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)

REGULATION (EU) 2019/1020 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 June 2019

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 33 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that products are compliant with Union harmonisation legislation and therefore fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment, public security and protection of any other public interests protected by that legislation. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union market for goods can thrive. Rules are therefore necessary to ensure this enforcement, regardless of whether products are placed on the market via offline or online means and regardless of whether they are manufactured in the Union or not.

(2) Union harmonisation legislation covers a large share of manufactured products. Non-compliant and unsafe products put citizens at risk, and might distort competition with economic operators selling compliant products within the Union.

(3) Strengthening the single market for goods through further enhancing efforts to keep non-compliant products from being placed on the Union market was identified as a priority in the Communication from the Commission of 28 October 2015 entitled ‘Upgrading the Single Market: more opportunities for people and business’. This

should be achieved by strengthening market surveillance, providing economic operators with clear, transparent and comprehensive rules, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

(4) The framework for market surveillance established by this Regulation should complement and strengthen existing provisions in Union harmonisation legislation relating to the ensuring of compliance of products and the framework for cooperation with organisations representing economic operators or end users, the market surveillance of products and controls on those products entering the Union market. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in Union harmonisation legislation. The corresponding provisions of this Regulation should therefore not apply in the areas covered by such specific provisions, for instance those set out in Regulations (EC) No 1223/2009[(3)], (EU) 2017/745[(4)] and (EU) 2017/746[(5)], including as regards the use of the European database on medical devices (EUDAMED), and (EU) 2018/858[(6)] of the European Parliament and of the Council.

(5) Directive 2001/95/EC of the European Parliament and of the Council[(7)] lays down the general safety requirements for all consumer products and provides for specific obligations and powers of the Member States in relation to dangerous products as well as for the exchange of information to that effect through the Rapid Information Exchange System (RAPEX). Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive. In order to achieve a higher level of safety for consumer products, the mechanisms for exchanges of information and rapid intervention situations provided for in Directive 2001/95/EC should be made more effective.

(6) The provisions on market surveillance of this Regulation should cover products that are subject to the Union harmonisation legislation listed in Annex I concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level and will help to increase the confidence of consumers and other end users in products placed on the Union market. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether this Regulation is also to apply to that legislation.

(7) Articles 15 to 29 of Regulation (EC) No 765/2008 of the European Parliament and of the Council[(8)] laying down the Community market surveillance framework and controls of products entering the Community market should be deleted and the respective provisions should be replaced by this Regulation. That framework includes the provisions on controls of products entering the Community market, in Articles 27, 28 and 29 of Regulation (EC) No 765/2008, which apply not only to products covered by the market surveillance framework, but to all products in so far as other Union law

does not contain specific provisions relating to the organisation of controls on products entering the Union market. It is therefore necessary that the scope of the provisions of this Regulation with regard to products entering the Union market extend to all products.

(8) In order to rationalise and simplify the overall legislative framework, while simultaneously pursuing the objectives of Better Regulation, the rules applicable to controls on products entering the Union market should be revised and integrated into a single legislative framework for controls on products at the Union's external borders.

(9) Responsibility for enforcing Union harmonisation legislation should lie with the Member States, and their market surveillance authorities should be required to ensure that the legislation is fully complied with. The Member States should, therefore, establish systematic approaches to ensure effectiveness of market surveillance and other enforcement activities. In this regard, the methodology and criteria for assessing risks should be further harmonised in all Member States in order to ensure a level playing field for all economic operators.

(10) In order to assist market surveillance authorities to strengthen consistency in their activities related to the application of this Regulation, an effective peer review system should be established for those market surveillance authorities wishing to participate.

(11) Certain definitions currently set out in Regulation (EC) No 765/2008 should be aligned with definitions set out in other Union legal acts and, where appropriate, reflect the architecture of modern supply chains. The definition of ‘manufacturer’ in this Regulation should not relieve manufacturers of any obligations they might have under Union harmonisation legislation where specific definitions of manufacturer are applied, which might cover any natural or legal person who modifies a product already placed on the market in such a way that compliance with the applicable Union harmonisation legislation might be affected and places it on the market, or any other natural or legal person who places a product on the market under its name or trade mark.

(12) Economic operators throughout the entire supply chain should be expected to act responsibly and in full accordance with the legal requirements applicable when placing or making products available on the market, so as to ensure compliance with the Union harmonisation legislation on products. This Regulation should be without prejudice to the obligations corresponding to the roles of each of the economic operators in the supply and distribution process pursuant to specific provisions in Union harmonisation legislation, and the manufacturer should retain ultimate responsibility for compliance of the product with requirements of the Union harmonisation legislation.

(13) The challenges of the global market and increasingly complex supply chains, as well as the increase of products that are offered for sale online to end users within the Union, call for the strengthening of enforcement measures, to ensure the safety of consumers. Furthermore, practical experience of market surveillance has shown that such supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional supply chains according to the existing legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. In order to ensure

that market surveillance authorities can carry out their responsibilities effectively and to avoid a gap in the enforcement system, it is appropriate to include fulfilment service providers within the list of economic operators against whom it is possible for market surveillance authorities to take enforcement measures. By including fulfilment service providers within the scope of this Regulation, market surveillance authorities will be better able to deal with new forms of economic activity in order to ensure the safety of consumers and the smooth functioning of the internal market, including where the economic operator acts both as an importer as regards certain products and as a fulfilment service provider as regards other products.

(14) Modern supply chains encompass a wide variety of economic operators who should all be subject to enforcement of Union harmonisation legislation, while taking due consideration of their respective roles in the supply chain, and the extent to which they contribute to the making available of products on the Union market. Therefore, it is necessary to apply this Regulation to economic operators that are directly concerned by Union harmonisation legislation listed in Annex I to this Regulation, such as the producer of an article and the downstream user as defined in Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(9)] and in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(10)], the installer as defined in Directive 2014/33/EU of the European Parliament and of the Council[(11)], the supplier as defined in Regulation (EC) No 1222/2009 of the European Parliament and of the Council[(12)] or the dealer as defined in Regulation (EU) 2017/1369 of the European Parliament and of the Council[(13)].

(15) In the case of a product offered for sale online or through other means of distance sales, the product should be considered to have been made available on the market if the offer for sale is targeted at end users in the Union. In line with the applicable Union rules on private international law, a case-by-case analysis should be carried out in order to establish whether an offer is targeted at end users in the Union. An offer for sale should be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State. For the case-by-case analyses, relevant factors, such as the geographical areas to which dispatch is possible, the languages available, used for the offer or for ordering, or means of payment, need to be taken into consideration. In the case of online sales, the mere fact that the economic operators' or the intermediaries' website is accessible in the Member State in which the end user is established or domiciled is insufficient.

(16) The development of e-commerce is also due, to a great extent, to the proliferation of information society service providers, usually through platforms and for remuneration, which offer intermediary services by storing third party content, without exercising control over that content, and therefore not acting on behalf of an economic operator. Removal of content regarding non-compliant products or, where this is not feasible, restricting access to non-compliant products offered through their services should be without prejudice to the rules laid down in Directive 2000/31/EC of the European Parliament and of the Council[(14)]. In particular, no general obligation should be imposed on information society service providers to monitor the information which they transmit or store, nor should a general obligation be imposed upon them to actively seek facts or

circumstances indicating illegal activity. Furthermore, hosting service providers should not be held liable as long as they do not have actual knowledge of illegal activity or information and are not aware of the facts or circumstances from which the illegal activity or information is apparent.

(17) While this Regulation does not deal with the protection of intellectual property rights, it should nevertheless be borne in mind that often counterfeit products do not comply with the requirements set out in the Union harmonisation legislation, present risks to health and safety of end users, distort competition, endanger public interests and support other illegal activities. Therefore, Member States should continue taking effective measures to prevent counterfeit products from entering the Union market pursuant to Regulation (EU) No 608/2013 of the European Parliament and of the Council[(15)].

(18) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this end, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element, allowing immediate intervention and corrective action in relation to the product. It is important that, for certain products, there should be an economic operator established in the Union so that market surveillance authorities have someone to whom requests can be addressed, including requests for information regarding a product's compliance with Union harmonisation legislation, and who can cooperate with market surveillance authorities in making sure that immediate corrective action is taken to remedy instances of non-compliance. The economic operators who should perform those tasks are the manufacturer, or the importer when the manufacturer is not established in the Union, or an authorised representative mandated by the manufacturer for this purpose, or a fulfilment service provider established in the Union for products handled by it when no other economic operator is established in the Union.

(19) The development of e-commerce poses certain challenges for market surveillance authorities with regard to the ensuring of compliance of products offered for sale online and the effective enforcement of Union harmonisation legislation. The number of economic operators offering products directly to consumers by electronic means is increasing. Therefore, economic operators with tasks regarding products subject to certain Union harmonisation legislation perform an essential role by providing market surveillance authorities with an interlocutor established in the Union, and by performing specific tasks in a timely manner to make sure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, other end users and businesses within the Union.

(20) The obligations of the economic operator with tasks regarding products subject to certain Union harmonisation legislation should be without prejudice to existing obligations and responsibilities of manufacturer, importer and authorised representative under the relevant Union harmonisation legislation.

(21) Obligations of this Regulation requiring an economic operator to be established in the Union in order to place products on the Union's market should only apply to areas where the need for an economic operator to act as a liaison point with the market surveillance