assess non-compliance, not only risks**. All National Market Surveillance Authorities (NMSAs), while they remain free to organise their work according to their priorities, should use a general (post-marketing) compliance and risk assessment methodology with the following initial steps:
    1. Check first whether a piece of product-specific legislation applies;
    2. Check whether the product-specific requirements are complied with or not. In some cases, refer to the risk assessment methodology devised and used by manufacturers, in particular when it is included in a harmonised standard, such as is the case for machinery;
    3. Assess then the need to notify via RAPEX in case of serious risks.
    4. If there are no product specific requirements, apply a risk assessment according to commonly agreed guidelines.
- **Right to object to Customs or NMSA measures**: Experience shows that in practice there are very few, if any, objections raised by Member States against restrictive measures on a product taken by another Member State, although market operators may have serious grounds to challenge the risk assessment and the subsequent lack of proportionality of the decision of the relevant authority. Therefore, we believe that the planned Regulation on market surveillance **should foresee an independent fast track appeals procedure triggered by the manufacturer in question against restrictive measures by NMSAs**, including requests of withdrawal or recall. Such a procedure could involve the Commission and at least 2 representatives from other Member States in order to find a rapid and proportionate solution in order to safeguard the free movement of goods within the Internal Market. Challenges before the competent courts always imply a lengthy and costly process, which should be used as a last resort in case of severe disagreement.
- **Risk assessment should apply to non**-harmonised goods according to widely accepted guidelines. Stakeholders should take part in the drafting of these guidelines.

3) For enhancing legal certainty in clarifying the concept of 'risk'

New Approach legislation applies to almost all electric, mechanical and metallic products. Its enforcement is based on checking if the marketed product complies with the essential

[3] Cf. Annex A of EN/ISO 14121-1:2007 standard (See Appendix 1)

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requirements of the law (usually in the Annex I of product-specific legislation), often with the support of harmonised standards. Orgalime has always been a supporter of New Approach legislation, whose success for over three decades has been recognised and set as a model in the 2008 New Legislative Framework (NLF).

We are therefore worried about the recent trend in enforcement of product legislation, which tends to disregard compliance with product-specific essential requirements and prefers a generic approach based on risks for the users or the environment. Unlike 'non-compliance', the concept of 'risk' is largely applied under the subjective interpretation and discretionary choices of customs and market inspectors: in practice, its application, for example in the context of the GPSD, generates many varying interpretations from one to another Member State, as to what constitutes a risk, whether it is acceptable, serious, less than serious, urgent, immediate, foreseeable or could impact so-called vulnerable consumers

Even worse, these subjective interpretations add confusion to an already complex legislative framework and lead National Market Surveillance Authorities (NMSAs) to devise soft regulation in the form of non-legislative acts such as "ADCO" recommendations"[4] or the Commission to issue "risk assessment" guidelines[5], sometimes without due regard to the legislation and the European standards (esp. in the non-harmonised area). The recent "Atlas on Child Appealing Designs for Household Appliances" is an example of such a deviation[6].

Orgalime believes that this situation is detrimental to a rapid, cost-efficient and equitable enforcement of the law and the legal certainty that market operators are entitled to expect. Eventually, **varying national enforcement decisions jeopardize the free circulation of goods** within the internal market, the original and essential goal of EU product harmonisation legislation.

Consequently, **Orgalime calls on the European Commission to** seize the opportunity of a single act for the market surveillance of all products to:

- **narrow down and clarify the concept of risk / serious risk** in the enforcement of NLF / GPSD legislation. This definition should be precise and should serve as a reference for both customs and market surveillance authorities;
- **invite customs and market surveillance authorities to:**
  - **take the manufacturer's risk assessment into consideration**, or any relevant documentary evidence related to it (e.g. declaration of conformity, use of standards, etc…) when performing their own risk assessment;
  - **take the use of the product as intended by the manufacturer as a starting point** and consider it in the light of user-related parameters, such as parental, caring staff or occupational supervision, which are necessary to assess whether residual risks for so-called vulnerable users were adequately mitigated.
  - **share their practices and use the best of them** in order to achieve at European level a common set of practices, thereby limiting the number of weak points of entry into Europe used by rogue traders.
- **Orgalime considers that the precautionary principle should not be introduced in the Regulation on market surveillance**. Its general application at the discretion of market inspectors would directly challenge the essence of harmonised legislation, whereby the legislator has set the acceptable level of risks for a given category of products. As highlighted in the EC Communication on the precautionary principle (2000)[1], it is a tool for the legislator, not for the enforcement authorities that do not have the adequate level of expertise (e.g. to assess scientific evidence).

[4] Ex: Recommendations of the Administrative Co-operation Working Group (LVD ADCO) of 16/11/2010)
[5] Ex: Decision 2010/15/EU laying down the new guidelines for the management of the "RAPEX" system and of the notification procedure established under Article 11 of the General Product Safety Directive (JOCE L22 of 26/01/2010)
[6] Ex: Atlas on Child Appealing Designs for Household Appliances - Joint Orgalime-CECED letter to the European Commission 19/4/2012.

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4) For authorities to act in case of non-compliance

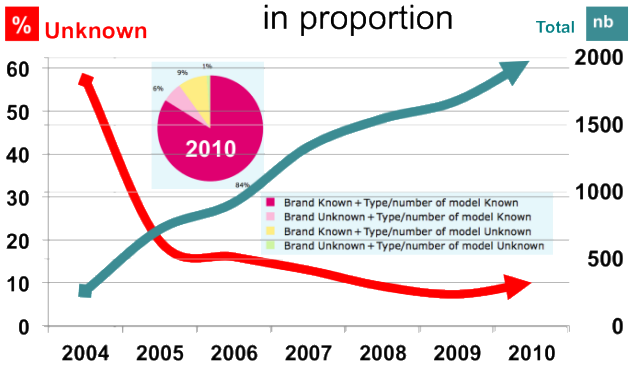
Orgalime is concerned about recent trends in the enforcement of European product legislation, which jeopardise the legal certainty that manufacturers enjoy on the basis of harmonised legislation. We call on the European Commission to secure the following key elements in its proposal for a Regulation on the market surveillance of non-food products:

- **NMSAs should take proportionate action in all cases of non-compliance**, whether there is a "risk to health and safety" or to other issues of public interest. Customs authorities and NMSAs should also act with proportionate sanctions against less than serious risk cases of non-compliance, including breach of environmental or energy related legislation. This is necessary to protect the market shares and investments of legitimate market operators with regard to innovation, product conformity, and ultimately their economic sustainability.
- **The envisaged EU market surveillance action plan should help Customs and NMSAs** to take action against both unsafe and otherwise non-compliant products, wherever necessary with appropriate co-ordination, joint actions and financial support (training, exchange programmes, etc.).

5) For deterrent sanctions instead of costly but ineffective traceability requirements?

Orgalime welcomes clarification of traceability rules, provided that they only lead to proportionate costs for market operators. Criticism over insufficient traceability mechanisms in internal market legislation is often overestimated, including for consumer products. For instance, the RAPEX statistics show that the brand and the model are known in 84% of cases (2011) and their origin in 92% of cases. Dialogue was made possible in most cases, whether for voluntary measures taken by market operators (38%) or compulsory ones[7].

Dangerous consumer products of unknown origin are decreasing in proportion



Data from EC DG Sanco/Rapex

We believe that deterrent sanctions will do more to enhance traceability than bureaucratic marking and registration requirements, for the following reasons:

- **Minimum traceability requirements**: Orgalime supports the NLF requirements to affix the name and (web or postal) address of the manufacturer on the product or on the packaging. However, it is our view that any obligation on importers to affix their address on all categories of products, especially those simple and harmless mass produced products which fall under the GPSD, should be implemented in a proportionate manner where the identity of the importer is not known during the manufacturing process. Under Regulation EC 765/2008, it is the responsibility of the distributor to serve as a contact point for NMSAs, to help them identify the importer. As a consequence, where products do not follow these NLF requirements, we believe that particular care should be taken by market surveillance authorities to ensure that the products are in conformity with EU legislation.
- **Extensive traceability requirements are costly and not necessary**: legitimate market operators are easy to find; rogue traders will stay hidden. Hence, we advise the Commission to protect lawful market operators from costly traceability requirements, such

[7] http://ec.europa.eu/consumers/safety/rapex/docs/2011_rapex_report_en.pdf

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as **registers**, **tracking tags**, or requiring affixing detailed postal addresses on simple and harmless non-harmonised consumer products.

- **Traceability is a tool for professionals and authorities** to find the legal person responsible for placing a product on the Single Market; hence, it serves a different purpose than brands, labels, voluntary certification marks and marks of origin that are set in place to inform the public.

6) For a workable GPSD: full alignment with the NLF would be a regulatory overshoot

Because the GPSD is a horizontal user-focused legislation, it cannot become a full harmonisation directive, unless essential requirements are set up for products intended for use by consumers, which would not already be covered by harmonised product-specific legislation. Aligning the GPSD with the NLF should be done carefully with respect to the following principles:

- **Binding requirements should be set by law**: it is the duty of the legislator to set policy goals in the law. This task cannot be delegated to standardisers by means of unspecific policy requirements set in the European Commission's standardisation mandates or the Commission recommendations set out in guidelines;
- **Standards are voluntary tools for manufacturers** used by them to design products according to the law: if they are not used, market surveillance controls should check, , the technical file on the basis of a substantiated request before checking further whether the product is unsafe or otherwise non-compliant;
- **CE marking should continue to be applicable only to products under Union harmonised legislation**, because it is the symbol of compliance with specific harmonised legislation. Nor should a declaration of conformity be required for non-harmonised consumer products.

7) For market surveillance of e-Commerce without new specific provisions

According to Regulation 765/2008/EC, products are placed on the market when they are made available for the first time to customers of the European Union. This includes the making available of products via a Web catalogue. Therefore, in our view:

- **Non-compliance does not depend on the distribution channel**: there is no need to set up specific requirements for the market surveillance of distant selling.
- **Products sold via the Internet should be primarily checked at the point of shipping** (storage warehouse), not at the point of delivery (e.g. private customer premises).
    - To facilitate market surveillance, e-commerce web sites should indicate the address of their storage/expedition warehouse, from which products are shipped to European consumers, and where they could be subject to pre-shipment controls.
    - International co-operation should be put in place to enable controls of Web sites and warehouses based outside of the EU/EEA territory that target EU customers, or to oblige them to deny the possibility to ship goods to any country of the EU/EEA.
    - Consumer communication campaigns should be put in place in all Member States to inform consumers that they take a risk for themselves and their families if they buy products from non-EU/EEA based web sites, which do not indicate whether or not such products comply with EU legislation.

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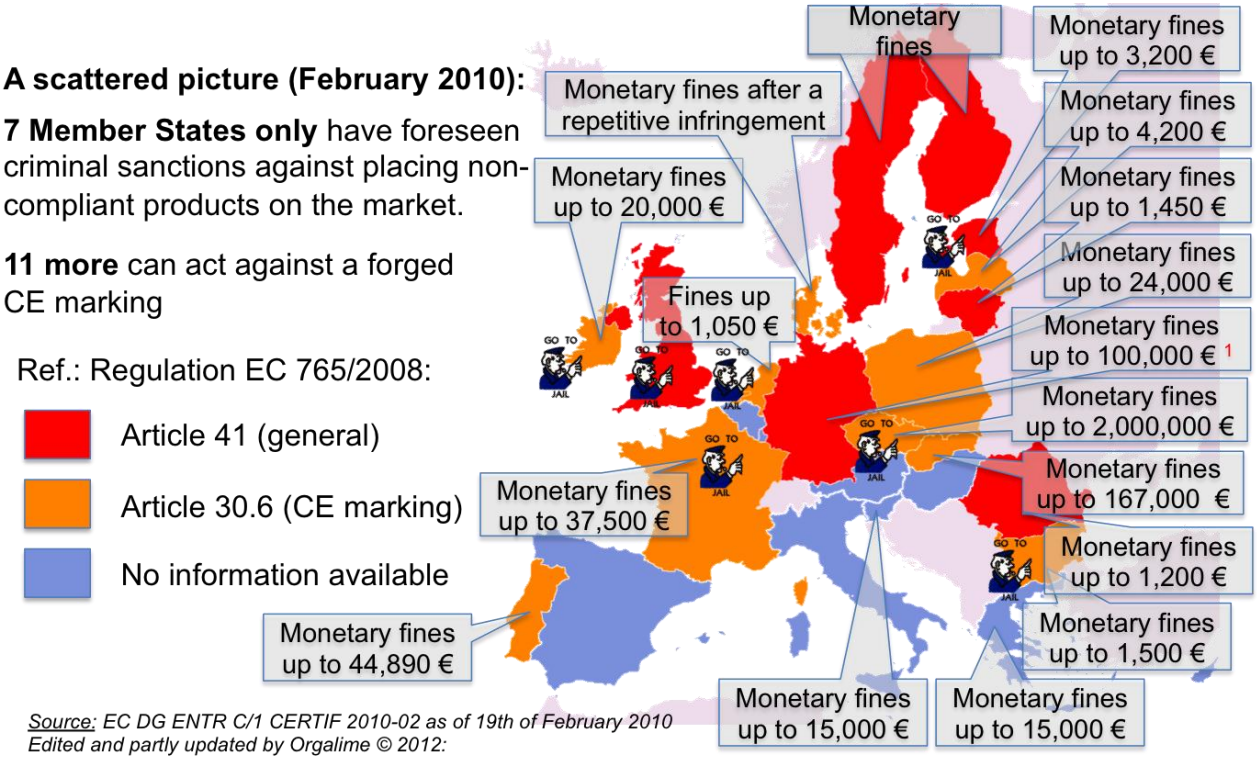
II. MARKET SURVEILLANCE COORDINATED AT EU/EEA LEVEL

8) For increased European coordination and stepping up national sanctions

There are very irregular levels of penalties among Member States, which in turn create the possibility of "*forum shopping*" for rogue traders to place their non-compliant products on the market[8].



Source: EC DG ENTR C/1 CERTIF 2010-02 as of 19th of February 2010
Edited and partly updated by Orgalime © 2012:
[1] *Since 01/12/2011 monetary fines in Germany can go up to 100,000 €*

Orgalime considers that the envisaged Regulation on market surveillance should be ambitious in providing co-ordination and financial support and put pressure on Member States to establish "*effective, proportionate and dissuasive penalties*", as already spelled out in both Regulation 765/2008 and the General Product Safety Directive (GPSD).

There are a number of examples at national[9] and European level that could be used in a proportionate but more generalised manner. **It has to be taken into account that non-compliance could be caused by either purposefully circumventing product requirements or by lack of understanding or knowledge given the increasingly complex requirements**.

The smooth operation of the Internal Market requires that economic operators are equal before the law and be subject to similar sanctions for a similar infringement. This means for example that if a product is recalled in one Member State it should also be taken off the market in other Member States. If not, there is not only an uneven level playing field, but also a risk that non-compliant products are on purpose put on markets with low market surveillance and known low penalties.

As in Regulation 765/2008/EC, the new Regulation should foresee the possibility of infringement procedures by the European Commission in case of failure by a Member State to fulfil its obligations under the proposed Regulation.

[8] Cf.: EC DG ENTR C/1 CERTIF 2010-02 (23-02-2010) and its Annex.
[9] Cf. Example of the Finnish transposition of the LVD (Electrical Safety Act)

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9) For a horizontal co-ordination to implement a common approach to compliance and risk assessment

Orgalime calls on the European Commission to establish a horizontal Forum which would involve sector specific Administrative Coordination Committees (AdCOs). This could ensure general consistency of practical interpretation of legislation and market surveillance approach towards products and economic operators at cross-sector level.

Only a single coordination body can ensure the consistent implementation of the New Legislative Framework as gradually all New Approach Directives are aligned with it. We believe it should promote a common approach to compliance and risk assessment by all NMSAs through IT tools, guidance documents, training programmes and exchange of national officials, experts and customs authorities, joint visit programmes, joint actions, best practices, information campaigns, common projects, exchange of experience, testing procedures, etc…

10) For establishing a means of regular dialogue with relevant EU business stakeholders

We call on the European Commission to set up an Advisory Board composed of relevant EU stakeholders (esp. manufacturers and importers) which could provide input to the horizontal Forum, for example along the lines of the European Accreditation Advisory Board. Such a consultative body would enable a coherent and regular dialogue with the Commission and NMSAs in order to provide input about risk assessment methods and priority settings for both market surveillance and import controls (where the designer and producer of a product can provide the technical data needed by the authorities to perform their market surveillance work?). Establishing a regular dialogue with relevant European stakeholders would enable the Commission and Member States to detect 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. It would provide feedback on guidance documents for the market surveillance authorities and economic operators.

III. FACILITATE THE NATIONAL IMPLEMENTATION OF MARKET SURVEILLANCE

11) For stimulating pooling and sharing of resources among Member States

Orgalime calls on the Commission to propose measures in the planned Safety and Market Surveillance package, which would promote the efficient use of market surveillance resources by Member States. In particular, we would like to make the following recommendations:

- **Share test results and infrastructures for market surveillance purposes**: “smart” sharing of the existing infrastructure among Member States can improve overall market surveillance in the internal market. Joint Actions in the consumer protection field have set the stepping-stone for such cooperation, although with a very limited budget. The envisaged market surveillance framework should provide strong recommendations and concrete means to enable Member States to mutually accept each other’s test results.
- **Open-up online channels of information sharing**: Orgalime welcomes the acquisition of ICSMS by the European Commission. We call on the Commission to use this IT tool for supporting the co-ordination work among Member States but also to enable relevant European stakeholders to feed in their technical expertise and experience with the design and placing on the market of products. An example of the type of information that could be

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made available is provided by the European machinery industries that have set up a resource database[10] of practical guides and technical documents for use by NMSAs.

- **Improve the scope, reliability and relevance of the EU Injury Database (IDB)[11]** on statistics detailing accidents and injuries at work, home and leisure activities. This would require an ambitious research programme involving a credible set of voluntary hospitals across the EU, in order to monitor user/consumer behaviour in relation to the main product categories. This would clarify the concept of foreseeable misuse and enable suppliers to improve the safety of their products. It would also help the market surveillance authorities to optimise their resources in improving the focus of their surveillance plans and strategies.

12) For dedicated funding to EU-wide market surveillance and border controls

- **The EU should finance the harmonisation and co-ordination of the enforcement of Internal Market legislation**: sharing resources and the deployment of best practices of market surveillance will contribute to a better use of available funding but will not be sufficient to tackle the challenges of rogue trading. Therefore, Orgalime calls for budgets to enable the European Commission set up common projects and systems to better use existing resources in Member States. A special financial framework might also be established to help Member States with special socio-economic and geographical challenges to carry out their duties, especially for those that have maritime freight ports. Such financial mechanisms exist in other areas of European legislation and could usefully provide food for thought[12].
- In 2009, Orgalime and ANEC already called for the possibility of setting up financial support within the framework of the European Structural funds to assist Member States.

13) For streamlining customs controls with market surveillance actions

Orgalime welcomes the recognition by the European Commission of the fact that any reform of market surveillance should take into account the consequences of globalisation in production and consumption. Thus, we expect that all the mechanisms set in the Market Surveillance and Safety Package should take into account the specific needs of customs authorities, which are facing the immense challenge posed by the diversity and the huge quantity of imported goods governed by EU requirements.

Orgalime has set out in an analytical position paper recommendations for enhancing custom controls and to allow for effective dialogue with interested stakeholders[13].

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[10] http://machinery-surveillance.eu/
[11] https://webgate.ec.europa.eu/sanco/heidi/index.php/Heidi/Lifestyle/Injuries/European_Injury_Database
[12] Cf. for instance the European External Borders Fund, which was set up to support Member States in guarding the Schengen Borders against illegal immigration.
[13] 10/5/2012 - Concrete suggestions for more efficient border controls and better cooperation with industry stakeholders