

Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (Text with EEA relevance)

CHAPTER V

MARKET SURVEILLANCE POWERS AND MEASURES

Article 14

Powers of market surveillance authorities

1 Member States shall confer on their market surveillance authorities the powers of market surveillance, investigation and enforcement necessary for the application of this Regulation and for the application of Union harmonisation legislation.

2 Market surveillance authorities shall exercise the powers set out in this Article efficiently and effectively, in accordance with the principle of proportionality, to the extent that such exercise relates to the subject matter and the purpose of the measures and the nature and the overall actual or potential harm resulting from the instance of non-compliance. Powers shall be conferred and exercised in accordance with Union and national law, including the principles of the Charter of Fundamental Rights of the European Union, as well as with principles of national law relating to freedom of expression and the freedom and pluralism of the media, with applicable procedural safeguards and with the Union rules on data protection, in particular Regulation (EU) 2016/679.

3 When conferring powers under paragraph 1, Member States may provide for the power to be exercisable in one of the following ways, as appropriate:

- a directly by the market surveillance authorities under their own authority;
- b by recourse to other public authorities in accordance with the division of powers and the institutional and administrative organisation of the Member State in question;
- c upon application to courts competent to grant the necessary decision to approve the exercise of that power, including, where appropriate, on appeal, if the application to grant the necessary decision was not successful.

4 The powers conferred on market surveillance authorities under paragraph 1 shall include at least the following:

- a the power to require economic operators to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the product, including access to embedded software in so far as such access is necessary for the purpose of assessing the product's compliance with applicable Union harmonisation legislation, in any form or format and irrespective of the medium of storage or the place where such documents, technical specifications, data or information are stored, and to take or obtain copies thereof;
- b the power to require economic operators to provide 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, where relevant for compliance with the applicable requirements under Union harmonisation legislation;

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- c the power to require economic operators to provide 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;
- d the power to carry out unannounced on-site inspections and physical checks of products;
- e the power to 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;
- f the power to start investigations on market surveillance authorities' own initiative in order to identify non-compliances and bring them to an end;
- g the power to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk;
- h the power 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;
- i the power to impose penalties in accordance with Article 41;
- j the power to 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;
- k the power, where no other effective means are available to eliminate a serious risk:
 - (i) 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; or
 - (ii) where a request according to point (i) has not been complied with, to require information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures.

5 Market surveillance authorities may use any information, document, finding, statement, or any intelligence as evidence for the purpose of their investigations, irrespective of the format in which and medium on which they are stored.

Article 15

Recovery of costs by market surveillance authorities

1 Member States may authorise their market surveillance authorities to reclaim from the relevant economic operator the totality of the costs of their activities with respect to instances of non-compliance.

2 The costs referred to in paragraph 1 of this Article may include the costs of carrying out testing, the costs of taking measures in accordance with Article 28(1) and (2), the costs of storage and the costs of activities relating to products that are found to be non-compliant and are subject to corrective action prior to their release for free circulation or their placing on the market.

Article 16

Market surveillance measures

1 Market surveillance authorities shall take appropriate measures if a product subject to Union harmonisation legislation, when used in accordance with its intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained:

- a is liable to compromise the health or safety of users; or
- b does not conform to applicable Union harmonisation legislation.

2 Where market surveillance authorities make findings referred to in point (a) or (b) of paragraph 1, they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action to bring the non-compliance to an end or to eliminate the risk within a period they specify.

3 For the purposes of paragraph 2, the corrective action required to be taken by the economic operator may include, inter alia:

- a bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or by ensuring that the product no longer presents a risk;
- b preventing the product from being made available on the market;
- c withdrawing or recalling the product immediately and alerting the public to the risk presented;
- d destroying the product or otherwise rendering it inoperable;
- e affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks that it might present, in the language or languages determined by the Member State in which the product is made available on the market;
- f setting prior conditions for making the product concerned available on the market;
- g alerting the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.

4 Corrective actions referred to in points (e), (f) and (g) of paragraph 3 may only be required in cases where the product is liable to present a risk only in certain conditions or only to certain end users.

5 If the economic operator fails to take corrective action referred to in paragraph 3 or where the non-compliance or the risk referred to in paragraph 1 persists, market surveillance authorities shall ensure that the product is withdrawn or recalled, or that its being made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly.

6 The information to the Commission and the other Member States pursuant to paragraph 5 of this Article shall be communicated through the information and communication system referred to in Article 34. That communication of information shall also be deemed to fulfil notification requirements for the applicable safeguard procedures of Union harmonisation legislation.

7 Where a national measure is considered to be justified in accordance with the applicable safeguard procedure, or where no market surveillance authority of another Member State concluded the contrary as referred to in Article 11(9), the competent market surveillance authorities in the other Member States shall take the necessary measures in respect of

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the non-compliant product and shall enter the relevant information in the information and communication system referred to in Article 34.

Article 17

Use of information, professional and commercial secrecy

Market surveillance authorities shall perform their activities with a high level of transparency and shall make available to the public any information that they consider to be relevant in order to protect the interests of end users. Market surveillance authorities shall respect the principles of confidentiality and of professional and commercial secrecy and shall protect personal data in accordance with Union and national law.

Article 18

Procedural rights of economic operators

1 Any measure, decision or order taken or made by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation shall state the exact grounds on which it is based.

2 Any such measure, decision or order shall be communicated without delay to the relevant economic operator, who shall at the same time be informed of the remedies available to it under the law of the Member State concerned and of the time limits to which those remedies are subject.

3 Before a measure, decision or order referred to in paragraph 1 is taken or made, the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 working days, unless it is not possible to give the economic operator that opportunity because of the urgency of the measure, decision or order, based on health or safety requirements or other grounds relating to the public interests covered by the relevant Union harmonisation legislation.

If the measure, decision or order is taken or made without the economic operator being given the opportunity to be heard, the economic operator shall be given that opportunity as soon as possible thereafter and that measure, decision or order shall be reviewed promptly by the market surveillance authority.

Article 19

Products presenting a serious risk

1 Market surveillance authorities shall ensure that products presenting a serious risk are withdrawn or recalled, where there is no other effective means available to eliminate the serious risk, or that their being made available on the market is prohibited. Market surveillance authorities shall notify the Commission thereof immediately, in accordance with Article 20.

2 A decision whether or not a product presents a serious risk shall be based on an appropriate risk assessment that takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety and the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

Article 20

Rapid Information Exchange System

1 Where a market surveillance authority takes or intends to take a measure pursuant to Article 19 and considers that the reasons which prompted the measure or the effects of the measure go beyond the territory of its Member State, it shall immediately notify the Commission of that measure in accordance with paragraph 4 of this Article. The market surveillance authority shall also inform the Commission without delay of the modification or withdrawal of any such measure.

2 If a product presenting a serious risk has been made available on the market, market surveillance authorities shall immediately notify the Commission of any voluntary measures taken and communicated to the market surveillance authority by an economic operator.

3 The information provided in accordance with paragraphs 1 and 2 shall include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the risk related to the product, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.

4 For the purposes of paragraphs 1, 2 and 3 of this Article, the Rapid Information Exchange System (RAPEX) provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of that Directive shall apply *mutatis mutandis*.

5 The Commission shall provide and maintain a data interface between RAPEX and the information and communication system referred to in Article 34 so as to avoid double data entry.

Article 21

Union testing facilities

1 The objective of the Union testing facilities is to contribute to enhancing laboratory capacity, as well as to ensuring the reliability and consistency of testing, for the purposes of market surveillance within the Union.

2 For the purposes of paragraph 1, the Commission may designate a public testing facility of a Member State as a Union testing facility for specific categories of products or for specific risks related to a category of products.

The Commission may also designate one of its own testing facilities as a Union testing facility for specific categories of products or for specific risks related to a category of products, or for products for which testing capacity is missing or is not sufficient.

3 Union testing facilities shall be accredited in accordance with Regulation (EC) No 765/2008.

4 The designation of Union testing facilities shall not affect the freedom of market surveillance authorities, the Network and the Commission to choose testing facilities for the purpose of their activities.

5 Designated Union testing facilities shall provide their services solely to market surveillance authorities, the Network, the Commission and other government or intergovernmental entities.

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6 Union testing facilities shall, within the area of their competence, perform the following activities:

- a carry out testing of products at the request of market surveillance authorities, the Network or the Commission;
- b provide independent technical or scientific advice at the request of the Network;
- c develop new techniques and methods of analysis.

7 The activities referred to in paragraph 6 of this Article shall be remunerated and may be financed by the Union in accordance with Article 36(2).

8 Union testing facilities may receive financing by the Union in accordance with Article 36(2) in order to increase their testing capacity or to create new testing capacity for specific categories of products or for specific risks related to a category of products for which the testing capacity is missing or is insufficient.

9 The Commission shall adopt implementing acts specifying the procedures for the designation of Union testing facilities. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

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