

A new year, new obligations for economic operations: Here comes the market surveillance regulation

As of 1 January 2021, a number of provisions of Regulation (EU) 2019/1020 of 20 June 2019 on market surveillance and compliance of products (the **Market Surveillance Regulation**) are now applicable.

The Market Surveillance Regulation's main aim is to ensure that products placed on the EU market are compliant with EU harmonisation legislation. While this legislation has applied for a long time and covers a large range of manufactured products, until now, critical rules, such as the rules governing the placing of products on the market, market surveillance and cooperation between (enforcement and market surveillance) authorities have been highly fragmented and spread across approximately 70 pieces of EU legislation.

These shortcomings called for the establishment of a uniform framework for market surveillance and the strengthening of existing provisions in the EU harmonisation legislation. The Market Surveillance Regulation not only reinforces the obligations for economic operators¹ on placing a product on the EU market (eg by expressly covering online sales or other means of distance sales), but also broadens the categories of economic operators that can be subject to these obligations (eg by introducing obligations that specifically apply to fulfilment service providers²).

Most of the obligations in the Market Surveillance Regulation apply to any product covered by one or more of 70 designated pieces of EU harmonised legislation³, which includes key regimes for the chemicals and waste sectors, such as the REACH Regulation⁴, the CLP Regulation⁵, the Biocidal Products Regulation⁶, the POPs Regulation⁷, the RoHS Directive⁸, the packaging and packaging waste Directive⁹, and the WEEE Directive¹⁰, and include¹¹ *inter alia*:

- the reinforcement of market surveillance, both in its internal dimension, increasing the powers of market surveillance authorities, and in its external dimension, strengthening the custom controls at the EU's external borders to avoid non-compliant product entering the EU market;
- the introduction of provisions dealing with specific challenges posed by distance sales, extending market surveillance rules to online and other distance sales¹², and providing that products offered through those means are deemed to be made available on the EU market if the offer is targeted at end users in the EU;
- the introduction of the category of “fulfilment service providers” among the economic operators that can be subject to enforcement measures by the market surveillance authorities and as operators typically responsible for products sold through distance sales; and

1. These include manufacturers, importers, authorised representatives, and fulfilment service providers.
2. According to Recital (11) of the Market Surveillance Regulation, a fulfilment service provider is “any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council, parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council, and any other postal services or freight transport services”.
3. According to Recital (4), the Market Surveillance Regulation complements and strengthens existing provisions in Union harmonisation legislation and, in accordance with the principle of *lex specialis*, should apply only insofar as there are no specific provisions with the same objective, nature or effect in Union harmonisation legislation.
4. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
5. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
6. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
7. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.
8. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
9. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.
10. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
11. The key provisions of Article 4 of the Regulation, laying down the tasks of economic operators, only apply to certain pieces of harmonised legislation. This does not include the abovementioned key chemicals and waste legislations, save for the RoHS Directive.
12. The provision on Distance Sales applies to all legislation covered by the EU harmonization legislation listed in Annex I to the Market Surveillance Regulation, not only those subject to Article 4.

– the set-up of a general obligation for economic operators to cooperate with market surveillance authorities to eliminate or mitigate risks connected with products that they have placed on the market. This obligation does not alter, but rather sums up the other cooperation obligations that might exist under each piece of EU harmonisation legislation¹³. For instance, while in certain cases – notably under the RoHS Directive – the cooperation duty aims to merely remedy any “non-conformity” of products with the relevant legislation, under the Market Surveillance Regulation it aims to also address – and eminently – the “risks” posed by those products. As a result, operators handling products covered by the RoHS Directive will be now subject to an additional cooperation obligation – aimed at addressing not only a product’s “non-compliance” but also its “risks”. Under the Market Surveillance Regulation, the cooperation obligation is generally triggered at the request of the market surveillance authority¹⁴, but in case of products subject to Article 4 (see also below) it appears to require a more proactive attitude from economic operators. When the economic operator

responsible for such a product has reason to believe that it presents a risk, it must inform the relevant market surveillance authorities and ensure that the immediate, necessary, corrective action is taken, regardless of whether it has been requested by the market surveillance authorities¹⁵.

Furthermore, Article 4 of the Market Surveillance Regulation introduces new rules for economic operators in relation to products subject to certain, expressly designated legislation¹⁶, requiring that they can only be placed on the market¹⁷ if there is an economic operator established in the EU who is ‘responsible’ for certain tasks in relation to it. | This concept is not new to the EU harmonisation legislation, but the new Market Surveillance Regulation provides criteria to identify the responsible operator on a general basis.

Note that the EU Commission (the **EC**) has started working on an update of its (existing 2016) Blue Guide on the implementation of EU product rules¹⁸ to capture the new rules introduced by the Market Surveillance Regulation¹⁹, and on an evaluation²⁰ of the New Legislative Framework, on which the Blue Guide is based.

13. In accordance with the principle of *lex specialis*, set out in Recital (4) of the Market Surveillance Regulation.

14. Article 7 combined with Articles 14 and 16(2)(3) of the Market Surveillance Regulation. For instance, when required by market surveillance authorities to do so, economic operators must: (a) provide relevant data on products’ compliance, technical aspects, supply chain, distribution network and quantities on the market, such as information required to ascertain the ownership of websites; (b) take appropriate action to remedy instances of non-compliance or to eliminate the risk; (c) remove product-related contents from an online interface or display a warning to end users, to eliminate a serious risk.

15. Article 4(3) of the Market Surveillance Regulation.

16. This obligation only applies to legislation that is expressly designated in Article 4, ie: Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5); Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51); Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99); Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1); Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24); Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1); Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10); Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88); Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (OJ L 178, 28.6.2013, p. 27); Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90); Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45); Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79); Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107); Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149); Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309); Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357); Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62); Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164).

17. For the purposes of this Regulation, ‘placing on the market’ means the first making available of a product on the Union market for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge. As these provisions apply from 16 July 2021, this means that products that were made available on the market at least once before that date, will not have to meet the requirements introduced by the Market Surveillance Regulation, unless this was required by existing legislation. It is also noteworthy that, under some pieces of harmonised legislation covered by the Market Surveillance Regulation (such as REACH and the POPs Regulation), the concept of “placing on the market” has been interpreted/defined differently as including any making available of the product on the market, regardless of whether it is for the first time.

18. Commission Notice – The ‘Blue Guide’ on the implementation of EU products rules 2016 C/2016/1958, OJ C 272, 26.7.2016, p. 1–149

19. The outcome of this update is expected later in 2021.

20. The New Legislative Framework for industrial products in the EU aims to improve the internal market for goods by improving market surveillance and boosting the quality of conformity assessments. A roadmap for the evaluation of the New Legislative Framework was published on 4 November 2020 (Ares(2020)6353387), and a public consultation is foreseen in the first quarter of 2021.

While most of the provisions of the Market Surveillance Regulation (including the obligations set out above) will only start to apply from 16 July 2021, the provisions concerning (i) the Union Product Compliance Network (the **Network**)²¹, (ii) the tasks of administrative cooperation groups (**ADCOs**)²² and the EU Commission (the **EC**)²³ applied from 1 January 2021. The purpose of the Network is to facilitate coordination and cooperation between the enforcement authorities of the Member States and the EC, and to streamline market surveillance practices within the Union. It will be composed of representatives from each Member State, the chairs of ADCOs and representatives from the EC, and the decisions taken by it will constitute non-binding recommendations.

The roles and tasks of the Network include, among other things:

- organising cross-sector joint market surveillance, defining their priorities and exchanging information and best practices, in particular regarding the implementation of national market surveillance strategies;
- developing guidance for the effective and uniform application of the Market Surveillance Regulation; and
- promoting cooperation and exchange of best practices between market surveillance authorities and customs authorities.

ADCOs must support the functioning of the Network by, *inter alia*:

- addressing sector specific issues related to market surveillance to facilitate the uniform application of Union harmonisation legislation;
- establishing and coordinating common projects, such as cross-border joint market surveillance activities;
- promoting communication between market surveillance authorities and the Network;
- facilitating sector-specific evaluations of products, including risk assessments, test methods and results and recent scientific developments.

The EC must support cooperation between market surveillance authorities through the Network by means of an executive secretariat, particularly by:

- providing technical and logistic support to the Network, its sub-groups, and the ADCOs;
- supporting the functioning of the Product Contact Points²⁴;
- developing and maintaining information and communication systems;
- organising joint market surveillance and assisting the Network to perform ancillary work in connection with the implementation of market surveillance activities;
- examining, at the request of the Network or on its own initiative, any question covering the application of the Market Surveillance Regulation and issuing guidelines, recommendations and best practices in order to encourage its consistent application.

Currently, these are the only provisions that apply now. The more substantive provisions (including those imposing new obligations on economic operators, and enhancing the relevant authorities' (inspection) powers will only become applicable in July 2021, and, hence, the practical implications of the Market Surveillance Regulation remain to be seen. However, economic operators in different supply chains should start preparing now, for example by allocating responsibilities in relation to the obligations set up by the Market Surveillance Regulation. In particular, fulfilment service providers and non-EU based suppliers of harmonised products sold directly to end-users should consider how the new rules will affect their supply chains and sales techniques.



21. Articles 29 to 31 of the Market Surveillance Regulation.

22. Article 32 of the Market Surveillance Regulation

23. Article 33 of the Market Surveillance Regulation

24. Product Contact Points are established under Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member State and are in charge of assisting the economic operators in addressing their requests for information, for instance on applicable national technical rules and administrative procedures or on whether goods are subject to prior authorisation under national law. Member States are required to set up procedures to ensure economic operators have access to Product Contact Points.