# Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (Text with EEA relevance)

## REGULATION (EU) 2019/515 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 19 March 2019

on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008

(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 Article 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) The internal market comprises an area without internal frontiers in which the free movement of goods is ensured in accordance with the Treaties. Quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. That prohibition covers any national measure which is capable of hindering, directly or indirectly, actually or potentially, intra-Union trade in goods. The free movement of goods is ensured in the internal market by the harmonisation of rules at Union level that set common requirements for the marketing of certain goods or, for goods or aspects of goods not exhaustively covered by Union harmonisation rules, by the application of the principle of mutual recognition as defined by the Court of Justice of the European Union.

(2) A well-functioning principle of mutual recognition is an essential complement to harmonisation of rules at Union level, especially considering that many goods have both harmonised and non-harmonised aspects.

(3) Obstacles to the free movement of goods between Member States may be unlawfully created if, in the absence of Union harmonisation rules covering goods or certain aspects of goods, a Member State's competent authority applies national rules to goods that are lawfully marketed in another Member State, requiring the goods to meet certain technical requirements, for example, requirements relating to designation, form, size, weight, composition, presentation, labelling or packaging. The application of such rules

**Changes to legislation:** *There are currently no known outstanding effects for the Regulation (EU) 2019/515 of the European Parliament and of the Council. (See end of Document for details)*

to goods that are lawfully marketed in another Member State could be contrary to Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), even if the rules apply to all goods without distinction.

(4) The principle of mutual recognition derives from the case-law of the Court of Justice of the European Union. According to this principle, Member States may not prohibit the sale on their territory of goods which are lawfully marketed in another Member State, even where those goods have been produced in accordance with different technical rules, including goods that are not the result of a manufacturing process. But the principle of mutual recognition is not absolute. Member States can restrict the marketing of goods that have been lawfully marketed in another Member State, where such restrictions are justified on the grounds set out in Article 36 TFEU or on the basis of other overriding reasons of public interest, recognised by the case-law of the Court of Justice of the European Union in relation to the free movement of goods, and where those restrictions are proportionate to the aim pursued. This Regulation imposes the obligation to clearly justify why market access has been restricted or denied.

(5) The concept of overriding reasons of public interest is an evolving concept developed by the Court of Justice of the European Union in its case-law in relation to Articles 34 and 36 TFEU. Where legitimate differences exist from one Member State to another, such overriding reasons might justify the application of national technical rules by the competent authorities. However, administrative decisions always need to be duly justified, to be legitimate, to be appropriate and to respect the principle of proportionality, and the competent authority has to make the least restrictive decision possible. In order to improve the functioning of the internal market for goods, the national technical rules should be fit for purpose and should not create disproportionate non-tariff barriers. Furthermore, administrative decisions restricting or denying market access in respect of goods that are lawfully marketed in another Member State must not be based on the mere fact that the goods under assessment fulfil the legitimate public objective pursued by the Member State in a different way from the way in which goods in that Member State fulfil that objective. In order to assist Member States, the Commission should provide non-binding guidance in relation to the case-law of the Court of Justice of the European Union on the concept of overriding reasons of public interest and how to apply the principle of mutual recognition. Competent authorities should have the opportunity to provide contributions and deliver feedback on the guidance.

(6) In its Conclusions on the Single Market Policy of December 2013, the Competitiveness Council noted that to improve framework conditions for businesses and consumers in the Single Market, all relevant instruments should be appropriately employed, including mutual recognition. The Council invited the Commission to report on cases where the functioning of the principle of mutual recognition is still inadequate or problematic. In its Conclusions on the Single Market Policy of February 2015, the Competitiveness Council urged the Commission to take steps to ensure that the principle of mutual recognition functioned effectively and to bring forward proposals to that effect.

(7) Regulation (EC) No 764/2008 of the European Parliament and of the Council[(3)] was adopted in order to facilitate the application of the principle of mutual recognition by establishing procedures to minimise the possibility of creating unlawful obstacles to the free movement of goods which have already been lawfully marketed in another Member State. Despite the adoption of that Regulation, many problems still exist as regards the application of the principle of mutual recognition. The evaluation carried out between 2014 and 2016 showed that the principle of mutual recognition does not function as it should, and that Regulation (EC) No 764/2008 has had limited effect in facilitating the application of that principle. The tools and procedural guarantees put in place by that Regulation failed in their aim of improving the application of the principle of mutual recognition. For example, the Product Contact Points network which was put in place in order to provide information to economic operators on applicable national rules and the application of the principle of mutual recognition is barely known or used by economic operators. Within that network, national authorities do not cooperate sufficiently. The requirement to notify administrative decisions restricting or denying market access is rarely complied with. As a result, obstacles to the free movement of goods in the internal market remain.

(8) Regulation (EC) No 764/2008 has several shortcomings, and should therefore be revised and strengthened. For the sake of clarity, Regulation (EC) No 764/2008 should be replaced by this Regulation. This Regulation should establish clear procedures to ensure the free movement of goods lawfully marketed in another Member State and to ensure that free movement can be restricted only where Member States have legitimate public interest grounds for doing so and that the restriction is justified and proportionate. This Regulation should also ensure that existing rights and obligations deriving from the principle of mutual recognition are observed, by both economic operators and national authorities.

(9) This Regulation should not prejudice the further harmonisation of conditions for the marketing of goods with a view to improving the functioning of the internal market, where appropriate.

(10) It is also possible for trade barriers to result from other types of measures falling under the scope of Articles 34 and 36 TFEU. Those measures can include, for example, technical specifications drawn up for public procurement procedures or requirements to use official languages in the Member States. However, such measures should not constitute national technical rules within the meaning of this Regulation and should not fall within its scope.

(11) National technical rules are sometimes given effect in a Member State by means of a prior authorisation procedure, under which formal approval has to be obtained from a competent authority before the goods can be placed on the market there. The existence of a prior authorisation procedure in itself restricts the free movement of goods. Therefore, in order to be justified with regard to the fundamental principle of the free movement of goods within the internal market, such a procedure has to pursue a public interest objective recognised by Union law, and it has to be proportionate and non-discriminatory. The compliance of such a procedure with Union law is to be

**Changes to legislation:** *There are currently no known outstanding effects for the Regulation (EU) 2019/515 of the European Parliament and of the Council. (See end of Document for details)*

assessed in the light of the considerations set out in the case-law of the Court of Justice of the European Union. Therefore, administrative decisions restricting or denying market access exclusively on the grounds that the goods do not have a valid prior authorisation should be excluded from the scope of this Regulation. When, however, an application for mandatory prior authorisation of goods is made, any administrative decision to reject the application on the basis of a national technical rule applicable in that Member State should only be taken in accordance with this Regulation, so that the applicant can benefit from the procedural protection which this Regulation provides. The same applies to voluntary prior authorisation of goods, where it exists.

(12) It is important to clarify that the types of goods covered by this Regulation include agricultural products. The term 'agricultural products' includes products of fisheries, as provided for in Article 38(1) TFEU. In order to help to identify which types of goods are subject to this Regulation, the Commission should assess the feasibility and benefits of further developing an indicative product list for mutual recognition.

(13) It is also important to clarify that the term 'producer' includes not only manufacturers of goods, but also persons who produce goods which were not the result of a manufacturing process, including agricultural products, as well as persons who present themselves as the producers of goods.

(14) Decisions of national courts or tribunals assessing the legality of cases in which, on account of the application of a national technical rule, goods lawfully marketed in one Member State are not granted access to the market in another Member State, and decisions of national courts or tribunals applying penalties, should be excluded from the scope of this Regulation.

(15) To benefit from the principle of mutual recognition, goods must be lawfully marketed in another Member State. It should be clarified that, for goods to be considered to be lawfully marketed in another Member State, the goods need to comply with the relevant rules applicable in that Member State, and need to be made available to end users in that Member State.

(16) To raise awareness on the part of national authorities and economic operators of the principle of mutual recognition, Member States should consider providing for clear and unambiguous 'single market clauses' in their national technical rules with a view to facilitating the application of that principle.

(17) The evidence required to demonstrate that goods are lawfully marketed in another Member State varies significantly from Member State to Member State. This causes unnecessary burdens, delays and additional costs for economic operators, and prevents national authorities from obtaining the information necessary for assessing the goods in a timely manner. This may inhibit the application of the principle of mutual recognition. It is therefore essential to make it easier for economic operators to demonstrate that their goods are lawfully marketed in another Member State. Economic operators should benefit from a self-declaration that provides competent authorities with all necessary information on the goods and on their compliance with the rules applicable in that other Member State. The use of voluntary declarations should not prevent national authorities from taking administrative decisions restricting or denying market access,

provided that such decisions are proportionate, justified and respect the principle of mutual recognition and are in accordance with this Regulation.

(18) It should be possible for the producer, importer or distributor to draw up a declaration of lawful marketing of goods for the purposes of mutual recognition ('mutual recognition declaration'). The producer is best placed to provide the information in the mutual recognition declaration as the producer knows the goods best and is in possession of the evidence necessary to verify the information in the mutual recognition declaration. The producer should be able to mandate an authorised representative to draw up such declarations on the producer's behalf and under the responsibility of the producer. However, where an economic operator is only able to provide the information on the lawfulness of the marketing of the goods in the declaration, it should be possible for another economic operator to provide the information that the goods are being made available to end users in the Member State concerned, provided that that economic operator takes responsibility for the information that it provided in the mutual recognition declaration and is able to provide the necessary evidence to verify this information.

(19) The mutual recognition declaration should always contain accurate and complete information on the goods. The declaration should therefore be kept up to date in order to reflect changes, for example changes in the relevant national technical rules.

(20) In order to ensure that the information provided in a mutual recognition declaration is comprehensive, a harmonised structure for such declarations should be laid down for use by economic operators wishing to make such declarations.

(21) It is important to ensure that the mutual recognition declaration is filled in truthfully and accurately. It is therefore necessary to require economic operators to be responsible for the information provided by them in the mutual recognition declaration.

(22) In order to enhance the efficiency and competitiveness of businesses operating in the field of goods that are not covered by Union harmonisation legislation, it should be possible to benefit from new information technologies for the purpose of facilitating the provision of the mutual recognition declaration. Therefore, economic operators should be able to make their mutual recognition declarations publicly available online, provided that the mutual recognition declaration is easily accessible and is in a reliable format.

(23) The Commission should ensure that a template for the mutual recognition declaration and guidelines for completing it are made available on the Single Digital Gateway in all of the official languages of the Union.

(24) This Regulation should also apply to goods in respect of which only some aspects are covered by Union harmonisation legislation. Where, pursuant to Union harmonisation legislation, the economic operator is required to draw up an EU declaration of conformity to demonstrate compliance with that legislation, that economic operator should be permitted to attach the mutual recognition declaration provided for by this Regulation to the EU declaration of conformity.