European Materials Handling Federation

FEM Position Paper on COM (2017)795 on compliance with and enforcement of Union harmonisation legislation

FEM represents European manufacturers of materials handling, lifting and storage equipment. Materials handling manufacturers have been advocating for many years the need to increase and improve the market surveillance system in Europe, as well as to identify and tackle non-compliance in an efficient manner, while protecting legitimate operators who make sizeable investments to understand and comply with applicable EU legislation.

Overall FEM is supportive of the Commission proposal on compliance with and enforcement of Union harmonisation legislation. We support the approach consisting of a mix of measures to improve compliance with applicable harmonisation legislation, provide the necessary incentives to economic operators, and ensure a level playing field amongst Market Surveillance Authorities (MSA) in terms of performing market surveillance checks and enforcing EU rules.

FEM particularly welcomes the Commission's objectives to achieve a true EU-wide coordination of market surveillance in Europe, and to increase external controls on products imported in the EU.

Another very important positive element is the aim to boost cooperation between economic operators and market surveillance authorities, notably through the Union Product Compliance Network which would allow the involvement of business representatives in separate or joint administrative coordination groups. We also support the set-up of national Product Contact Points (already applicable in the non-harmonised area), in the framework of EU harmonisation legislation as well. This would enable economic operators to obtain information on applicable legislation for specific products from these Contact Points.

All these elements certainly need to be preserved. In addition, we would like to make some proposals for clarifications and improvements to complete the proposal, thereby paving the way to a uniform, efficient and proportionate market surveillance framework in the EU.

1. The complexity of simultaneous application of several EU pieces of legislation

The new proposal COM (2017)795 applies in parallel with Regulation (EC) 765/2008 on accreditation and market surveillance, the General Product Safety Directive 2001/95/EC, and the sector-specific harmonisation legislation (e.g. Machinery Directive, Radio Equipment Directive, Low Voltage Directive etc.). The different applicable legal acts make it challenging for economic operators to understand and comply with all the existing requirements.

Moreover, the proposal includes the lex specialis clause in Article 2(2), according to which more specific provisions related to market surveillance and enforcement in the EU harmonisation legislation

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would apply. One may have difficulties to grasp how this clause will apply in practice for provisions related to the "person responsible for compliance information" or availability of the Declaration of Conformity (DoC), in relation to the existing requirements in the EU sectorial legislation (e.g. Machinery Directive). It is important to clarify the relationship between the future compliance and enforcement Regulation and the corresponding provisions in the product-specific legislation. In the interest of regulatory simplification, there should be no additional requirement in the future Regulation for manufacturers whose rights and obligations are already set in the product-specific legislation.

➔ The legal framework on market surveillance and enforcement should be clarified, bearing in mind the simultaneous application of different EU acts and the presence of a lex specialis clause

2. Definitions

FEM believes that the concept of "formal non-compliance" should be included in the set of definitions (in Article 3) and in Article 12(3), according to the specified procedures in Decision 768/2008, to have a clear distinction between purely formal or administrative non-compliance and technical non-compliance, related to a "serious risk". This is in order to avoid that disproportionate market surveillance actions are taken against cases of formal non-compliance, such as a misprint of the DoC, or the incorrect size of the CE mark.

➔ There should be a clear distinction between the concepts of formal non-compliance and technical non-compliance in the future Regulation

3. Person responsible for compliance

We agree that for each product placed on the EU market, MSA should be able to easily identify the person who is responsible for providing information on the compliance of the given product with the applicable legislation. For manufacturers established in the EU, this rule is straightforward since the responsible person is usually the manufacturer. In different EU harmonisation legislation, the name and address of the responsible economic operators (manufacturer and importer) are required to be affixed on the product or its packaging, and specified in the DoC accompanying the product. As long as this requirement is fulfilled, there is no need for an additional person responsible for compliance information.

The proposal requires also the identity and contact details of the person responsible for compliance to be made available to the general public. FEM does not see the added value of providing access of this person's identity and contact details to the wider public if this information can be indicated on an accompanying document (as specified in Article 4(5)), which can be the DoC.

➔ The role of the "person responsible for compliance" should be further clarified, in relation to importers and authorised representatives, required under specific sectorial legislation

4. Electronic Declaration of Conformity

FEM can support the making available of the DoC by digital means (Article 5), as long as this is done on a voluntary basis. This must not become a requirement which is limited to a website, but should give sufficient flexibility to manufacturers to choose the most adequate means of providing this document to MSA (for instance, by email, as a pdf file).

However, we do not agree with the obligation to make the DoC available to the general public. This document is not intended to be accessed by the general public, but by MSA and professional users. Moreover, to protect confidentiality, the public availability of the DoC cannot be mandatory.

➔ Manufacturers should have flexibility on the means chosen to provide the DoC

5. Market Surveillance Authorities' risk-based analysis

The proposal also refers to a risk-based approach in several articles (12, 15 (1), 18) which is intended to guide MSA in determining whether a product presents risks or not. It is crucial that the MSA's risk assessment should be as harmonised and unambiguous as possible across the Member States and in accordance to common and objective criteria, to prevent a discretionary evaluation of the product concerned, by one local market surveillance authority or the other. The risk assessment criteria should in principle be taken from the specific EU harmonised legislation and not covered in the future Regulation on compliance and enforcement.

➔ There should be a common scheme used by MSA when performing controls based on a risk-based approach, which should be defined by clear and objective criteria

6. Powers and duties of MSA

FEM fears that some of the powers and duties granted to MSA in Article 14 go beyond their means and competences, and are rather more appropriate for police or judiciary bodies. As a result, if applied, these powers may become disproportionate to the intended purpose of the investigations, especially if these investigations are prompted by a case of formal non-compliance.

Two particular examples we noted are:

- the power to perform system audits on economic operators (Article 14.3(b))

MSA are responsible for checking if the product placed on the market complies with the applicable legislation, but it is not in their role and competence to investigate what the manufacturer did before placing a product on the market.

- the power to ask any representative or member of staff to give explanations of facts, information or documents related to the subject of the inspection (Article 14.3(e)(3))

When performing assessments and investigations, MSA deal with companies. It should not be possible to target requests at any individual employees. Requesting information from employees that do not have the competence and knowledge to respond to the MSA questions does not have any added value for the investigation that is carried out.

We also feel further clarification is needed to explain what is/are the subject(s) of the investigations referred to in several instances in article 14.

In addition, the new legislative proposal shall consider setting a proportionate timeframe for the MSA to conclude their investigation and provide the results back to the economic operator, in order to avoid uncertainty on the market about a product deemed non-compliant. Moreover, Articles 17 shall give indications that are more precise on how to appeal against a decision taken by the MSA.

➔ The powers granted to MSA should be limited to what is necessary and appropriate for national enforcement administrations to perform their market surveillance tasks and prevent or remove non-compliant products from the market.