VDMA Comments April 2013

Proposal for a regulation on market surveillance of products (COM(2013) 75 final)

I. Introduction

"Market surveillance has not kept pace with the developments in the Union regulatory framework" the European Commission asserts in its draft regulation. While the single market for the free movement of goods is fully implemented and products circulate on the basis of European legislation, the Commission has recognised that the revision of the European-wide provisions on market surveillance is overdue. Employees and consumers can be put at risk by products not compliant with the law. Responsible players in the economy are placed at a disadvantage by ineffective market surveillance in comparison with those who deliberately exploit gaps in the implementation of regulations. The capital goods sector is reliant on effective market surveillance and therefore welcomes the aim of the Commission to strengthen European legislation.

II. VDMA comments

VDMA had advocated for developing on regulation 765/2008 when drafting a proposal on market surveillance. Despite several positive elements, core points were not fully taken up:

1. The draft proposed by the Commission takes a risk-based approach and, as a result, not all objects of legal protection are covered by market surveillance. Therefore, a risk-based approach is not appropriate. It should be dispensed with in favour of an approach which covers all objects of legal protection such as safety, health, environment and consumer protection.
2. Notwithstanding proof being required by member states that they are implementing market surveillance, the extension of the obligation to report as proposed in the draft must be viewed extremely critically.
3. We welcome standardisation of procedures and promotion of the exchange of information which will help to improve collaboration between market surveillance agencies, verify the effectiveness of measures and avoid overlaps. However, this aim will not be served by the proposed extended obligations for reporting and notification.
4. The notification and information systems RAPEX and ICSMS should be merged in the medium term since maintaining two databases is prone to errors.
5. The draft requires sanctions from member states that are "effective, proportionate and dissuasive". Therefore, guidelines for implementation through national legislation should be included in order to achieve this objective.
6. A balance between the powers of market surveillance authorities and recognition of the initiative of economic operators must be maintained. Measures taken by players in the market should always be given precedence over measures by the state.
7. The costs and resources needed to transmit technical documentation to the market surveillance agency should not increase. Manufacturers should still be able to determine themselves in which official language of the European Union technical documents are written.
8. Mandatory certification of products by independent third parties is no replacement for market surveillance by member states.

III. Practical problems

Dishonest manufacturers market products that do not comply with legal provisions and so gain an unfair competitive advantage. Dealers and importers should also be aware of their obligations and verify that products comply with the relevant regulations. Thus, it makes sense to record the whole supply chain through the planned regulation on market surveillance.

Capital goods are very durable and are therefore used over many years or even decades. The defects regarding compliance of the product with regulations apply throughout the whole life-cycle, whether to safety, consumer protection or environmental protection. The safety of employees is also often at stake since capital goods are generally means of production. The planned regulation of market surveillance should be supplemented by an interface to implement industrial health and safety in order to ensure effective collaboration of market surveillance agencies with agencies which implement industrial health and safety.

IV. Proposal of the Commission

Regulation 765/2008 provided a solid foundation for further development of regulation on market surveillance. Nonetheless, it contains some general provisions which do not fully ensure effective surveillance and verification of state measures with regard to European requirements to a satisfactory extent. Instead of building on regulation 765/2008, the Commission used the provisions of the directive on general product safety in compiling a draft for a regulation on market surveillance. We do not consider this approach to be appropriate.

Scope of application and terminology

In accordance with Article 2(1) **products manufactured for the company's own use** and possibly also put into operation should be covered. These products are primarily means of production provided by the employer and are not strictly speaking placed on the market. State agencies responsible for implementing industrial health and safety are tasked with surveillance of such products. Therefore, it is the proposal of VDMA that regulations are introduced regarding collaboration on market surveillance with state agencies responsible for industrial health and safety. They could be included in Section VI "Collaboration".

The draft regulation uses the basis created by the decision on the New Legislative Framework and brings **all economic operators within the scope** of application of the regulation. It is important that economic operators such as distributors, agents and importers throughout the whole supply chain assume certain duties to ensure product safety and that this is determined at a European level. These duties include, for example, compliance with transport and storage conditions or documentation requirements contained in harmonisation legislation. This will ensure standard implementation of market surveillance.

The draft regulation extends the definition of risk to include non-compliance of a product; this, however, results in consequences for the legal system. If **only a risk-based approach** is taken, as is the case in this draft proposed by the Commission, not all objects of legal protection are covered by market surveillance. Therefore, a risk-based approach is not appropriate and should be relinquished in favour of an approach that covers all objects of legal protection such as health, safety, environment and consumer protection. Formal non-compliance should also lead to corrective measures as provided for in the draft regulation. Non-compliant and unsafe products must both be subject to state measures, while maintaining the principle of proportionality of state measures.

This is important for capital goods, for example, which fall in the scope of application of an eco-design regulation. Such goods must comply with requirements defining environmentally

friendly product design. Non-compliance in this case runs the risk of placing manufacturers who adapt their products to the stringent provisions of eco-design at a competitive disadvantage. These products cannot be covered by a narrow definition of risk.

Exchange of information instead of reporting obligations - promoting transparency
The general market surveillance obligations are welcomed by VDMA since they go beyond the provisions of sectoral legal acts. However, despite proof being required by member states that they are implementing market surveillance, the **extension of obligations to report** as proposed in the draft must be viewed extremely critically since experience has shown that valuable resources of national authorities are tied up with implementing administrative activities, thus leading to a loss in effectiveness. Reporting obligations can be avoided by using tools for the evaluation of existing information in ICSMS. In this case evaluation of information from ICSMS would replace a formal obligation to report. In order to increase transparency, reporting market surveillance activities of a member state in accordance with Article 6(1) to the **ICSMS information system is an important element**.

The **provision of contact data and scope of responsibilities** is expressly welcome as a means to make the relevant authorities "accessible". The authorities responsible for market surveillance currently tend to be seen as somewhat anonymous. People involved or affected by ICSMS often do not know which authority to contact.

Balance between rights of economic operators and market surveillance authorities
In accordance with Article 6(2) voluntary measures taken by economic operators are given priority over state measures. This is extremely welcomed by VDMA, as is the fact that paragraph 3 requires authorities to maintain the principle of proportionality. The structure of measures in accordance with Article 9(4), (a) to (d) which an authority can take against non-compliant products is a decisive contribution to maintaining proportionality of means.

Standardised procedures and mutual recognition of test results
When assessing risks, an authority also considers the test results and risk assessments of economic operators and other authorities. Article 13 regulates **implementation of risk assessment** in order to ensure it is applied consistently. VDMA welcomes this. For risk assessment according to Article 13(4), so-called top level products are not a benchmark for the evaluation of the safety or risk posed by other products. It is essential that this provision in the draft is kept.

Mandatory certification of products by independent third parties is no replacement for market surveillance by member states since products can be identified by market surveillance authorities that do not comply with regulations even though they have been tested and certified by a third party agency. Testing by a third party agency, whether in the form of a type examination or in the form of external production surveillance, is merely a snapshot at the time of the test.

Closer cooperation between market surveillance and customs authorities
The provisions of regulation 765/2008 were adopted in the main and developed further. This is welcomed by VDMA in order to improve cooperation on market surveillance between customs authorities and controls at external frontiers.

Improved exchange of information and closer collaboration
The provisions of the draft in accordance with Articles 19 to 22 refer to the databases RAPEX and ICSMS. The ICSMS database has proved to be a useful information system in practice. Regulations on reporting obligations via the RAPEX system are not suitable for the exchange of data and consequently for the avoidance of duplication. If the intention is to maintain two systems, then **RAPEX and ICSMS could be linked** together more closely.

VDMA calls for a fusion of the two systems in the medium term in order to simplify their use and to limit the error rate inherent in the maintenance of two databases.

The provisions on **mutual administrative assistance** are expressly welcomed since the issue is to monitor the single market as a whole. There are no longer borders to commodity flows between member states and therefore borders should not prevent surveillance of the market.

Cooperation with the authorities of non-EU countries is welcomed since it is here that preventative measures can be taken. Avoiding the import of unsafe or legally non-compliant products to the EU must be given priority and checks at external frontiers should be improved.

The establishment of a **European market surveillance forum** is welcomed, in particular the participation of industry and SME representatives. In order to ensure a continuing and qualitative dialogue with industry, VDMA proposes to develop provisions so that representatives of industry are included permanently and at all levels of the forum.

The coordination process integrated in the assessment procedure for products subject to harmonisation regulations is not considered to be appropriate. The deadline of 60 days stipulated in Article 11 and the required formal steps are too cumbersome and time-consuming. Instead VDMA proposes provisions to link the regulation to sectoral rules. Therefore, we propose the following: In each of the committees of the market surveillance authorities composed of representatives from member states (AdCos) which deal with sectoral rules, a board should be formed which would deal with disputed market surveillance measures efficiently.

In accordance with Article 28, **EU reference laboratories** are to be established. Accreditation of these laboratories is missing in paragraph 2 of the provisions defining the preconditions which such laboratories must meet. It is important that the same standards and evaluation criteria are maintained to ensure comparability of results with nationally accredited agencies.

Stronger sanctions

The Commission is leaving member states to determine the severity of sanctions on infringements of product requirements. However, it does require that sanctions must be “effective, proportionate and dissuasive”. Furthermore, the member states must inform the Commission of the corresponding provisions. This is sensible to ensure that the maximum severity of sanctions between member states does not diverge overly, thus providing loop holes for non-compliant and unsafe products. VDMA calls for fines to be earmarked for the purpose of market surveillance since such funds would be an efficient contribution to market surveillance.

V. Suggestions for improvement - details:

- **Article 8(1):** economic operators must provide authorities with the required documents and information a language, which can be easily understood. VDMA suggests formulating this even more clearly in order to avoid economic operators being required, for example, to translate technical documentation into a language which is the official language of the country represented by the authority. This would mean economic operators being burdened with translation costs for these documents.

  Product-specific harmonisation provisions, such as the Machinery Directive 2006/42/EC, determine that the manufacturer can compile technical documentation with which he can prove compliance of the machine with the provisions of the Machinery Directive and

which are compiled as part of the compliance assessment procedure in one or more official languages of the European Union. An obligation to translate these documents into the official language of the member state where the authority is located cannot be deduced from this provision. The provision proposed in the draft regulation, whereby documents must be written in easily understandable language, can give rise to misunderstandings and misinterpretations which would result in considerable costs for manufacturers, in particular SMEs.

Justification: The provision of the Machinery Directive allows manufacturers to compile technical documentation in a language which is the official language of the member state where the company is registered. In other cases, a manufacturer will compile these documents in English because this language is used throughout the company as a means of communication, for example, although this language is not the official language of the country where the manufacturer is registered. In yet another case, parts of technical documentation are compiled in languages which are the official language of another member state where subsidiaries or branches are located. These subsidiaries carry out parts of the compliance evaluation procedure and document these parts in the technical documentation.

- **Article 9(1):** When assessing risks, an authority also considers the test results and risk assessments of economic operators and other authorities. Clarification is needed on the meaning of “other persons” since their test results and risk assessments are also to be used.

- **Article 9(5):** The Commission can use implementing acts to define how economic operators provide authorities with the necessary information. This is intended as a committee procedure in accordance with Article 32(2). This clause should be deleted because the provisions determining transmission of a manufacturer’s information to authorities is sufficiently regulated by the planned legal act. VDMA proposes to implement this clause according to the example of the Machinery Directive, as described in the proposal regarding Article 8(1).

- **Article 10(8):** Imposing the costs on manufacturers of products held to be unsafe or non-compliant after investigation is justified. However, manufacturers of products that are held to be compliant following investigations should never be burdened with costs. VDMA called for staffing levels at market surveillance agencies to be increased. Therefore, it would make sense to use budgetary funds in a targeted manner to expand the personnel capacities of authorities. Furthermore, consideration should be given as to how funds from administrative offences and fines can be channelled into the budget.

- **Supplementing Article 10:** If a product is determined to be non-compliant where the manufacturer commissioned a third party with carrying out parts of the compliance assessment procedure, the market surveillance authority should implement measures to check and if necessary to limit or cancel accreditation, licensing and the appointment of the third party.

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