Overview


The new Market Surveillance Regulation is part of the “Goods package” which also contained the proposal for a regulation of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another member state, adopted in March 2019 (the Mutual Recognition Regulation).

Both regulations reflect the EU’s stated objective to reinforce trust in the EU single market by ensuring compliance with, and enforcement of product legislation (through the Market Surveillance Regulation) and at the same time improving and facilitating mutual recognition for goods (through the Mutual Recognition Regulation).

The Market Surveillance Regulation seeks to improve product compliance controls at the EU borders by:

1. laying down rules and procedures for economic operators;
2. strengthening market surveillance of products covered by EU harmonisation legislation; and
3. providing a framework for controls at the EU border.

These measures will have the greatest impact on online sales.

New Tasks for Operators

The Market Surveillance Regulation prohibits the placing on the market of certain goods unless an economic operator established in the EU is identified as responsible for ensuring the availability of the conformity documentation, cooperating with market surveillance authorities and informing authorities when they have reasons to believe that a product presents a risk. This can be:

- the manufacturer of the goods,
- the importer (where the manufacturer is not established in the EU),
- an authorised representative, or
- a fulfilment service provider, when none of the above are established in the EU.

This requirement applies to some of the goods covered by the Market Surveillance Regulation (see Article 4(5)), including construction products, machinery, toys, radio equipment, pressure equipment, and electrical and electronic equipment.

Companies placing these products on the EU market, who do not yet identify a responsible person established in the European Union, or who rely on an economic operator established in the United Kingdom, should assess their obligations and take the necessary steps.
Products offered for sale online, or through other distance sales means, are presumed to be made available on the EU market if the offer is targeted at end users in the EU, i.e., if the economic operator directs its activities to a Member State by any means.

The Market Surveillance Regulation also establishes an obligation of cooperation with market surveillance authorities for all economic operators, including information society service providers.

**Market Surveillance**

Market surveillance national authorities are granted strengthened powers to ensure effective market surveillance of products subject to Union harmonisation legislation sold offline and online, within their territory.

The provisions on market surveillance include the following:

- market surveillance authorities must conduct appropriate checks of products, including where appropriate physical and laboratory checks;
- the selection of products for checks must follow a risk-based approach taking into account among other possible hazards linked to the products, past non-compliance and consumer complaints;
- the Commission may adopt uniform rules for checks of products where specific risks or serious breaches of EU legislation have been continuously identified;
- market surveillance authorities’ powers must include at least:
  - the power to require economic operators to provide relevant document (including access to embedded software, information on their supply chain and information needed to ascertain ownership of websites);
  - the power to enter any premises;
  - the power to take samples;
  - the power to require economic operators to take the appropriate corrective action in the event of non-compliance (including product withdrawals, recalls or destruction);
  - the power to impose penalties;
  - the power to remove content from websites or to restrict access to the online interface;
- products deemed non-compliant in one Member State shall be presumed to be non-compliant in the other Member States.

**Controls at the EU Border**

The Market Surveillance Regulation confirms the basic principle of risk-based controls whilst providing new elements, such as the market surveillance authorities providing information on categories of products, or the identity of economic operators, with a higher risk of non-compliance, to customs authorities. The Commission is entitled to adopt implementing measures laying down benchmarks and techniques for checks on the basis of common risk analysis at EU level.

Where customs authorities suspend the release of a product for free circulation (for example because no EU responsible person is indicated on the product or packaging), market surveillance authorities will have four days to request the suspension to be maintained.

**Greatest Impact on Online Sales**

While the Market Surveillance Regulation is not singling out e-commerce, it will have the greatest impact on online sales crossing the EU’s border; B2C sales where the Business is outside of the EU, and the Consumer in the EU.

Currently, for this type of B2C sales, there is no enterprise formally responsible for regulatory compliance. Consumers are ‘importers’, responsible for compliance: they are supposed to ensure that what they buy online from vendors outside of the EU complies with EU rules. In practice, they rarely do, and there exists no incentive, no penalty for operators to control compliance themselves.

This is about to change, as the Market Surveillance Regulation requires non-EU vendors to have a representative in the EU, and makes the fulfilment service provider responsible when there is no representative. A fulfilment service provider is a person or company offering at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved; courier and postal companies are specifically excluded.

**EU Legislation Covered**

The Regulation applies to products subject to identified EU harmonisation legislation, unless the legislation contains more specific provisions on market surveillance and enforcement. The identified EU harmonisation legislation includes:
• EU legislation on products, such as:
  ○ EU Regulations on medical devices and in vitro diagnostic medical devices
  ○ the Ecodesign Directive, the Ecolabel Regulation and the Energy Labelling Regulation
  ○ vehicles legislation (type-approval of motor vehicles, permissible sound level and exhaust system of motor vehicles, end-of-life vehicles, air conditioning systems in motor vehicles, type-approval of hydrogen-powered motor vehicles, general safety of motor vehicles, their trailers and systems, components and separate technical units, two- or three-wheel vehicles, labelling of tyres)
  ○ the machinery Directive
  ○ the batteries Directive
  ○ the toy safety Directive
• EU legislation on chemicals:
  ○ the Fertilisers Regulation
  ○ the Detergents Regulation
  ○ the Persistent Organic Pollutants Regulation
  ○ the Volatile Organic Compounds Directive
  ○ the REACH Regulation
  ○ the CLP Regulation
  ○ the Ozone Depleting Substances Regulation
  ○ the Cosmetics Regulation
  ○ the Biocidal Products Regulation
  ○ the RoHS Directive (restriction of the use of certain hazardous substances in electrical and electronic equipment)
• EU legislation on waste:
  ○ the packaging and packaging waste Directive
  ○ the WEEE Directive

The full list of EU legislation covered by the Regulation is available in the annexes to the Regulation published here.

Looking Ahead

The provisions of the Regulation will apply from July 16, 2021, with the exception of a few provisions (on the setting up of a network for coordination and cooperation between enforcement authorities and the Commission and on the financing thereof), which will apply from January 1, 2021.

Companies placing goods (products and chemicals) on the EU market should take steps to understand and prepare for the impact of the Regulation on their operations and how they will be impacted by the authorities’ increased surveillance and control powers. Such powers are not unlimited and actions towards market actors must remain within the limits established by the applicable legislation and general principles of EU law.

Steptoe’s regulatory and trade teams are uniquely positioned to help you understand this new regulatory framework, and assessing the risk it creates for your operations.

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