Position Paper

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For simpler compliance with and smarter enforcement of EU harmonisation legislation

Orgalime comments on the amendments of the European Parliament to the Commission proposal on "Compliance and Enforcement"

COD/2011/0150 – Rapporteur: Nicola Danti

This position follows up Orgalime's general 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]. See our separate position paper of 05/04/2018 [2].

Executive summary

Orgalime believes that there is an urgent need to restore mutual trust and confidence among both economic operators and market surveillance authorities to find smarter solutions that could ensure a high level of protection of both the health and safety of product users and the level-playing field among market operators.

Orgalime calls on the European policy maker to promote simplicity, flexibility, efficiency, cooperation and proportionality in shaping this proposal of the EU Commission for:

1. Clear enforcement legislation consistent with the New Legislative Framework, where all requirements can be assessed easily without unenforceable prescriptive requirements
2. A stronger level playing field between economic operators based inside and outside of the European Union thanks to more physical checks on the ground
3. An intelligent and efficient approach to market surveillance involving business stakeholders through transparent and unbiased memoranda of understandings
4. An enhanced cooperation among market surveillance authorities, facilitated by an active European forum or product compliance network
5. A clear-cut scope, which focuses on improving the efficiency and effectiveness of market surveillance without adding product specific requirements
6. Preserving the highest degree of legal certainty on the Single Market by limiting authorities' discretionary powers that would lead to new national barriers to trade
7. Keeping proportionality in the application of market surveillance powers, thereby avoiding too harsh an impact on the operators that are willing but not always able to comply (often small businesses) while being firm on rogue traders and their repeated offenses.

Therefore, we invite both the European Parliament and the Council to refrain from imposing more bureaucratic, unenforceable 'obligations' on economic operators. These would not achieve the goal that we support of a level playing field on the Union market with less segmented and more skilled Member States' market surveillance administrations.

[1] https://ec.europa.eu/docsroom/documents/26824
[2] http://www.orgalime.org/position/simpler-compliance-and-smarter-enforcement-eu-harmonisation-legislation-comments-commission (05/04/2018)

Orgalime, the European Technology Industries, speaks for 45 trade federations representing the mechanical, electrical, electronic, metalworking & metal technologies industries of 23 European countries. The industry employs nearly 11 million people in the EU and in 2017 accounted for some €2000 billion of output. The industry represents over a quarter of the output of manufactured products and over a third of the manufactured exports of the European Union.

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1. Clear enforcement legislation consistent with the New Legislative Framework, where all requirements can be assessed easily and without unenforceable prescriptive requirements

Orgalime welcomes the European Parliament's ambition to establish better conditions for a level playing field between manufacturers based in the EU and those established outside. This, however, cannot result in imposing additional so-called "compliance requirements" which inevitably lead to more bureaucracy for both economic operators and enforcement authorities.

The main goal of this Commission proposal is to make market surveillance more effective and efficient across the whole of the EU single market. Orgalime wholeheartedly supports this ambition. However, it can, in our opinion only be achieved by stepping up market surveillance activities by a significant increase of their financing and staffing means.

Such in-the-field market surveillance is a prerequisite for economic operators, especially those established outside of the EU, to take any additional obligations seriously.

Without effective physical checks, any new pre-marketing requirements are borne to failure, including requirements to publish traceability or compliance information on a website (EC proposal Article 4 and 5); to set up an EU conformity database (amendment 34); to affix traceability means on the product (amendment 231) and a marking of origin (amendments 175, 190, 232, 234); to make the use of harmonised standards mandatory by law (amendments 315, 316, 498, 499, 501 and 503) or requiring third-party certification for imports into the EU (amendments 397, 471, 562).

In our view, new requirements would:

- **Unnecessarily add** pre-marketing **complexity, a bureaucratic burden and costs** for manufacturers (especially SMEs), while authorities already have the possibility to retrieve such compliance information from the responsible person indicated in Article 4.
- Add yet more check points for **market surveillance authorities**, thereby counter-productively leading them to:
    - **favour administrative checks** of the declaration of conformity or certificates (that can be forged) **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, in line with Decision 768/2008 (New Legislative Framework).
- **Generate confusion as to the meaning** and relevance of the declaration of conformity or certificates to the non-specialist general public that would be lured to consider uploaded information as verified by an official authority, including 'certified' phoney uploads from rogue economic operators.

➔ **Therefore, Orgalime recommends:**

- **rejecting the proposal of a "European conformity database" (amendment 34), a mandatory traceability system (amendment 231) or any other pre-marketing requirements which would conflict with Union harmonisation legislation (amendments 20 to 27, 224 to 227 and 230)**
- **rejecting references to a marking of origin**, which has no relevance for market surveillance purposes **(amendments 175, 190, 232, 234) and would block the file in the Council again**
- **making the use of harmonised standards mandatory by law (amendments 315, 316, 498, 499, 501 and 503)**
- introducing systematic **third-party certification** for imports into the EU **(amendments 397, 471, 562).**

2. A stronger level playing field between economic operators based inside and outside of the European Union

Not only would **additional requirements**, such as those described above, be largely ineffective – for in practice they cannot be enforced –, they would furthermore represent a **new source of discrepancies and inequalities between**:

- on the one hand **careless or rogue traders** (especially those established outside of the EU) who will continue to ignore these new administrative obligations as they already ignore the present ones,
- and on the other hand, **legitimate manufacturers** who will yet again face additional unfair competition as they struggle with the cost of bringing their products in compliance.

Efficient processes are the simplest ones, those that allow flexibility and proportionality for most willing operators, while remaining strict on the unwilling ones.

➔ **Orgalime supports amendments 220 and 222 on Article 4, which remove the obligation for publishing the name of the person responsible on a website, while provide more flexibility in offering the possibility to provide a website address as an alternative to a physical address.**

➔ **We support amendments that would remove the obligation of Article 5 to publish the declaration of conformity on the manufacturer's website (amendments 35 and especially 236).**

➔ **We support amendment 241, which makes electronic labelling possible. This is a modern solution to enable products with an electronic display screen to make all legal affixing requirements available to authorities and other users.**

3. An intelligent approach to market surveillance involving business stakeholders

Market surveillance authorities need to acquire expertise and support to be able to conduct a fully knowledgeable risk analysis and to be efficient in carrying out their tasks. Therefore, the public-private partnership foreseen in Article 8 of the Commission proposal needs to be made possible.

As such, we call on Members of the Parliament and Member States representatives to approve this provision on memoranda of understanding (MoU) between Member States authorities and associations of businesses, with all the attached necessary reassurances that these will be transparent, unbiased and leave authorities' independence intact.

➔ **Orgalime supports amendments 267, 270, 272 and 273 that preserve the possibility for authorities to engage into MoUs with business associations and other stakeholders (under Article 8)**, if they wish to, **while subjecting them to competition laws, criteria and procedures set in EC implementing acts**.

➔ **We also support introducing a procedure under Article 12 to terminate a memorandum of understanding that would become biased (amendment 338)** and getting the support of the Union Product Compliance Network under **Article 33 to help drafting such Memoranda of Understanding** (**amendment 518**).

➔ Conversely, **we call for the rejection of amendments 41 and 264** which delete in part or in full Article 8, **amendment 123** which removes the task of the EUPC to assist in the drawing up and implementation of the memoranda of understanding referred to in Article 8, as well as **amendments 265 and 269** that add unnecessary requirements to their operation.

4. An enhanced cooperation among market surveillance authorities

Orgalime welcomes improving the coordination of efforts of national enforcement authorities with the support of the Union Product Compliance Network (EUPC), which will, in our view, facilitate the efficiency of market surveillance authorities. We especially welcome any further means 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 or workers under an employer's supervision) or consumers.

➔ **Orgalime supports amendments to Article 12** (Activities of market surveillance authorities), and especially amendments:

- 297 on assisting economic operators to remedy non-compliance.
- 300 for a dialogue between MSAs and economic operators in relation with Article 7.
- 301 for more inter-MSA coordination.
- 302 on requirements for MSAs such as frequency checks.
- 310 & 311 on harmonising the methodology and criteria for the MSA's risk assessment.
- 323 on setting up a set of procedures and a requirement for an **injury database**.
- 327 and 329 on protecting the principle of confidentiality and proportionality, professional secrets.

➔ **Orgalime also supports amendments to Article 32** (Composition of the EUPC), and especially amendments:

- 113 stressing the participation of experts from industry, small and medium enterprises and other stakeholders in ad hoc meetings of the network.
- 515 calling the EUPC to take reports of stakeholders into consideration.
- 517 introducing the possibility for meetings to be open to all stakeholders.

5. A clear-cut scope, without specific reference to product specific requirements

We are pleased to see that many Members of the IMCO Committee have duly considered the need to ensure proportionality and effectiveness in the way market surveillance authorities carry out their activities.

Essential requirements are devised in Union product specific or purpose specific harmonisation legislation, while the current proposal aims at the efficient and effective enforcement of any such requirements. Therefore, should new policy objectives or requirements be deemed necessary for the placing of products on the Union market, these should not be introduced in the current proposal but in ad hoc Union harmonisation legislation.

➔ Consequently, **Orgalime calls for the inclusion of non-harmonised goods into the scope in the interest of a more effective market surveillance (amendments 174, 182). Furthermore, Orgalime calls on the European policy maker to refrain from any specific reference to undefined 'emerging risks' that may arise from the use of new technologies, including the Internet of Things (amendments 10, 155, 200, 350, 561), artificial intelligence (amendments 151, 155, 561, 563), cybersecurity threats (amendments 180, 181, 191, 198, 402) or even the fight against counterfeiting (5, 150, 172, 275, 286, 287, 320/321, 391, 487).**

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6. Preserving the highest degree of legal certainty on the Single Market

One of the greatest assets of Union harmonisation legislation, as aligned with the 2008 New Legislative Framework (NLF), is the legal certainty and predictability that it provides to economic operators. Therefore, we call on rejecting suggestions that may jeopardise this legal certainty and predictability in market surveillance authorities' decisions. The New Legislative Framework and Union harmonisation legislation clearly set in the law the acceptable risks and means to mitigate them at best for product users (both consumers and workers), the environment or society at large.

Should the precautionary principle be deemed applicable in the face of scientific uncertainty, it is up to the future policymakers' decision on a case by case basis, when devising new Union legislation or revising existing legislation, as devised in the Commission Communication n°2000/0001 of 2 February 2000 [3].

The precautionary principle can in no way be left to the discretionary powers of local enforcement inspectors, for they have neither the capacity and proficiency nor the legitimacy to ascertain what is an acceptable risk for society or not. Their mission is to enforce the law, the whole law, but only the law, in an independent, transparent and proportionate manner (as requested under Article 12).

➔ Consequently, **Orgalime rejects amendments enabling market surveillance authorities to make use of the precautionary principle (amendments 55, 299, 305, 337, 394, 395).**

7. Keeping proportionality in the application of market surveillance powers

➔ **Orgalime supports** stressing the **proportionality and confidentiality principle (amendments 68 and 355, 327/329 or 335/336, 412, 444).**

➔ **Orgalime supports amendments that bring more balance and proportionality in the application of the extended powers of market surveillance authorities and especially amendments to the EC proposal under:**

- **Article 14, deleting system audits inspections (amendments 356/357, 73, 358)**, and mitigating the right to take samples free of charge (**361/362, 365 to 370, 372/373**).
- **Article 33**, **insisting on involving business associations** prior to adopting coordination procedures in administrative coordination committees **(amendment 522**)
- **Article 61**, stressing the need to protect the level playing field among economic operators (amendment 551) and or that call for leniency for first time or minor non-compliance cases (amendments 557/558)

➔ **Orgalime also supports calling market surveillance authorities to take action (under Article 14) in order to protect the legitimate interests of stakeholders and honest manufacturers**, such as in cases of repeated abuse or intentional instances (**amendments 382, 387**), by informing the economic operator concerned before making the information on the non-conformity public (**amendments 388/390**) and only when deemed relevant (**amendment 389**).

➔ **We also welcome** including a **definition of formal non-compliance** under Article 3 which refers to Decision 768/2008 (amendment 196) and excluding the application of the presumption of non-conformity introduced by Article 25 paragraph 3 to cases of formal non-compliance (amendment 465).

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52000DC0001

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➔ Conversely, **Orgalime rejects amendments that would either weaken the dissuasion** in case of controls and asserted non-compliance (**amendments 421, 481 to 485, 500**) or disproportionately **exaggerate deterrence** (**amendments 525, 526, 527** on Article 34) and **penalties** (**amendment 555** which proposes a penalty of 5% of the turnover of companies on Article 62).

➔ **We equally oppose amendments that would tear down the principles and the legal certainty enshrined in Union harmonisation legislation aligned with the NLF** (**amendments 461, 498/499, 501/503, 562 and 564 on article 62**).

Summary

Topic /Article	➔ Support	➔ Reject
Recital 13	-	5, 150, 151
Recital 16	-	10, 155
Art. 1. Subject matter	-	172, 175, 180, 181 190
Art. 3. Definitions	196	191, 198, 200
Art. 4. Person responsible for compliance information	222	20, 21, 22, 23, 24, 25, 26, 27, 34, 224, 225, 226, 227, 230, 231, 232, 234
Art. 4.4 Information for general public	220	-
Conformity database	-	-
Art. 5. Declaration of Conformity	35, 236, 241	-
Art. 6. Information to economic operators	-	-
Art. 7. Compliance partnership arrangements	-	-
Art. 8. Memoranda of Understanding with stakeholders	267, 270, 272, 273	41, 264, 265, 269
Art. 10. Obligations of market surveillance authorities as regards organisation		275, 286, 287
Art. 12. Activities of market surveillance authorities	297, 300, 301, 302, 310, 311, 323	55, 299, 305, 315, 316, 320, 321, 337
Art. 12.4 Reporting on activities by MSA	327, 329	-
Art. 12.5 Market surveillance activities	335, 336, 338	337
Art. 13. National market surveillance strategies	-	350
Art. 14. Powers and duties of market surveillance authorities	68, 73, 355, 356, 357, 358, 361, 362, 365, 366, 367, 368, 369, 370, 372, 373, 382, 387, 388, 389, 390, 412	391, 394, 395
Art. 15. Market Surveillance measures	-	397
Art. 17. Restrictive measures	-	-
Art. 18. Products presenting a serious risk	-	421
Art. 21. Financing and recovery of costs by MSA	444	461, 481, 482, 483, 484, 485
Art. 25. Use of evidence	465	461
Art. 25.4 Presumption of non-conformity	-	-
Art. 26. Controls on products entering the Union market	-	471
Art. 27.		487
Art. 27.1 (e) Suspension of release for free circulation	-	-
Art. 28. Release of products		498, 499
Art. 29. Authorised economic operator	-	500, 501, 503
Art. 31. Union Product Compliance Network	-	-
Art. 32. Composition of the Union Product Compliance Network	113, 515, 517	-
Art. 33. Coordinated enforcement tasks	518, 522	123
Art 34. Information and communication system	551, 557, 558	525, 526, 527
Art. 61. Penalties	-	555, 562, 564
Art. 62. Evaluation	-	561, 563

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