



Mélanie Bruneau is a partner, Antoine de Rohan Chabot is an associate and Cecilia Sbrolli is a junior attorney at K&L Gates. Ms Bruneau can be contacted on +32 (2) 336 1940 or by email: melanie.bruneau@klgates.com. Mr de Rohan Chabot can be contacted on +32 (2) 336 1941 or by email: antoine.derohanchabot@klgates.com. Ms Sbrolli can be contacted on +32 (2) 336 1942 or by email: cecilia.sbrolli@klgates.com.

Published by Financier Worldwide Ltd
©2019 Financier Worldwide Ltd. All rights reserved.
Permission to use this reprint has been granted by the publisher.

■ **EXPERT BRIEFING** November 2019

European Union adopts new regulation on market surveillance and product compliance: economic operators in the internal market subject to reinforced obligations

BY MÉLANIE BRUNEAU, ANTOINE DE ROHAN CHABOT AND CECILIA SBROLLI

On 20 June 2019, the European Parliament and the Council of the European Union adopted Regulation (EU) 2019/1020 the “Market Surveillance Regulation” on market surveillance and compliance

of products, part of the so-called ‘Goods package’.

The Goods package is a broader legislative initiative, which aims to ensure that products placed on the European Union (EU) single market are safe and compliant

with EU legislation protecting public interests, such as health and safety in general, health and safety at the workplace, consumers, the environment and public security.



As a result, the provisions of the Market Surveillance Regulation will be applicable to products subject to 90 identified EU regulations and directives, in sectors such as medical devices, cosmetics, vehicles, toy safety, chemicals, packaging and waste.

The stated purpose of the Market Surveillance Regulation is to meet the challenges presented by global markets and complex supply chains, as well as the increased number of products sold online to end users in the EU.

To that end, the Market Surveillance Regulation aims to: (i) consolidate the existing framework for market surveillance activities regarding products placed on the EU market; (ii) address the challenges of EU and cross-border e-commerce and online trade; (iii) encourage joint activities by market surveillance authorities, other relevant authorities or with organisations representing economic operators or end users from several Member States; (iv) improve the digital exchange of information between authorities and the European Commission; (v) create a union product compliance network (UPCN) serving as a platform for coordination and cooperation between enforcement authorities of the Member States and the Commission; and (vi) create a strengthened framework for controls on products entering the single market and for improved cooperation between market surveillance authorities and customs authorities.

Extended legal obligations for all EU economic operators

One of the notable aspects of the Market Surveillance Regulation is the significant role attributed to 'economic operators'. Indeed, under the Market Surveillance Regulation, products subject to the

regulations and directives identified therein cannot be placed on the market unless an economic operator established in the EU is identified. The economic operator is responsible for ensuring the availability of the conformity documentation, cooperating with market surveillance authorities and informing authorities when they have reason to believe that a product presents a risk.

For the purposes of the Market Surveillance Regulation, an economic operator can be: (i) a manufacturer established in the EU; (ii) an importer, if the manufacturer is not established in the EU; (iii) an authorised representative with a written mandate from the manufacturer empowering it to act on the manufacturer's behalf; or (iv) a fulfilment service provider established in the EU, in case there is no other economic operator established in the EU.

Fulfilment service providers (FSPs) now become economic operators in the EU

Traditionally, economic operators as the manufacturer of the goods, the importer (where the manufacturer is not established in the EU) or the authorised representative, have been allocated responsibility for placing products on the EU market.

However, the number of economic operators offering products directly to consumers through e-commerce is increasing, and increasingly complex supply chains can now involve economic operators that do not fit easily into traditional supply chain roles under the existing legal framework. FSPs, which perform many of the same functions as importers, but which might not always correspond to the traditional definition of importer in EU law, are now included in this scenario.

Furthermore, with the development of internet sales, consumers can end up being in the position of the 'importer' within the EU. In practice, consumers directly importing products from outside of the EU have limited ability to ensure that those products comply with EU legislation.

For these reasons, and to avoid any potential enforcement gap, EU authorities have decided to extend the definition of economic operator in the Market Surveillance Regulation to now include FSPs, which are defined as providers offering at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services; parcel delivery services; and any other postal services or freight transport services.

The Market Surveillance Regulation considers that in the context of distance sales (including online sales), products offered for sale online or through other means of distance sales are deemed to be made available on the market if the offer is targeted at end users in the EU, i.e., if the relevant economic operator directs, by any means, its activities to an EU Member State.

Relevant case-by-case factors utilised to determine if an offer is targeted at EU end users are notably the geographical areas to which dispatch is available and the available languages in the offer or for ordering. It is to be noted that the mere fact that the website (of the economic operator or of the intermediaries) is accessible in the Member State in which the end user is established or domiciled is unsatisfactory to consider the sale to be targeted at end users in that Member State (and in the EU).



Adoption of national market surveillance strategies by EU Member States

The Market Surveillance Regulation provides that EU Member States will organise and carry out market surveillance by designating one or more unbiased and independent market surveillance authority, informing the European Commission (EC) and other Member States of the areas of competence of each authority.

The Market Surveillance Regulation further requires EU Member States to draw up an “overarching national market surveillance strategy” at least every four years (with the first being in place by 16 July 2022), which will promote a consistent, comprehensive and integrated approach to market surveillance and to the enforcement of EU harmonisation legislation within each EU Member State. The strategy will consider all sectors covered by EU harmonisation legislation and all stages of the supply chain, including imports and digital supply chains.

Strengthened powers for national market surveillance authorities

The Market Surveillance Regulation grants strengthened powers to national market surveillance authorities in order to ensure effective market surveillance of products subject to EU harmonisation legislation sold both offline and online, within their respective territory.

These notably include the power to require economic operators to provide information, such as relevant documents, technical specifications, data or information on compliance and technical aspects of the product, relevant information on the supply

chain, on the details of the distribution network, on quantities of products on the market and on other product models that have the same technical characteristics as the product in question, as well as relevant information required for the purpose of ascertaining the ownership of websites, where the information in question is related to the subject matter of the investigation.

In addition to their power to require information from economic operators, national market surveillance authorities shall also have the power to: (i) carry out unannounced on-site inspections and physical checks of products; (ii) enter any premises, land or means of transport that the economic operator in question uses for purposes related to the economic operator’s trade, business, craft or profession, in order to identify non-compliance and to obtain evidence; and (iii) start investigations on their own initiative in order to identify cases of non-compliance and bring them to an end.

Furthermore, the Market Surveillance Regulation also empowers national market surveillance authorities to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk and to take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled.

Market surveillance authorities may also impose “effective, proportionate and dissuasive” penalties for infringements of

the Market Surveillance Regulation and of the EU harmonisation legislation and acquire product samples, including under a cover identity, to inspect those samples and to reverse-engineer them in order to identify non-compliance and to obtain evidence.

Where no other effective means are available to eliminate a serious risk, market surveillance authorities will also have the power to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface. Failing that, authorities may require internet service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures.

Next steps

Most of the provisions of the Market Surveillance Regulation will be applicable as of 16 July 2021 (except that provisions regarding coordinated enforcement shall enter into force on 1 January 2021). Therefore, companies placing goods subject to EU harmonisation legislation on the EU market should anticipate and prepare for these new rules.

Notably, companies which have not yet appointed a responsible person established in the EU, or which have done so but through an economic operator based in the UK, should assess their obligations and take the necessary steps ahead of 16 July 2021. ■

This article first appeared as exclusive online content for November 2019 on www.financierworldwide.com. Permission to use this reprint has been granted by the publisher. © 2019 Financier Worldwide Limited.

FINANCIER
WORLDWIDE corporate finance intelligence